This document is scheduled to be published in the
Federal Register on 08/31/2012 and available online at
http://federalregister.gov/a/2012-19079, and on **FDsys.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 424, and 476

[CMS-1588-F]

RIN 0938-AR12

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems. Some of the changes implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and other legislation. These changes will be applicable to discharges occurring on or after October 1, 2012, unless otherwise specified in this final rule. We also are updating the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. The updated rate-of-increase limits will be effective for cost reporting periods beginning on or after October 1, 2012.

We are updating the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implementing certain statutory changes made by the Affordable Care Act. Generally, these changes will be applicable to discharges occurring on or after October 1, 2012, unless otherwise specified in this final rule.

In addition, we are implementing changes relating to determining a hospital's full-time equivalent (FTE) resident cap for the purpose of graduate medical education (GME) and indirect medical education (IME) payments. We are establishing new requirements or revised requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities (IPFs)) that are participating in Medicare. We also are establishing new administrative, data completeness, and extraordinary circumstance waivers or extension requests requirements, as well as a reconsideration process, for quality reporting by ambulatory surgical centers (ASCs) that are participating in Medicare.

We are establishing requirements for the Hospital Value-Based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program.

DATES: *Effective date*: This final rule is effective on October 1, 2012.

FOR FURTHER INFORMATION, CONTACT:

Tzvi Hefter, (410) 786-4487, and Ing-Jye Cheng, (410) 786-4548, Operating Prospective Payment, MS-DRGs, Hospital Acquired Conditions (HAC), Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded

Hospitals, Medicare Disproportionate Share Hospital (DSH), and Postacute Care Transfer Issues.

Michele Hudson, (410) 786-4487, and Judith Richter, (410) 786-2590, Long-Term Care Hospital Prospective Payment System and MS-LTC-DRG Relative Weights Issues.

Bridget Dickensheets, (410) 786-8670, Market Basket for LTCHs Issues.

Siddhartha Mazumdar, (410) 786-6673, Rural Community Hospital Demonstration Program Issues.

James Poyer, (410) 786-2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing--Program Administration, Validation, and Reconsideration Issues.

Shaheen Halim, (410) 786-0641, Hospital Inpatient Quality Reporting--Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Elizabeth Goldstein, (410) 786-6665, Hospital Inpatient Quality Reporting--Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Mary Pratt, (410) 786-6867, LTCH Quality Data Reporting Issues.

Kim Spalding Bush, (410) 786-3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

James Poyer, (410) 786-2261, and Barbara Choo, (410) 786-4449, Inpatient Psychiatric Facility Quality Reporting Issues and PPS-Exempt Cancer Hospital Quality Reporting Issues.

Anita Bhatia, (410) 786-7236, Ambulatory Surgical Center Quality Reporting (ASCQR) Program Issues.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through the U.S. Government Printing Office Web page at: http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web (the Superintendent of Documents' home Web page address), by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512-1661; type swais, then login as guest (no password required).

Tables Available Only through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to this final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables will be available only through the Internet. The IPPS tables for this final rule are available only through the Internet on the CMS Web site at: http://www.cms.hhs.gov/Medicare/medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. Click on the link on the left side of the screen

titled, “FY 2013 IPPS Final Rule Home Page” or “Acute Inpatient – Files for Download”. The LTCH PPS tables for this FY 2013 final rule are available only through the Internet on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html under the list item for Regulation Number CMS-1588-F. For complete details on the availability of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Nisha Bhat at (410) 786-4487.

Acronyms

3M	3M Health Information System
AAMC	Association of American Medical Colleges
ACGME	Accreditation Council for Graduate Medical Education
AHA	American Hospital Association
AHIC	American Health Information Community
AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
ALOS	Average length of stay
ALTHA	Acute Long Term Hospital Association
AMA	American Medical Association
AMGA	American Medical Group Association
AOA	American Osteopathic Association
APR DRG	All Patient Refined Diagnosis Related Group System

ARRA	American Recovery and Reinvestment Act of 2009, Pub. L. 111-5
ASC	Ambulatory surgical center
ASCA	Administrative Simplification Compliance Act of 2002, Pub. L. 107-105
ASCQR	Ambulatory Surgical Center Quality Reporting
ASITN	American Society of Interventional and Therapeutic Neuroradiology
BBA	Balanced Budget Act of 1997, Pub. L. 105-33
BBRA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106-113
BIPA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
BLS	Bureau of Labor Statistics
CAH	Critical access hospital
CARE	[Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART	CMS Abstraction & Reporting Tool
CBSAs	Core-based statistical areas
CC	Complication or comorbidity
CCR	Cost-to-charge ratio
CDAC	[Medicare] Clinical Data Abstraction Center
CDAD	*Clostridium difficile*-associated disease
CDC	Center for Disease Control and Prevention
CIPI	Capital input price index

CMI	Case-mix index
CMS	Centers for Medicare & Medicaid Services
CMSA	Consolidated Metropolitan Statistical Area
COBRA	Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99-272
COLA	Cost-of-living adjustment
CoP	[Hospital] condition of participation
CPI	Consumer price index
CRNA	Certified Registered Nurse Anesthetist
CY	Calendar year
DPP	Disproportionate patient percentage
DRA	Deficit Reduction Act of 2005, Pub. L. 109-171
DRG	Diagnosis-related group
DSH	Disproportionate share hospital
ECI	Employment cost index
EDB	[Medicare] Enrollment Database
EHR	Electronic health record
EMR	Electronic medical record
FAH	Federation of Hospitals
FDA	Food and Drug Administration
FFY	Federal fiscal year
FQHC	Federally qualified health center
FTE	Full-time equivalent

FY	Fiscal year
GAAP	Generally Accepted Accounting Principles
GAF	Geographic Adjustment Factor
GME	Graduate medical education
HACs	Hospital-acquired conditions
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA	Health Care Financing Administration
HCO	High-cost outlier
HCRIS	Hospital Cost Report Information System
HHA	Home health agency
HHS	Department of Health and Human Services
HICAN	Health Insurance Claims Account Number
HIPAA	Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191
HIPC	Health Information Policy Council
HIS	Health information system
HIT	Health information technology
HMO	Health maintenance organization
HPMP	Hospital Payment Monitoring Program
HSA	Health savings account
HSCRC	[Maryland] Health Services Cost Review Commission
HSRV	Hospital-specific relative value

HSRVcc	Hospital-specific relative value cost center
HQA	Hospital Quality Alliance
HQI	Hospital Quality Initiative
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR	Information collection requirement
IGI	IHS Global Insight, Inc.
IHS	Indian Health Service
IME	Indirect medical education
I-O	Input-Output
IOM	Institute of Medicine
IPF	Inpatient psychiatric facility
IPPS	[Acute care hospital] inpatient prospective payment system
IRF	Inpatient rehabilitation facility
IQR	Inpatient Quality Reporting
LAMCs	Large area metropolitan counties
LOS	Length of stay
LTC-DRG	Long-term care diagnosis-related group

LTCH	Long-term care hospital
LTCHQR	Long-Term Care Hospital Quality Reporting
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MCC	Major complication or comorbidity
MCE	Medicare Code Editor
MCO	Managed care organization
MCV	Major cardiovascular condition
MDC	Major diagnostic category
MDH	Medicare-dependent, small rural hospital
MedPAC	Medicare Payment Advisory Commission
MedPAR	Medicare Provider Analysis and Review File
MEI	Medicare Economic Index
MGCRB	Medicare Geographic Classification Review Board
MIEA-TRHCA	Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Pub. L. 109-432
MIPPA	Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173
MMEA	Medicare and Medicaid Extenders Act of 2010, Pub. L. 111-309
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110-173

MRHFP	Medicare Rural Hospital Flexibility Program
MRSA	Methicillin-resistant *Staphylococcus aureus*
MSA	Metropolitan Statistical Area
MS-DRG	Medicare severity diagnosis-related group
MS-LTC-DRG	Medicare severity long-term care diagnosis-related group
NAICS	North American Industrial Classification System
NALTH	National Association of Long Term Hospitals
NCD	National coverage determination
NCHS	National Center for Health Statistics
NCQA	National Committee for Quality Assurance
NCVHS	National Committee on Vital and Health Statistics
NECMA	New England County Metropolitan Areas
NHSN	National Healthcare Safety Network
NQF	National Quality Forum
NTIS	National Technical Information Service
NTTAA	National Technology Transfer and Advancement Act of 1991 (Pub. L. 104-113)
NVHRI	National Voluntary Hospital Reporting Initiative
OACT	[CMS'] Office of the Actuary
OBRA 86	Omnibus Budget Reconciliation Act of 1986, Pub. L. 99-509
OES	Occupational employment statistics
OIG	Office of the Inspector General

OMB	Executive Office of Management and Budget
OPM	U.S. Office of Personnel Management
O.R.	Operating room
OSCAR	Online Survey Certification and Reporting [System]
PCH	PPS-exempt cancer hospital
PCHQR	PPS-exempt cancer hospital quality reporting
PMSAs	Primary metropolitan statistical areas
POA	Present on admission
PPI	Producer price index
PPS	Prospective payment system
PRM	Provider Reimbursement Manual
ProPAC	Prospective Payment Assessment Commission
PRRB	Provider Reimbursement Review Board
PRTFs	Psychiatric residential treatment facilities
PSF	Provider-Specific File
PS&R	Provider Statistical and Reimbursement (System)
QIG	Quality Improvement Group, CMS
QIO	Quality Improvement Organization
RCE	Reasonable compensation equivalent
RHC	Rural health clinic
RHQDAPU	Reporting hospital quality data for annual payment update
RNHCI	Religious nonmedical health care institution

RPL	Rehabilitation psychiatric long-term care (hospital)
RRC	Rural referral center
RTI	Research Triangle Institute, International
RUCAs	Rural-urban commuting area codes
RY	Rate year
SAF	Standard Analytic File
SCH	Sole community hospital
SFY	State fiscal year
SIC	Standard Industrial Classification
SNF	Skilled nursing facility
SOCs	Standard occupational classifications
SOM	State Operations Manual
SSO	Short-stay outlier
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248
TEP	Technical expert panel
TMA	TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Pub. L. 110-90
TPS	Total Performance Score
UHDDS	Uniform hospital discharge data set

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

2. Summary of the Major Provisions

3. Summary of Costs and Benefits

B. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

2. Hospitals and Hospital Units Excluded from the IPPS

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

4. Critical Access Hospitals (CAHs)

5. Payments for Graduate Medical Education (GME)

C. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) Applicable to FY 2013

D. Issuance of a Notice of Proposed Rulemaking

II. Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights

A. Background

B. MS-DRG Reclassifications

C. Adoption of the MS-DRGs in FY 2008

D. FY 2013 MS-DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount

1. Background on the Prospective MS-DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Pub. L. 110-90

2. Prospective Adjustment to the Average Standardized Amounts Required by Section 7(b)(1)(A) of Pub. L. 110-90

3. Recoupment or Repayment Adjustments in FYs 2010 through 2012 Required by Pub. L. 110-90

4. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

5. Prospective Adjustment for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Pub. L. 110-90 and Section 1886(d)(3)(vi) of the Act

6. Recoupment or Repayment Adjustment Authorized by Section 7(b)(1)(B) of Pub. L. 110-90

7. Background on the Application of the Documentation and Coding Adjustment to the Hospital-Specific Rates

8. Documentation and Coding Adjustment to the Hospital-Specific Rates for FY 2011 and Subsequent Fiscal Years

9. Application of the Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

a. Background

b. Documentation and Coding Adjustment to the Puerto Rico-Specific Standard Amount

10. Prospective Adjustments for FY 2010 Documentation and Coding Effect

E. Refinement of the MS-DRG Relative Weight Calculation

1. Background

2. Summary of Policy Discussions in FY 2012

3. Discussion for FY 2013

F. Preventable Hospital-Acquired Conditions (HACs), Including Infections

1. Background

2. HAC Selection

3. Present on Admission (POA) Indicator Reporting

4. HACs and POA Reporting in ICD-10-CM and ICD-10-PCS

5. Changes to the HAC Policy for FY 2013

a. Additional Diagnosis Codes to Existing HACs

b. New Candidate HAC Condition: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures

c. New Candidate HAC Condition: Iatrogenic Pneumothorax with Venous Catheterization

6. RTI Program Evaluation Summary

a. RTI Analysis of FY 2011 POA Indicator Reporting Across Medicare Discharges

b. RTI Analysis of FY 2011 POA Indicator Reporting of Current HACs

c. RTI Analysis of FY 2011 Frequency of Discharges and POA Indicator Reporting for Current HACs

d. RTI Analysis of Circumstances When Application of HAC Provisions Would Not Result in MS-DRG Reassignment for Current HACs

e. RTI Analysis of Coding Changes for HAC-Associated Secondary Diagnoses for Current HACs

f. RTI Analysis of Estimated Net Savings for Current HACs

g. Previously Considered Candidate HACs-- RTI Analysis of Frequency of Discharges and POA Indicator Reporting

h. Current and Previously Considered Candidate HACs--RTI Report on Evidence-Based Guidelines

i. Proposals Regarding Current HACs and Previously Considered Candidate HACs

G. Changes to Specific MS-DRG Classifications

1. Pre-Major Diagnostic Categories (Pre-MDCs)

a. Ventricular Assist Device

b. Allogeneic Bone Marrow Transplant

2. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat): Influenza with Pneumonia

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Mitral Valve Repair with Implant

b. Endovascular Implantation of Branching or Fenestrated Grafts in Aorta

4. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders): Disorders of Porphyrin Metabolism

5. Medicare Code Editor (MCE) Changes

a. MCE New Length of Stay Edit for Continuous Invasive Mechanical Ventilation for 96 Consecutive Hours or More

b. Sleeve Gastrectomy Procedure for Morbid Obesity

6. Surgical Hierarchies

7. Complications or Comorbidity (CC) Exclusions List

a. Background

b. CC Exclusions List for FY 2013

(1) No Revisions Based on Changes to the ICD-9-CM Diagnosis Codes for FY 2013

(2) Suggested changes to MS-DRG Severity Levels for Diagnosis Codes for FY 2013

(A) Protein-Calorie Malnutrition

(B) Antineoplastic Chemotherapy Induced Anemia

(C) Cardiomyopathy and Congestive Heart Failure, Unspecified

(D) Chronic Total Occlusion of Artery of the Extremities

(E) Acute Kidney Failure with Other Specified Pathological Lesion in Kidney

(F) Pressure Ulcer, Unstageable

8. Review of Procedure Codes in MS-DRGs 981 through 983, 984 through 986, and 987 through 989

a. Moving Procedure Codes from MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into MDCs

b. Reassignment of Procedures among MS-DRGs 981 through 983, 984 through 986, and 987 through 989

c. Adding Diagnosis or Procedure Codes to MDCs

9. Changes to the ICD-9-CM Coding System, Including Discussion of the Replacement of the ICD-9-CM System with the ICD-10-CM and ICD-10-PCS Systems in FY 2014

a. ICD-9-CM Coding System

b. Code Freeze

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims

d. ICD-10 MS-DRGs

10. Public Comments on Issues Not Addressed in the Proposed Rule

H. Recalibration of MS-DRG Weights

1. Data Sources for Developing the Proposed Weights

2. Methodology for Calculation of the Proposed Relative Weights

3. Development of National Average CCRs

4. Bundled Payments for Care Improvement (BPCI) Initiative

a. Background

b. Treatment of Data from Hospitals Participating in the BPCI Initiative

I. Add-On Payments for New Services and Technologies

1. Background

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

3. FY 2013 Status of Technology Approved for FY 2012 Add-On Payments: AutoLaser Interstitial Thermal Therapy (AutoLITT™)

4. FY 2013 Applications for New Technology Add-On Payments

a. Glucarpidase (Trade Brand Voraxaze®)

b. DIFICID™ (Fidaxomicin) Tablets

c. Zilver® PTX® Drug-Eluting Stent

d. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

B. Core-Based Statistical Areas for the Hospital Wage Index

C. Worksheet S-3 Wage Data for the FY 2013 Wage Index

1. Included Categories of Costs

2. Excluded Categories of Costs

3. Use of Wage Index Data by Providers Other Than Acute Care Hospitals under the IPPS

D. Verification of Worksheet S-3 Wage Data

E. Method for Computing the FY 2013 Unadjusted Wage Index

F. Occupational Mix Adjustment to the FY 2013 Wage Index

1. Development of Data for the FY 2013 Occupational Mix Adjustment Based on the 2010 Occupational Mix Survey

2. Calculation of the Occupational Mix Adjustment for FY 2013

G. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2013 Occupational Mix Adjusted Wage Index

1. Analysis of the Occupational Mix Adjustment and the Occupational Mix Adjusted Wage Index

2. Application of the Rural, Imputed, and Frontier Floors

a. Rural Floor

b. Imputed Floor and Proposal for an Alternative, Temporary Methodology for Computing the Imputed Floor

c. Frontier Floor

3. FY 2013 Wage Index Tables

H. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification/Redesignation

2. FY 2013 MGCRB Reclassifications

a. FY 2013 Reclassification Requirements and Approvals

b. Applications for Reclassifications for FY 2014

3. Redesignations of Hospitals under Section 1886(d)(8)(B) of the Act

4. Reclassifications under Section 1886(d)(8)(B) of the Act

5. Reclassifications under Section 508 of Pub. L. 108-173

6. Waiving Lugar Redesignation for the Out-Migration Adjustment

7. Cancellation of Acquired Rural Status Due to MDH Expiration

I. FY 2013 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

J. Process for Requests for Wage Index Data Corrections

K. Labor-Related Share for the FY 2013 Wage Index

IV. Other Decisions and Changes to the IPPS for Operating Costs and Graduate Medical Education (GME) Costs

A. Hospital Readmission Reduction Program

1. Statutory Basis for the Hospital Readmissions Reduction Program

2. Overview

3. FY 2013 Proposed and Final Policies for the Hospital Readmissions Reduction Program

a. Overview

b. Base Operating DRG Payment Amount, Including Special Rules for SCHs and MDHs and Hospitals Paid under Section 1814 of the Act

c. Adjustment Factor (Both the Ratio and Floor Adjustment Factor)

d. Aggregate Payments for Excess Readmissions and Aggregate Payment for All Discharges

e. Applicable Hospital

4. Limitations on Review

5. Reporting Hospital-Specific Information, Including Opportunity to Review and Submit Corrections

B. Sole Community Hospitals (SCHs) (§ 412.92)

1. Background

2. Reporting Requirement and Clarification of Duration of Classification for Hospitals Incorrectly Classified as Sole Community Hospitals

3. Change to Effective Date of Classification for MDHs Applying for SCH Status Upon the Expiration of the MDH Program

C. Rural Referral Centers (RRCs): Annual Update to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

1. Case-Mix Index (CMI)

2. Discharges

D. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Expiration of the Affordable Care Act Provision for FYs 2011 and 2012

2. Background

3. Affordable Care Act Provisions for FYs 2011 and 2012

4. Payment Adjustment for FY 2013 and Subsequent Years

E. Indirect Medical Education (IME) Adjustment (§ 412.105)

1. IME Adjustment Factor for FY 2013

2. Timely Filing Requirements under Fee-for-Service Medicare

a. IME and Direct GME

b. Nursing and Allied Health Education

c. Disproportionate Share Hospital (DSH) Payments

d. Summary of Public Comments, Our Responses, and Final Policies

3. Other Related Policy Changes

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 412.106)

1. Background

2. Policy Change Relating to Treatment of Labor and Delivery Beds in the Calculation of the Medicare DSH Payment Adjustment and the IME Payment Adjustment

G. Expiration of the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

H. Changes in the Inpatient Hospital Update

1. FY 2013 Inpatient Hospital Update

2. FY 2013 Puerto Rico Hospital Update

I. Payment for Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs (§§ 412.105, 413.75 through 413.83)

1. Background

2. Teaching Hospitals: Change in New Program Growth from 3 Years to 5 Years

3. Policies and Clarifications Related to 5-Year Period Following Implementation of Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes under Section 5503 of the Affordable Care Act

4. Preservation of Resident Cap Positions from Closed Hospitals (Section 5506 of the Affordable Care Act)

a. Background

b. Change in Amount of Time Provided for Submitting Applications under Section 5506 of the Affordable Care Act

c. Change to the Ranking Criteria under Section 5506

d. Effective Dates of Slots Awarded under Section 5506

e. Clarification of Relationship Between Ranking Criteria One, Two, and Three

f. Modifications to the Section 5506 CMS Evaluation Form

5. Notice of Closure of Teaching Hospitals and Opportunity to Apply for Available Slots

a. Background

b. Notice of Closure of Teaching Hospitals

c. Application Process for Available Resident Slots

J. Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

K. Rural Community Hospital Demonstration Program

1. Background

2. Budget Neutrality Offset Amount for FY 2013

L. Hospital Routine Services Furnished under Arrangements

M. Technical Change

V. Changes to the IPPS for Capital-Related Costs

A. Overview

B. Additional Provisions

1. Exception Payments

2. New Hospitals

3. Hospitals Located in Puerto Rico

C. Prospective Adjustment for the FY 2010 Documentation and Coding Effect

1. Background

2. Prospective Adjustment for the Effect of Documentation and Coding in FY 2010

3. Documentation and Coding Adjustment to the Puerto Rico-Specific Capital Rate

D. Changes for Annual Update for FY 2013

VI. Changes for Hospitals Excluded from the IPPS

A. Excluded Hospitals

B. Report of Adjustment (Exceptions) Payments

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2013

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

b. Hospitals Excluded from the LTCH PPS

3. Limitation on Charges to Beneficiaries

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS-LTC-DRG) Classifications and Relative Weights for FY 2013

1. Background

2. Patient Classifications into MS-LTC-DRGs

a. Background

b. Changes to the MS-LTC-DRGs for FY 2013

3. Development of the FY 2013 MS-LTC-DRG Relative Weights

a. General Overview of the Development of the MS-LTC-DRG Relative Weights

b. Development of the MS-LTC-DRG Relative Weights for FY 2013

c. Data

d. Hospital-Specific Relative Value (HSRV) Methodology

e. Treatment of Severity Levels in Developing the MS-LTC-DRG Relative Weights

f. Low-Volume MS-LTC-DRGs

g. Steps for Determining the FY 2013 MS-LTC-DRG Relative Weights

C. Use of a LTCH-Specific Market Basket under the LTCH PPS

1. Background

2. Overview of the FY 2009-Based LTCH-Specific Market Basket

3. Development of a LTCH-Specific Market Basket

a. Development of Cost Categories

b. Cost Category Computation

c. Selection of Price Proxies

d. Methodology for the Capital Portion of the FY 2009-Based LTCH-Specific Market Basket

e. FY 2013 Market Basket for LTCHs

f. FY 2013 Labor-Related Share

D. Changes to the LTCH Payment Rates for FY 2013 and Other Changes to the LTCH PPS for FY 2013

1. Overview of Development of the LTCH Payment Rates

2. FY 2013 LTCH PPS Annual Market Basket Update

a. Overview

b. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

c. Market Basket under the LTCH PPS for FY 2013

d. Annual Market Basket Update for LTCHs for FY 2013

3. LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

E. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Facilities and the Increase in Number of Beds in LTCHs and LTCH Satellite Facilities

1. Background

2. The 25-Percent Payment Adjustment Threshold

3. The "IPPS Comparable Per Diem Amount" Payment Option for Very Short Stays under the Short-Stay Outlier (SSO) Policy

4. One-Time Prospective Adjustment to the Standard Federal Rate under § 412.523(d)(3)

a. Overview

b. Data used to Estimate Aggregate FY 2003 TEFRA Payments

c. Data used to Estimate Aggregate FY 2003 LTCH PPS Payments

d. Methodology to Evaluate Whether a One-Time Prospective Adjustment under § 412.523(d)(3) is Warranted

e. Methodology to Estimate FY 2003 LTCH Payments under the TEFRA Payment System

f. Methodology to Estimate FY 2003 LTCH PPS Payments

g. Methodology for Calculating the One-Time Prospective Adjustment under § 412.523(d)(3)

h. Public Comments and CMS' Responses

i. Final Policy Regarding the One-Time Prospective Adjustment under § 412.523(d)(3)

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of Measures Adopted for the Hospital IQR Program

b. Maintenance of Technical Specifications for Quality Measures

c. Public Display of Quality Measures

2. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures from the Hospital IQR Program

b. Hospital IQR Program Measures Removed in Previous Rulemakings

c. Removal of Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

(1) Removal of One Chart-Abstracted Measure

(2) Removal of 16 Claims-Based Measures

d. Suspension of Data Collection for the FY 2014 Payment Determination and Subsequent Years

3. Measures for the FY 2015 and FY 2016 Hospital IQR Program Payment Determinations

a. Additional Considerations in Expanding and Updating Quality Measures under the Hospital IQR Program

b. Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

(1) Process for Retention of Hospital IQR Program Measures Adopted in Previous Payment Determinations

(2) Additional Hospital IQR Program Measures for FY 2015 Payment Determination and Subsequent Years

c. Hospital IQR Program Quality Measures for the FY 2016 Payment Determination and Subsequent Years

4. Possible New Quality Measures and Measure Topics for Future Years

5. Form, Manner, and Timing of Quality Data Submission

a. Background

b. Procedural Requirements for the FY 2015 Payment Determination and Subsequent Years

c. Data Submission Requirements for Chart-Abstracted Measures

d. Sampling and Case Thresholds Beginning with the FY 2015 Payment Determination

e. HCAHPS Requirements for the FY 2014, FY 2015, and FY 2016 Payment Determinations

f. Data Submission Requirements for Structural Measures

g. Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

6. Supplements to the Chart Validation Process for the Hospital IQR Program for the FY 2015 Payment Determination and Subsequent Years

a. Separate Processes for Sampling and Scoring for Chart-Abstracted Clinical Process of Care and HAI Measures

(1) Background and Rationale

(2) Selection and Sampling of Clinical Process of Care Measures for Validation

(3) Selection and Sampling of HAI Measures for Validation

(4) Validation Scoring for Chart-Abstract Clinical Process of Care and HAI Measures

(5) Criteria to Evaluate Whether a Score Passes or Fails

b. Number and Manner of Selection for Hospitals Included in the Base Annual Validation Random Sample

c. Targeting Criteria for Selection of Supplemental Hospitals for Validation

7. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2015 Payment Determination and Subsequent Years

8. Public Display Requirements for the FY 2015 Payment Determination and Subsequent Years

9. Reconsideration and Appeal Procedures for the FY 2015 Payment Determination

10. Hospital IQR Program Disaster Extensions or Waivers

11. Electronic Health Records (EHRs)

a. Background

b. HITECH Act EHR Provisions

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

2. Covered Entities

3. Quality Measures for PCHs for FY 2014 Program and Subsequent Program Years

a. Considerations in the Selection of the Quality Measures

b. PCHQR Program Quality Measures for FY 2014 Program and Subsequent Program Years

(1) CDC/NHSN-Based Healthcare-Associated Infection (HAI) Measures

(2) Cancer-Specific Measures

4. Possible New Quality Measure Topics for Future Years

5. Maintenance of Technical Specifications for Quality Measures

6. Public Display Requirements for the FY 2014 Program and Subsequent Program Years

7. Form, Manner, and Timing of Data Submission for FY 2014 Program and Subsequent Program Years

a. Background

b. Procedural Requirements for FY 2014 Program and Subsequent Program Years

c. Reporting Mechanisms for FY 2014 Program and Subsequent Program Years

(1) Reporting Mechanism for the HAI Measures

(2) Reporting Mechanism for the Cancer-Specific Measures

d. Data Submission Timelines for FY 2014 Program and Subsequent Program Years

e. Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2014 Program and Subsequent Program Years

C. Hospital Value-Based Purchasing (VBP) Program

1. Statutory Background

2. Overview of the FY 2013 Hospital VBP Program

3. FY 2014 Hospital VBP Program Measures

4. Other Previously Finalized Requirements for the Hospital VBP Program

5. Hospital VBP Payment Adjustment Calculation Methodology

a. Definitions of the Term "Base Operating DRG Payment Amount" for Purposes of the Hospital VBP Program

b. Calculating the Funding Amount for Value-Based Incentive Payments Each Year

c. Methodology to Calculate the Value-Based Incentive Payment Adjustment Factor

d. Timing of the Base Operating DRG Payment Amount Reduction and Value-Based Incentive Payment Adjustment for FY 2013 and Future Hospital VBP Program Years

e. Process for Reducing the Base Operating DRG Payment Amount and Applying the Value-Based Incentive Payment Adjustment for FY 2013

6. Review and Corrections Processes

a. Background

b. Review and Corrections Process for Claims-Based Measure Rates

c. Review and Corrections Process for Condition-Specific Scores, Domain-Specific Scores, and Total Performance Scores

7. Appeal Process under the Hospital VBP Program

a. Background

b. Appeal Process

8. Measures for the FY 2015 Hospital VBP Program

a. Relationship Between the National Strategy and the Hospital VBP Program

b. FY 2015 Measures

c. General Process for Hospital VBP Program Measure Adoption for Future Program Years

9. Measures and Domains for the FY 2016 Hospital VBP Program

a. FY 2016 Measures

b. Quality Measure Domains for the FY 2016 Hospital VBP Program

10. Performance Periods and Baseline Periods for the FY 2015 Hospital VBP Program

a. Clinical Process of Care Domain Performance Period and Baseline Periods for FY 2015

b. Patient Experience of Care Domain Performance Period and Baseline Period for FY 2015

c. Efficiency Domain Measure Performance Period and Baseline Period for FY 2015

d. Outcome Domain Performance Periods for FY 2015

(1) Mortality Measures

(2) AHRQ PSI Composite Measure

(3) CLABSI Measure

e. Performance Periods for FY 2016 Measures

11. Performance Standards for the Hospital VBP Program for FY 2015 and FY 2016

a. Background

b. Performance Standards for the FY 2015 Hospital VBP Program Measures

c. Performance Standards for FY 2016 Hospital VBP Program Measures

d. Adopting Performance Periods and Standards for Future Program Years

12. FY 2015 Hospital VBP Program Scoring Methodology

a. General Hospital VBP Program Scoring Methodology

b. Domain Weighting for the FY 2015 Hospital VBP Program for Hospitals That Receive a Score on All Four Proposed Domains

c. Domain Weighting for Hospitals Receiving Scores on Fewer than Four Domains

13. Applicability of the Hospital VBP Program to Hospitals

a. Background

b. Exemption Request Process for Maryland Hospitals

14. Minimum Numbers of Cases and Measures for the FY 2015 Program

a. Background

b. Minimum Numbers of Cases and Measures for the FY 2015 Outcome Domain

c. Medicare Spending Per Beneficiary Measure Case Minimum

15. Immediate Jeopardy Citations

D. Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Statutory History

2. LTCH Program Measures for the FY 2014 Payment Determination and Subsequent Fiscal Years Payment Determinations

a. Process for Retention of LTCHQR Program Measures Adopted in Previous Payment Determinations

b. Process for Adopting Changes to LTCHQR Program Measures

3. CLABSI, CAUTI, AND Pressure Ulcer Measures

4. LTCHQR Program Quality Measures for the FY 2016 Payment Determinations and Subsequent Fiscal Years Payment Determinations

a. Considerations in Updating and Expanding Quality Measures under the LTCHQR Program for FY 2016 and Subsequent Payment Update Determinations

b. New LTCHQR Program Quality Measures Beginning with the FY 2016 Payment Determination

(1) Quality Measure #1 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

(2) LTCH Quality Measure #2 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Percentage of Residents or Patients Who Were Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682)

(3) LTCH Quality Measure #3 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)

(4) LTCH Quality Measure #4 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Ventilator Bundle (Application of NQF #0302)

(5) LTCH Quality Measure #5 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Restraint Rate per 1,000 Patient Days

5. Timeline for Data Submission under the LTCHQR Program for the FY 2015 Payment Determination

6. Timeline for Data Submission under the LTCHQR Program for the FY 2016 Payment Determination

7. Public Display of Data Quality Measures

E. Quality Reporting Requirements under the Ambulatory Surgical Centers Quality Reporting (ASCQR) Program

1. Background

2. Requirements for Reporting under the ASCQR Program

a. Administrative Requirements

(1) Requirements Regarding QualityNet Account and Administrator for the CYs 2014 and 2015 Payment Determinations

(2) Requirements Regarding Participation Status for the CY 2014 Payment Determination and Subsequent Payment Determination Years

b. Requirements Regarding Form, Manner, and Timing for Claims-Based Measures for CYs 2014 and 2015 Payment Determinations

(1) Background

(2) Minimum Threshold for Claims-Based Measures Using QDCs

c. ASCQR Program Validation of Claims-Based and Structural Measures

3. Extraordinary Circumstances Extension or Waiver for the CY 2014 Payment Determination and Subsequent Payment Determination Years

4. ASCQR Program Reconsideration Procedures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

F. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

1. Statutory Authority

2. Application of the Payment Update Reduction for Failure to Report for FY 2014 Payment Determination and Subsequent Years

3. Covered Entities

4. Quality Measures

a. Considerations in Selecting Quality Measures

b. Quality Measures Beginning with FY 2014 Payment Determination and Subsequent Years

(1) HBIPS-2 (Hours of Physical Restraint Use)

(2) HBIPS-3 (Hours of Seclusion Use)

(3) HBIPS-4 (Patients Discharged on Multiple Antipsychotic Medications)

(4) HBIPS-5 (Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification)

(5) HBIPS-6 (Post Discharge Continuing Care Plan Created)

(6) HBIPS-7 (Post Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider upon Discharge)

c. Maintenance of Technical Specifications for Quality Measures

5. Possible New Quality Measures for Future Years

6. Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

7. Form, Manner, and Timing of Quality Data Submission for the FY 2014 Payment Determination and Subsequent Years

a. Background

b. Procedural Requirements for the FY 2014 Payment Determination and Subsequent Years

c. Reporting and Submission Requirements for the FY 2014 Payment Determination

d. Reporting and Submission Requirements for the FY 2015 and FY 2016 Payment Determinations

e. Population, Sampling, and Minimum Case Threshold for FY 2014 and Subsequent Years

f. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2014 Payment Determination and Subsequent Years

8. Reconsideration and Appeals Procedure for the FY 2014 Payment Determination and Subsequent Years

9. Waivers from Quality Reporting Requirements for the FY 2014 Payment Determination and Subsequent Years

10. Electronic Health Records (EHRs)

IX. MedPAC Recommendations and Other Related Reports and Studies for the IPPS and LTCH PPS

A. MedPAC Recommendations for the IPPS for FY 2013

B. Studies and Reports on Reforming the Hospital Wage Index

1. Secretary's Report to Congress on Wage Index Reform

2. Institute of Medicine (IOM) Study on Medicare's Approach to Measuring Geographic Variations in Hospitals' Wage Costs

X. Quality Improvement Organization (QIO) Regulation Changes Relating to Provider and Practitioner Medical Record Deadlines and Claim Denials

XI. Other Required Information

A. Requests for Data from the Public

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

2. ICRs for Add-On Payments for New Services and Technologies

3. ICRs for the Occupational Mix Adjustment to the FY 2013 Index (Hospital Wage Index Occupational Mix Survey)

4. Hospital Applications for Geographic Reclassifications by the MGCRB

5. ICRs for Application for GME Resident Slots

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

8. ICRs for Hospital Value-Based Purchasing (VBP) Program

9. ICRs for the Long-Term Care Hospital Quality Reporting (LTCHOR) Program

10. ICRs for the Ambulatory Surgical Center (ASC) Quality Reporting Program

11. ICRs for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

Regulation Text

Addendum—Schedule of Standardized Amounts, Update Factors, and Rate-of-Increase Percentages Effective with Cost Reporting Periods Beginning on or after October 1, 2012 and Payment Rates for LTCHs Effective with Discharges Occurring on or after October 1, 2012

I. Summary and Background

II. Changes to the Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2013

A. Calculation of the Adjusted Standardized Amount

B. Adjustments for Area Wage Levels and Cost-of-Living

C. Calculation of the Prospective Payment Rates

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2013

A. Determination of Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2013

C. Capital Input Price Index

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2013

V. Changes to the Payment Rates for the LTCH PPS for FY 2013

A. LTCH PPS Standard Federal Rate for FY 2013

B. Adjustment for Area Wage Levels under the LTCH PPS for FY 2013

1. Background

2. Geographic Classifications/Labor Market Area Definitions

3. LTCH PPS Labor-Related Share

4. LTCH PPS Wage Index for FY 2013

5. Budget Neutrality Adjustment for Changes to the Area Wage Level Adjustment

C. LTCH PPS Cost-of-Living Adjustment for LTCHs Located in Alaska and Hawaii

D. Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

E. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2013

VI. Tables Referenced in this Final Rulemaking and Available through the Internet on the CMS Web Site

Appendix A--Economic Analyses

I. Regulatory Impact Analysis

A. Introduction

B. Need

C. Objectives of the IPPS

D. Limitations of Our Analysis

E. Hospitals Included in and Excluded From the IPPS

F. Effects on Hospitals and Hospital Units Excluded from the IPPS

G. Quantitative Effects of the Policy Changes under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

2. Analysis of Table I

3. Impact Analysis of Table II

H. Effects of Other Policy Changes

1. Effects of Policy on HACs, Including Infections

2. Effects of Policy Relating to New Medical Service and Technology Add-On Payments

3. Effects of Policy Changes Relating to SCHs

4. Effects of Payment Adjustment for Low-Volume Hospitals for FY 2013

5. Effects of Policy Changes Relating to Payment Adjustments for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME)

6. Effects of the Policy Changes Relating to Direct GME and IME

a. Effects of Clarification and Policy Regarding Timely Filing Requirements for Claims for Medicare Advantage Enrollees under Fee-for-Service Medicare

b. Effects of Policy Changes Relating to New Teaching Hospitals: New Program Growth from 3 Years to 5 Years

c. Effects of Changes Relating to 5-Year Period Following Implementation of Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes under Section 5503 of The Affordable Care Act

d. Preservation of Resident Cap Positions from Closed Hospitals (Section 5506 of the Affordable Care Act)

7. Effects of Changes Relating to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

8. Effects of Implementation of Rural Community Hospital Demonstration Program

9. Effects of Change in Effective Date for Policies Relating to Hospital Services Furnished under Arrangements

I. Effects of Changes in the Capital IPPS

1. General Considerations

2. Results

J. Effects of Payment Rate Changes and Policy Changes under the LTCH PPS

1. Introduction and General Considerations

2. Impact on Rural Hospitals

3. Anticipated Effects of LTCH PPS Payment Rate Change and Policy Changes

4. Effect on the Medicare Program

5. Effect on Medicare Beneficiaries

K. Effects of Requirements for Hospital Inpatient Quality Reporting (IQR) Program

L. Effects of PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

M. Effects of Hospital Value-Based Purchasing (VBP) Program Requirements

N. Effects of New Measures Added to the LTCH Quality Reporting (LTCHQR) Program

O. Effects of Quality Reporting Requirements for Ambulatory Surgical Centers

P. Effects of Requirements for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

Q. Effects of Requirements for Provider and Practitioner Medical Record Deadlines and Claims Denials

R. Alternatives Considered

S. Overall Conclusion

1. Acute Care Hospitals

2. LTCHs

II. Accounting Statements and Tables

A. Acute Care Hospitals

B. LTCHs

III. Regulatory Flexibility Act (RFA) Analysis

IV. Impact on Small Rural Hospitals

V. Unfunded Mandate Reform Act (UMRA) Analysis

VI. Executive Order 12866

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

II. Inpatient Hospital Update for FY 2013

A. FY 2013 Inpatient Hospital Update

B. Update for SCHs for FY 2013

C. FY 2013 Puerto Rico Hospital Update

D. Update for Hospitals Excluded from the IPPS

E. Update for LTCHs

III. Secretary's Recommendation

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This final rule makes payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it makes payment and policy changes for

inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). It also makes policy changes to programs associated with Medicare IPPS hospitals and LTCHs.

Under various statutory authorities, we are making changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2013. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).

- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.

- Sections 123(a) and (c) of Pub. L. 106-113 and section 307(b)(1) of Pub. L. 106-554 (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.

- Sections 1814(l), 1820, and 1834(g) of the Act, which specifies that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.

- Section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix.

- Section 1886(d)(4)(D) of the Act, which addresses certain hospital-acquired conditions (HACs), including infections. Section 1886(d)(4)(D) of the Act specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) are high cost, high volume, or both; (b) are assigned to a higher paying MS-DRG when present as a secondary diagnosis (that is, conditions under the MS-DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions. Section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were present on admission (POA). Section 1886(d)(4)(D)(i) of the Act specifies that effective for discharges occurring on or after October 1, 2008, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS-DRG if a selected condition is not POA.

- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.

- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase in payments to a subsection (d) hospital for a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.

- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary. Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient VBP Program to hospitals for discharges occurring on or after October 1, 2012.

- Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act, which establishes the "Hospital Readmissions Reduction Program" effective for discharges from an "applicable hospital" beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

2. Summary of the Major Provisions

a. MS-DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount

Section 7(b)(1)(A) of Pub. L. 110-90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Pub. L. 110-90, the Secretary shall make an appropriate prospective adjustment under section 1886(d)(3)(A)(vi) of the Act.

Section 7(b)(1)(B) of Pub. L. 110-90 requires the Secretary to make an additional one-time adjustment to the standardized amounts to offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Pub. L. 110-90.

After accounting for adjustments made in FYs 2008 and 2009, we have found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of -3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Pub. L. 110-90. Without making this adjustment, our actuaries estimated that annual aggregate payments would be increased by approximately $4 billion. Furthermore, an additional one-time adjustment of -5.8 percent would be required to fully recapture overpayments (estimated at approximately $6.9

billion) due to documentation and coding that occurred in FY 2008 and FY 2009, as required by section 7(b)(1)(B) of Pub. L. 110-90.

CMS has thus far implemented a -2.0 percent (of a required -3.9 percent) prospective adjustment, and completed the full one-time -5.8 percent recoupment adjustment (-2.9 percent in both FYs 2011 and 2012). In FY 2013, we are completing the remaining -1.9 percent prospective adjustment, while also making a +2.9 percent adjustment to remove the effect of the FY 2012 one-time recoupment adjustment. We have also determined that a cumulative adjustment of -5.4 percent is required to eliminate the full effect of documentation and coding changes on future payments to SCHs and MDHs. After accounting for adjustments made to the hospital-specific rate in FY 2011 and FY 2012, an additional prospective adjustment of -0.5 percent is necessary to complete the full -5.4 adjustment. For FY 2013, we are making a full -0.5 percent adjustment to the hospital-specific rate, in keeping with our policy of applying equivalent adjustments, when applicable, to other subsection (d) hospital payment systems.

In the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to make an additional adjustment to account for documentation and coding effects that occurred in FY 2010. After review of comments and recommendations from MedPAC, CMS analyzed FY 2010 claims using the same methodology as previously applied to FYs 2008 and 2009 claims. CMS estimated that there was a 0.8 percentage point effect due to documentation and coding that did not reflect an actual increase in patient severity. However, in light of public comments we received on the proposed rule, we are not making an adjustment to account for this effect at this time. Therefore, the total

documentation and coding adjustment for FY 2013 is a +1.0 percent adjustment (-1.9 plus +2.9) to the standardized amount and a -0.5 percent adjustment to the hospital-specific rate.

b. Hospital-Acquired Conditions (HACs)

Section 1886(d)(4)(D) specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) are high cost, high volume, or both; (b) are assigned to a higher paying MS-DRG when present as a secondary diagnosis (that is, conditions under the MS-DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions.

In this final rule, we are adding two new conditions, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Pneumothorax with Venous Catheterization, for the HAC payment provisions for FY 2013 under section 1886(d)(4)(D) of the Act. We note that the SSI Following CEID Procedures condition will be a new subcategory of the SSI HAC category. We also are adding diagnosis codes 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the existing Vascular Catheter-Associated Infection HAC category for FY 2013.

c. Reduction of Hospital Payments for Excess Readmissions

We are finalizing a number of policies to implement section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, which establishes the Hospital Readmissions Reduction Program. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions of selected applicable conditions, which are acute myocardial infarction, heart failure, and pneumonia. We are finalizing provisions related to the applicable hospitals that are included in the Hospital Readmissions Reduction Program, the methodology to calculate the adjustment factor, the portion of the hospital's payment that is reduced by the adjustment factor, and the process under which the hospitals have the opportunity to review and submit corrections for their readmissions information prior to the information being posted on the Hospital Compare Web site.

d. Long-Term Care Hospital-Specific Market Basket

We are updating LTCH payment rates with a separate market basket comprised of data from only LTCHs, which we refer to as a "LTCH-specific market basket." We are implementing a stand-alone LTCH market basket based on FY 2009 Medicare cost report data. The method used to calculate the cost weights and the price proxies used are generally similar to those used in the FY 2008-based RPL market basket that was finalized for the FY 2012 IPPS/LTCH PPS final rule. The primary difference is that we are using data from LTCH providers only.

e. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Satellite Facilities and the Increase in the Number of Beds in LTCHs and LTCH Satellite Facilities

Moratoria on the implementation of certain LTCH payment policies and on the development of new LTCHs and LTCH satellite facilities and on bed increases in existing LTCHs and LTCH satellite facilities established under sections 114(c) and (d) of the MMSEA (Pub. L. 110-173) as amended by section 4302 of the ARRA (Pub. L. 111-5) and further amended by sections 3106 and 10312 of the Affordable Care Act are set to expire during CY 2012, under current law.

The moratoria established by these provisions delayed the full implementation of the following policies for 5 years beginning at various times in CY 2007:

- The full application of the "25-percent payment adjustment threshold" to certain LTCHs, including hospitals-within-hospitals (HwHs) and LTCH satellite facilities for cost reporting periods beginning on or after July 1, 2007, and before July 1, 2012, or cost reporting periods beginning on or after October 1, 2007, and before October 1, 2012, as applicable under the regulations at §§ 412.534 and 412.536.

- The inclusion of an "IPPS comparable per diem amount" option for payment determinations under the short stay outlier (SSO) adjustment at § 412.529 of the regulations for LTCH discharges occurring on or after December 29, 2007, but prior to December 29, 2012.

- The application of any one-time budget neutrality adjustment to the LTCH PPS standard Federal rate provided for in § 412.523(d)(3) of the regulations from December 29, 2007, through December 28, 2012.

- In general, the development of new LTCHs and LTCH satellite facilities, or increases in the number of beds in existing LTCHs and LTCH satellite facilities from

December 29, 2007, through December 28, 2012, unless one of the specified exceptions to the particular moratorium was met.

In this final rule, we are extending the existing delay of the full implementation of the 25-percent payment adjustment threshold for an additional year; that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, as applicable. We are providing a 1-year moratorium on the application of the "25-percent threshold" payment adjustment for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013. However, the moratorium will expire for several types of LTCHs with cost reporting periods beginning before July 1, 2012 and September 30, 2012, prior to the effective date of the moratorium finalized in this rule. This gap in the continued application of the moratorium is a result of the July 1, 2007 effective date of section 114(c)(1) of the MMSEA, as amended by section 4302(a)(1) of the ARRA, which was based on the former July 1 through June 30 regulatory cycle for the LTCH PPS. In order to address this situation for this group of LTCHs, we are finalizing a policy that applies a supplemental moratorium on a per discharge basis beginning with discharges occurring on or after October 1, 2012, and continuing through the LTCH's cost reporting period.

We are providing for an additional 1-year extension in the delay of the full application of the 25-percent payment adjustment threshold policy because we believe that, based on a recent research initiative, we could soon be in a position to propose revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary. In light of this potential result, we believe it is prudent to

avoid requiring LTCHs (or CMS systems) to implement the full reinstatement of the policy for what could be a relatively short period of time.

We are not making any changes to the SSO policy as it currently exists in the regulations at § 412.529. Accordingly, consistent with the existing regulations at § 412.529(c)(3), for SSO discharges occurring on or after December 29, 2012, the "IPPS comparable per diem amount" option at § 412.529(c)(3)(i)(D) will apply to payment determinations for cases with a covered length of stay that was equal to or less than one standard deviation from the geometric average length of stay for the same MS- DRG under the IPPS (that is, the "IPPS comparable threshold").

The moratoria on the development of new LTCHs or LTCH satellite facilities and on an increase in the number of beds in existing LTCHs or LTCH satellite facilities are set to expire on December 29, 2012, under current law.

We are making a one-time prospective adjustment under § 412.523(d)(3) of the regulations (which will not apply to payments for discharges occurring on or before December 28, 2012, consistent with the statute) and to transition the application of this adjustment over a 3-year period. Regulations at § 412.523(d)(3) provide for the possibility of making a one-time prospective adjustment to the LTCH PPS rates so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.

f. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, hospitals are required to report data on measures selected by the Secretary for the Hospital IQR Program in order to receive the full annual percentage increase. In past rules, we have established measures for reporting and the process for submittal and validation of the data.

In this final rule, we are making programmatic changes to the Hospital IQR Program for the FY 2015 payment determination and subsequent years. These changes will streamline and simplify the process for hospitals and reduce burden. We are reducing the number of measures in the Hospital IQR Program from 72 to 59 for the FY 2015 payment determination. We are removing 1 chart-abstracted measure and 16 claims based measures from the program for the FY 2015 payment determination and subsequent years. We are removing these measures for a number of reasons, including that these measures are losing NQF endorsement, are included in an existing composite measure, are duplicative of other measures in the Hospital IQR Program, or could otherwise be reported on Hospital Compare in the future under the authority of section 3008 of the Affordable Care Act. In addition, we are adopting three claims-based measures, one chart-abstracted measure and a survey-based measure regarding care transitions, which we will collect using the existing HCAHPS survey, to the measure set for the FY 2015 payment determination and subsequent years. We are adopting a structural measure for the FY 2016 payment determination and subsequent years.

In an effort to streamline the rulemaking process, we are retaining measures for all subsequent payment determinations, unless specifically stated otherwise, through rulemaking. We are adopting a policy under which we will use a subregulatory process

to make nonsubstantive updates to the Hospital IQR Program measures. To ensure that hospitals that participate in the Hospital IQR Program are submitting data for a full year, we are providing that hospitals that would like to participate in the Hospital IQR Program for the first time, or that previously withdrew from the Program and would like to participate again, must submit a completed Notice of Participation by December 31 of the calendar year preceding the first quarter of the calendar year in which chart-abstracted data submission is required for any given fiscal year. In addition, if a hospital wishes to withdraw from the program, it will have until May 15 prior to the start of the payment year affected to do so. In order reduce the burden associated with validation, we are reducing the base annual validation sample from 800 to 400, with an additional targeted sample of up to 200 hospitals. All hospitals failing validation in a previous year will be included in the 200 hospital supplement, with a random sample drawn from hospitals meeting one or more additional targeting criteria. We are calculating scores for both the chart-abstracted clinical process of care and HAC measure sets and then calculating a total score reflecting a weighted average of each of the two individual scores. Hospitals must achieve a total score of 75 percent to pass validation.

g. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the

Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent.

We previously published the requirements and related measures to implement the Hospital Inpatient VBP Program in a final rule issued in the **Federal Register** on April 29, 2011 (76 FR 26490, May 6, 2011), in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660), and in the CY 2012 OPPS/ASC final rule (76 FR 74527 through 74547). In this final rule, we are adding requirements for the Hospital VBP Program. Specifically, we are adding for the FY 2015 program two additional outcome measures--an AHRQ Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We are adding a measure of Medicare Spending per Beneficiary in the Efficiency domain. We are also finalizing a number of other requirements for the program, including an appeals process, case minimums, a review and corrections process for claims-based measures, and the scoring methodology for FY 2015.

3. Summary of Costs and Benefits

- **FY 2013 Documentation and Coding Adjustment**: Section 7(b)(1)(A) of Pub. L. 110-90 requires that, if the Secretary determines that implementation of the MS-DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Pub. L. 110-90, the Secretary shall make an appropriate prospective adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 7(b)(1)(B) of

Pub. L. 110-90 requires the Secretary to make an additional one-time adjustment to the standardized amounts to offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Pub. L. 110-90.

After accounting for adjustments made in FYs 2008 and 2009, we have found a remaining documentation and coding effect of 3.9 percent. As we have discussed in prior rules, an additional cumulative adjustment of -3.9 percent will be necessary to meet the requirements of section 7(b)(1)(A) of Pub. L. 110-90. Without making this adjustment, our actuaries estimated that annual aggregate payments would be increased by approximately $4 billion. Furthermore, an additional one-time adjustment of -5.8 percent will be required to fully recapture overpayments (estimated at approximately $6.9 billion) due to documentation and coding that occurred in FY 2008 and FY 2009, as required by section 7(b)(1)(B) of Pub. L. 110-90.

CMS has thus far implemented a -2.0 percent (of a required -3.9 percent) prospective adjustment, and completed the full one-time -5.8 percent recoupment adjustment (-2.9 percent in both FYs 2011 and 2012). In FY 2013, we are completing the remaining -1.9 percent prospective adjustment, while also making a +2.9 percent adjustment to remove the effect of the FY 2012 one-time recoupment adjustment. We have also determined that a cumulative adjustment of -5.4 percent is required to eliminate the full effect of documentation and coding changes on future payments to SCHs and MDHs. After accounting for adjustments made to the hospital-specific rate in FY 2011

and FY 2012, an additional prospective adjustment of -0.5 percent is necessary to complete the full -5.4 percent adjustment. We are making a full -0.5 percent adjustment to the hospital-specific rate, in keeping with our policy of applying equivalent adjustments, when applicable, to other subsection (d) hospital payment systems.

In addition, in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to make an additional adjustment to account for documentation and coding effects that occurred in FY 2010. After review of comments and recommendations from MedPAC, CMS analyzed FY 2010 claims using the same methodology as previously applied to FYs 2008 and 2009 claims. CMS estimated that there was a 0.8 percentage point effect due to documentation and coding that did not reflect an actual increase in patient severity. However, in light of the public comments that we received on the proposed rule, we are not making an adjustment to account for this effect at this time. Therefore, the total IPPS documentation and coding adjustment of +1.0 percent (-1.9 plus +2.9) will increase total payments by approximately $1.069 billion. The total adjustment to the hospital-specific rate will be -0.5, and will decrease total payment by $22.7 million. The combined impact of the final FY 2013 documentation and coding adjustments will increase total payments by approximately $1.042 billion.

- **Hospital-Acquired Conditions (HACs).** For FY 2013, we are continuing to implement section 1886 (d)(4)(D) of the Act that addresses certain hospital-acquired conditions (HACs), including infections. We are adding two additional conditions for FY 2013, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Iatrogenic Pneumothorax with Venous Catheterization. The

projected savings estimate for these two conditions is less than $1 million, with the total estimated savings from HACs for FY 2013 projected at $24 million dollars.

- **Reduction to Hospital Payments for Excess Readmissions**. We are making a number of policies to implement section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, which establishes the Hospital Readmissions Reduction Program. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment amount to account for excess readmissions of selected applicable conditions, which are acute myocardial infarction, heart failure, and pneumonia. This provision is not budget neutral. A hospital's readmission payment adjustment is the higher of a ratio of a hospital's aggregate dollars for excess readmissions to their aggregate dollars for all discharges, or 0.99 (that is, or a 1-percent reduction) for FY 2013. In this final rule, we estimate that the Hospital Readmissions Reduction Program will result in a 0.3 percent decrease, or approximately $280 million, in payments to hospitals.

- **Long-Term Care Hospital-Specific Market Basket**. The FY 2009-based LTCH-specific market basket update (as measured by percentage increase) for FY 2013 is currently estimated to be 2.6 percent, which is slightly lower than the market basket update based on the FY 2008-based RPL market basket at 2.7 percent (currently used under the LTCH PPS). Therefore, we project that there will be no significant fiscal impact on the LTCH PPS payment rates in FY 2013 as a result of this policy. In addition, we are updating the labor-related share under the LTCH PPS for FY 2013 based on the relative importance of each labor-related cost category in the FY 2009-based LTCH-

specific market basket. Although this policy will result in a decrease in the LTCH PPS labor-related share for FY 2013, we are projecting that there will be no effect on aggregate LTCH PPS payments due to the regulatory requirement that any changes to the LTCH area wage adjustment (including the labor-related share) are adopted in a budget neutral manner.

- **Update to the LTCH PPS Standard Federal Rate, including the Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Satellite Facilities and the Increase in the Number of Beds in LTCHs and LTCH Satellite Facilities.** Based on the best available data for the 428 LTCHs in our database, we estimate that the changes we are presenting in the preamble and Addendum of this final rule, including the update to the standard Federal rate for FY 2013, the changes to the area wage adjustment for FY 2013, and changes to short-stay outliers and high-cost outliers will result in an increase in estimated payments from FY 2012 of approximately $92 million (or approximately 1.7 percent). Although we generally project an increase in payments for all LTCHs in FY 2013 as compared to FY 2012, we expect rural LTCHs to experience a larger than average increase in payments (3.3 percent) primarily due to the changes to the area wage level adjustment. Rural hospitals generally have a wage index of less than 1; therefore, the decrease to the labor-related share results in their wage index reducing a smaller portion of the standard Federal rate, resulting in an estimated increase in payments in FY 2013 as compared to FY 2012. In addition, the effect of the extension of the moratorium on the application of the "25 percent threshold" payment adjustment policy, as provided by

section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, that is generally effective for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, is estimated to result in a payment impact of approximately $170 million to LTCHs. (We note that, for certain LTCHs and LTCH satellite facilities with cost reporting periods beginning or after July 1, 2012, and before October 1, 2012, we are providing a supplemental moratorium for discharges beginning on or after October 1, 2012, and through the end of the cost reporting period. Overall, we estimate that the increase in aggregate LTCH PPS payments in FY 2013 will be $262 million.

- **Hospital Inpatient Quality Reporting (IQR) Program**. In this final rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for FY 2015. We estimate that approximately 95 hospitals may not receive the full annual percentage increase in any fiscal year. However, at this time, information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for FY 2015.

We are adding supplements to the chart validation process for the Hospital IQR Program. Starting with the FY 2015 payment determination, we are finalizing a modest increase to the current Hospital IQR Program validation sample of 18 cases per quarter to 27 cases per quarter in order to capture data on CLABSI, CAUTI, and SSI measures. However, in order not to increase the Hospital IQR validation program's overall burden

to hospitals, we are reducing the total sample size of hospitals included in the annual validation sample from 800 eligible hospitals to up to 600 eligible hospitals.

We provide payment to hospitals for the cost of sending charts to the CDAC contractor at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Our experience shows that the average chart received by the CDAC contractor is approximately 275 pages. The requirement of an additional 9 charts per hospital submitted for validation, combined with the decreased sample size, will result in approximately 1,800 additional charts per quarter being submitted to CMS by all selected hospitals. Thus, we estimate that we would expend approximately $66,600 per quarter to collect the additional charts we need to validate all measures.

- **Hospital VBP Program.** The Hospital VBP Program is statutorily mandated to be budget neutral. We believe that the program's benefits will be seen in improved patient outcomes, safety, and experience of care. We cannot estimate these benefits in actual dollars and improved quality of care because the payment adjustments based on hospital performance will not begin to be made until FY 2013.

B. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these "subsection (d) hospitals."

Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations.

If the hospital is an approved teaching hospital, it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical

improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. Through and including FY 2006, a Medicare-dependent, small rural hospital (MDH) received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. As discussed below, for discharges occurring on or after October 1, 2007, but before October 1, 2012, an MDH will receive the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. (We note that the statutory provision for payments to MDHs expires at the end of FY 2012, that is, after

September 30, 2012.) SCHs are the sole source of care in their areas, and MDHs are a major source of care for Medicare beneficiaries in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services "in accordance with a prospective payment system established by the Secretary." The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR Part 412, Subparts A through M.

2. Hospitals and Hospital Units Excluded from the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105-33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106-113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106-554) provide for the implementation of PPSs for rehabilitation hospitals and units (referred to as inpatient rehabilitation facilities (IRFs)), LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR Parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123(a) and (c) of Pub. L. 106-113 and section 307(b)(1) of Pub. L. 106-554 (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR Part 412, Subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR Parts 413 and 415.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved

graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR Part 413.

C. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) Applicable to FY 2013

The Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010, made a number of changes that affect the IPPS and the LTCH PPS. (Pub. L. 111-148 and Pub. L. 111-152 are collectively referred to as the "Affordable Care Act.") A number of the provisions of the Affordable Care Act affect the updates to the IPPS and the LTCH PPS and providers and suppliers. The provisions of the Affordable Care Act that were applicable to the IPPS and the LTCH PPS for FYs 2010, 2011, and 2012 were implemented in the June 2, 2010 **Federal Register** notice (75 FR 31118), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50042) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51476).

In this final rule, we are implementing, or continuing in FY 2013 to implement, the following provisions (or portions of the following provisions) of the Affordable Care Act that are applicable to the IPPS, the LTCH PPS, and PPS-exempt cancer hospitals:

- Section 3001 of Pub. L. 111-148, which provides for establishment of a hospital inpatient value-based purchasing program under which value-based incentive payments will be made in a fiscal year to hospitals that meet performance standards for the performance period for that fiscal year.

- Section 3004 of Pub. L. 111-148, which provides for the submission of quality data for LTCHs in order to receive the full annual update to the payment rates beginning with the FY 2014 rate year.

- Section 3005 of Pub. L. 111-148, which provides for the establishment of a quality reporting program for PPS-exempt cancer hospitals with respect to FY 2014, and for subsequent program years.

- Section 3025 of Pub. L. 111-148, which establishes a hospital readmissions reduction program and requires the Secretary to reduce payments to applicable hospitals with excess readmissions effective for discharges beginning on or after October 1, 2012.

- Section 3125 and 10314 of Pub. L. 111-148, which modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals, effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume.

- Section 3401 of Pub. L. 111-148, which provides for the incorporation of productivity adjustments into the market basket updates for IPPS hospitals and LTCHs.

- Section 10324 of Pub. L. 111-148, which provides for a wage adjustment for hospitals located in frontier States.

- Sections 3401 and 10319 of Pub. L. 111-148 and section 1105 of Pub. L. 111-152, which revise certain market basket update percentages for IPPS and LTCH PPS payment rates for FY 2013.

- Section 3137 of Pub. L. 111-148, which requires the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index under the IPPS. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by MedPAC in its June 2007 Report to Congress and to consult with relevant affected parties.

- Section 5503 of Pub. L. 111-148, as amended by Pub. L. 111-152 and section 203 of Pub. L. 111-309, which provides for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals, and the "redistribution" of the estimated number of FTE resident slots to other qualified hospitals. In addition, section 5503 requires the application of these provisions to IME in the same manner as the FTE resident caps for direct GME.

- Section 5506 of Pub. L. 111-148, which added a provision to the Act that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the aggregate number of FTE resident cap slots distributed is equal to the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively.

D. Issuance of a Notice of Proposed Rulemaking

On May 11, 2012, we published in the **Federal Register** (77 FR 27870), a proposed rule that set forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals in FY 2013. We also set forth proposed changes relating to payments for IME costs and payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, in the proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2013.

Below is a summary of the major changes that we proposed to make:

1. Changes to MS-DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we include--

- Proposed changes to MS-DRG classifications based on our yearly review.
- Proposed application of the documentation and coding adjustment for FY 2013 resulting from implementation of the MS-DRG system.
- A discussion of the Research Triangle Institute, International (RTI) reports and recommendations relating to charge compression.
- Proposed recalibrations of the MS-DRG relative weights.
- Proposed changes to hospital-acquired conditions (HACs) and a listing and discussion of HACs, including infections, that would be subject to the statutorily required adjustment in MS-DRG payments for FY 2013.
- A discussion of the FY 2013 status of new technologies approved for add-on payments for FY 2012 and a presentation of our evaluation and analysis of the FY 2013

applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108-173, obtained in a town hall meeting).

2. Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to the proposed rule, we are proposing revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include the following:

- The proposed FY 2013 wage index update using wage data from cost reporting periods beginning in FY 2009.
- Analysis and implementation of the proposed FY 2013 occupational mix adjustment to the wage index for acute care hospitals.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications.
- The proposed adjustment to the wage index for acute care hospitals for FY 2013 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- The timetable for reviewing and verifying the wage data used to compute the proposed FY 2013 hospital wage index.
- Determination of the labor-related share for the proposed FY 2013 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

In section IV. of the preamble of the proposed rule, we discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR Parts 412, 413, and 476, including the following:

- The proposed rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates.
- Proposed clarification regarding the duration of the classification status of SCHs.
- The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed payment adjustment for low-volume hospitals for FY 2013.
- The statutorily required IME adjustment factor for FY 2013, a clarification of the requirements of timely filing of claims for Medicare Advantage enrollees for IME, direct GME, and nursing and allied health education payment purposes, and a proposal to apply the timely filing requirements to the submission of no-pay bills for purposes of calculating the DSH payment adjustment.
- Proposal for counting labor and delivery beds in the formula for determining the payment adjustment for disproportionate share hospitals and IME payments.
- Discussion of the expiration of the MDH program in FY 2012.
- Proposed changes to the inpatient hospital update for FY 2013, including incorporation of a productivity adjustment.

- Proposed changes relating to GME and IME payments, including proposed changes in new growth period for new residency programs from 3 years to 5 years for new teaching hospitals; proposals and clarifications related to the 5-year period following implementation of reductions and increases to hospitals' FTE resident caps; and proposals and clarifications related to the preservation of resident cap positions from closed hospitals.

- Proposed conforming changes to regulations relating to reporting requirements for pension costs for Medicare cost-finding purposes.

- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.

- Proposed delay in the effective date of policies relating to hospital routine services furnished under arrangements.

4. FY 2013 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2013 and the proposed MS-DRG documentation and coding adjustment for FY 2013.

5. Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of the proposed rule, we discuss proposed changes to payments to certain excluded hospitals.

6. Changes to the LTCH PPS

In section VII. of the preamble of the proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2013. Specifically, we proposed the following major changes: a 1-year extension of the moratorium on the full implementation of the "25-percent threshold" payment adjustment at 42 CFR 412.534 and 412.536; a "one-time prospective adjustment" to the standard Federal rate phased in over a 3-year period (which would not be applicable to payments for discharges occurring on or before December 28, 2012, consistent with the statute); an LTCH-specific market basket; and annual updates to the LTCH PPS standard Federal rate and to other payment factors.

7. Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of the proposed rule, we address--

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full applicable percentage increase.
- The proposed establishment of a quality reporting program for PPS-exempt cancer hospitals.
- Proposed requirements for the Hospital Value-Based Purchasing Program.
- Proposed requirements for the quality reporting measures under the LTCH Quality Reporting (LTCHQR) Program.
- Proposed quality data reporting and other requirements for Ambulatory Surgical Center Quality Reporting (ASCQR) Program.
- The establishment of the Inpatient Psychiatric Facility Quality Reporting Program (IPFQRP).

8. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2013 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, we addressed the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2013 for certain hospitals excluded from the IPPS.

9. Determining Prospective Payment Rates for LTCHs

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2013 prospective standard Federal rate. We proposed to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the fixed-loss amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

10. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, LTCHs, ASCs, and IPFs.

11. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2013 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs).

- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.

- The standard Federal rate for hospital inpatient services furnished by LTCHs.

12. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2012 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs under the IPPS, for hospitals and distinct part hospital units excluded from the IPPS. We addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2012 report or to obtain a copy of the report, contact MedPAC at (202) 220-3700 or visit MedPAC's Web site at: http://www.medpac.gov.

We received approximately 436 timely pieces of correspondence from the public in response to the FY 2013 IPPS/LTCH PPS proposed rule. We summarize these public comments and present our responses under the specific subject areas of this final rule.

II. Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as DRGs) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. MS-DRG Reclassifications

For general information about the MS-DRG system, including yearly reviews and changes to the MS-DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766), the FY 2011

IPPS/LTCH PPS final rule (75 FR 50053 through 50055), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51485 through 51487).

C. Adoption of the MS-DRGs in FY 2008

For information on the adoption of the MS-DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

D. FY 2013 MS-DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount

1. Background on the Prospective MS-DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Pub. L. 110-90

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS-DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS-DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 751 MS-DRGs. By increasing the number of MS-DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS-DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS-DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that

final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of -4.8 percent to the national standardized amount. We provided for phasing in this -4.8 percent adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of -1.2 percent for FY 2008, -1.8 percent for FY 2009, and -1.8 percent for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Pub. L. 110-90. Section 7(a) of Pub. L. 110-90 reduced the documentation and coding adjustment made as a result of the MS-DRG system that we adopted in the FY 2008 IPPS final rule with comment period to -0.6 percent for FY 2008 and -0.9 percent for FY 2009, and we finalized the FY 2008 adjustment through rulemaking, effective October 1, 2007 (72 FR 66886).

For FY 2009, section 7(a) of Pub. L. 110-90 required a documentation and coding adjustment of -0.9 percent, and we finalized that adjustment through rulemaking (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made by Pub. L. 110-90, are cumulative. As a result, the -0.9 percent documentation and coding

adjustment for FY 2009 was in addition to the -0.6 percent adjustment for FY 2008, yielding a combined effect of -1.5 percent.

2. Prospective Adjustment to the Average Standardized Amounts Required by Section 7(b)(1)(A) of Pub. L. 110-90

Section 7(b)(1)(A) of Pub. L. 110-90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Pub. L. 110-90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act.

Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

3. Recoupment or Repayment Adjustments in FYs 2010 through 2012 Required by Pub. L. 110-90

If, based on a retroactive evaluation of claims data, the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different from the prospective documentation and coding adjustments

applied under section 7(a) of Pub. L. 110-90, section 7(b)(1)(B) of Pub. L. 110-90 requires the Secretary to make an additional adjustment to the standardized amounts under section 1886(d) of the Act. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Pub. L. 110-90. This adjustment is in addition to making an appropriate adjustment to the standardized amounts under section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A) of Pub. L. 110-90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 precisely matched the changes that occurred in those years. Pub. L. 110-90 requires that the Secretary only make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

4. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Pub. L. 110-90, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008 using the methodology first described in the FY 2009 IPPS/LTCH PPS final rule (73 FR 43768 and 43775) and later discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43768 through 43772). We performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims (75 FR 50057 through 50068). The results of the analysis for the FY 2011 proposed and final

rules, and subsequent evaluations in FY 2012, supported that the 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS-DRG system. We were persuaded by both MedPAC's analysis (as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50064 through 50065)) and our own review of the methodologies recommended by various commenters that the methodology we employed to determine the required documentation and coding adjustments was sound.

5. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Pub. L. 110-90 and Section 1886(d)(3)(A)(vi) of the Act

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43767 through 43777), we opted to delay the implementation of any documentation and coding adjustment until a full analysis of case-mix changes based on FY 2009 claims data could be completed. We refer readers to the FY 2010 IPPS/RY LTCH PPS final rule for a detailed description of our proposal, responses to comments, and finalized policy. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 1.054 percent. After accounting for the -0.6 percent and the -0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of -3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Pub. L. 110-90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Unlike section

7(b)(1)(B) of Pub. L. 110-90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an "appropriate" adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believe we have some discretion as to the manner in which we apply the prospective adjustment of -3.9 percent. We indicated that applying the full prospective adjustment of -3.9 percent for FY 2011, in combination with the proposed recoupment adjustment of -2.9 percent in FY 2011 (discussed below) would require an aggregate adjustment of -6.8 percent. As we discussed extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. Therefore, we stated that we believed it was appropriate to not implement the -3.9 percent prospective adjustment in FY 2011 because we finalized a -2.9 percent recoupment adjustment for that year. Accordingly, we did not propose a prospective adjustment under section 7(b)(1)(A) of Pub. L. 110-90 for FY 2011 (75 FR 23868 through 23870). We note that, as a result, payments in FY 2011 (and in each future year until we implement the requisite adjustment) would be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Pub. L. 110-90. Our actuaries estimate that this 3.9 percentage point increase will result in an aggregate payment of approximately $4 billion. We also noted that payments in FY 2010 were also expected to be 3.9 percent higher than they would have been if we had implemented an adjustment

under section 7(b)(1)(A) of Pub. L. 110-90, which our actuaries estimated increased aggregate payments by approximately $4 billion in FY 2010.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that because further delay of this prospective adjustment will result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a -2.0 percent prospective adjustment (a reduction of a proposed -3.15 percent adjustment) to the standardized amount to partially eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27887), for FY 2013, we proposed to complete the prospective portion of the adjustment required under section 7(b)(1)(B) of Pub. L. 110-90. We proposed a -1.9 percent adjustment to the standardized amount for FY 2013. We stated that this adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009. We indicated we believe it is imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future years until a full adjustment is made. We believe that the offsetting nature of the FY 2012 recoupment adjustment (described in section II.D.6. of the proposed rule (77 FR 27887 through 27888) and the

preamble of this final rule) will mitigate any negative financial impacts of this prospective adjustment.

Comment: MedPAC submitted a comment fully supporting the proposed documentation and coding adjustments, citing its 2011 comment letter regarding the FY 2012 IPPS/LTCH PPS proposed rule for its support of the CMS methodology and the calculation of documentation and coding effect estimates. MedPAC reiterated its recommendation that Congress grant the Secretary the authority to recapture overpayments due to documentation and coding effects that occurred after FY 2009.

Response: We appreciate MedPAC's analysis and continued support of the methodology to calculate the impact of documentation and coding on hospital payments. As stated in the proposed rule, at this point, we only have the authority to prospectively adjust the standardized amount to prevent future overpayments due to the effects of documentation and coding. We believe that any overpayments made in FY 2008 and FY 2009 have already been recaptured, and any additional past overpayments cannot be recovered without additional statutory authority.

Comment: Many commenters, including national hospital associations, continue to argue that the methodology employed by CMS significantly overstated the impact of documentation and coding changes. Commenters believed that the CMS methodology assumes that case-mix index has held constant over several fiscal years, and they view this as a flawed assumption. Commenters submitted a case-mix trend analysis, noting that this analysis was updated for new claims data and revised relative to similar analyses submitted as public comment on documentation and coding in prior IPPS rulemaking.

According to the commenters, their case-mix trend analysis indicated only a 3.5 percent documentation and coding increase, which equals the total adjustment already implemented by CMS. These commenters argued that no further cuts are necessary to the standardized amount, and that the proposed adjustments are excessive.

Response: We disagree that the presented trend analysis provides a more accurate estimate of the documentation and coding effect. We continue to believe that the proposed methodology, which removes real-case mix growth from the calculation, yields a more straightforward and direct estimate. We also believe that the estimates obtained using our methodology are consistent with real case-mix growth as demonstrated by MedPAC in its 2011 public comment submitted on the FY 2012 IPPS/LTCH PPS proposed rule. We refer readers to our response in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51494-51496) for a more detailed response.

Comment: One commenter, a national hospital association, disagreed with CMS' response from prior year rulemaking that "changes in case-mix do not necessarily follow a consistent pattern over time." The commenter indicated that the simple linear regression of case-mix growth it submitted was the most conservative estimate of potential documentation and coding effect, and that more advanced, nonlinear statistical methods were better statistical fits, and suggested an even smaller impact due to documentation and coding.

Response: We are not convinced that further statistical testing of a case-mix trend based analysis would yield more accurate results, nor did we intend to suggest that nonlinear regression of case-mix growth would be a more appropriate measure of

documentation and coding effects. The estimates submitted by the commenter presented a theoretical documentation and coding effect ranging from +3.5 percent to -1.9 percent. As discussed in prior year rulemaking, the inclusion of additional years in the suggested CMI trend based analysis caused documentation and coding effect estimates to vary significantly, and now the commenter argues that different statistical interpretations also may cause large fluctuations. With respect to the trend analysis, we continue to believe that the determination of an appropriate historical trend is less straightforward than our proposed methodology, which removes real case-mix growth from the calculation. Again, we refer readers to our more detailed response to public comments in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51494 through 51496).

Comment: One commenter stated that coding offsets exceeding total case-mix growth duplicate the productivity adjustment mandated by the Affordable Care Act and should not be implemented. The commenter stated that decreases in real case-mix represent an improvement in productivity already adjusted for in the productivity adjustment.

Response: Section 3401(a) of the Affordable Care Act requires that the IPPS operating market basket update be adjusted by changes in economy-wide productivity for FY 2012 (and each subsequent fiscal year). The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, cost reporting period, or other annual period). We disagree with the commenter that this statutory provision somehow

interacts with our documentation and coding adjustment authority. This statutory provision does not in any way reference our statutory documentation and coding adjustment authority, nor does our documentation and coding authority in any way reference the market basket adjustment for economy-wide productivity. The methodology used for determining the IPPS rates, and specifically our methodology for estimating documentation and coding effects was made available to the general public (through notice and comment rulemaking) prior to the enactment of the Affordable Care Act. However the law did not reference nor change our authority in light of the productivity adjustment.

In addition, as we have previously indicated, our methodology for estimating documentation and coding removes changes in real case-mix from the calculation. Although we disagree that decreases in real case-mix represent an improvement in productivity in the context of section 3401(a), even if for purposes of discussion one were to accept this assertion, this is not a documentation and coding adjustment issue. The proper place for any offset would be to the productivity adjustment. Section 3401(a) of the Affordable Care Act provides no authority for such an adjustment for decreases in real case-mix.

After consideration of the public comments we received, we do not believe that any alternative methodologies would produce more accurate estimates of documentation and coding effects. We are finalizing, as proposed, a -1.9 percent documentation and coding adjustment to the standardized amount. This adjustment will complete our

statutory obligation to account for remainder of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009.

6. Recoupment or Repayment Adjustment Authorized by Section 7(b)(1)(B) of Pub. L. 110-90

As discussed in section II.D.3. of this preamble, section 7(b)(1)(B) of Pub. L. 110-90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Pub. L. 110-90. This determination must be based on a retrospective evaluation of claims data. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of -5.8 percent in FYs 2011 and 2012 would be necessary in order to meet the requirements of section 7(b)(1)(B) of Pub. L. 110-90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in rate adjustments over more than one year in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made an adjustment to the standardized amount of -2.9 percent,

representing approximately half of the aggregate adjustment required under section 7(b)(1)(B) of Pub. L. 110-90, for FY 2011. An adjustment of this magnitude allowed us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Pub. L. 110-90 (that is, no later than FY 2012).

As we stated in prior rulemaking, a major advantage of making the -2.9 percent adjustment to the standardized amount in FY 2011 was that, because the required recoupment adjustment is not cumulative, we anticipated removing the FY 2011 -2.9 percent adjustment from the rates (in other words, making a positive 2.9 percent adjustment to the rates) in FY 2012, at the same time that the law required us to apply the remaining approximately -2.9 percent adjustment required by section 7(b)(1)(B) of Pub. L. 110-90.

Therefore, for FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Pub. L. 110-90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining -2.9 percent adjustment, in addition to removing the effect of the -2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Because these adjustments, in effect, balanced out, there was no year-to-year change in the standardized amount due to this recoupment adjustment for FY 2012.

The -2.9 percent adjustment in each of the two previous fiscal years completed the required recoupment for overpayments due to documentation and coding effects on

discharges occurring in FYs 2008 and 2009. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27888), we proposed to make a final +2.9 percent adjustment to the standardized amount. This adjustment would remove the effect of the one-time -2.9 percent adjustment implemented in FY 2012. As stated in the proposed rule, we continue to believe that this is a reasonable and fair approach that satisfies the requirements of the statute while substantially moderating the financial impact on hospitals.

We did not receive any specific public comments regarding this adjustment. We did receive public comments requesting an additional +0.72 percent adjustment to account for cumulative overestimates of documentation and coding effects. We will address these comments in a later section. We are finalizing a +2.9 percent adjustment, as proposed, completing the recoupment portion of section 7(b)(1)(B) of Pub. L. 110-90. We note that with this positive adjustment, according to our estimates, all overpayments made in FY 2008 and FY 2009 have been fully recaptured with appropriate interest, and the standardized amount has been returned to the appropriate baseline.

7. Background on the Application of the Documentation and Coding Adjustment to the Hospital-Specific Rates

Under section 1886(d)(5)(D)(i) of the Act, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge. Under section 1886(d)(5)(G) of the Act, MDHs are paid based on

the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate based on the greatest of the FY 1982, FY 1987, or FY 2002 costs per discharge. (We note that, under current law, the MDH program expires at the end of FY 2012, as discussed in section IV.G. of this final rule.) In the FY 2008 IPPS final rule with comment period (72 FR 47152 through 47188), we established a policy of applying the documentation and coding adjustment to the hospital-specific rates. In that final rule with comment period, we indicated that because SCHs and MDHs use the same DRG system as all other hospitals, we believe they should be equally subject to the budget neutrality adjustment that we are applying for adoption of the MS-DRGs to all other hospitals. In establishing this policy, we relied on section 1886(d)(3)(A)(vi) of the Act, which provides us with the authority to adjust "the standardized amount" to eliminate the effect of changes in documentation and coding that do not reflect real changes in case-mix.

However, in the final rule that appeared in the **Federal Register** on November 27, 2007 (72 FR 66887 through 67888), we rescinded the application of the documentation and coding adjustment to the hospital-specific rates effective October 1, 2007. In that final rule, we indicated that, while we still believe it would be appropriate to apply the documentation and coding adjustment to the hospital-specific rates, upon further review, we decided that the application of the documentation and coding adjustment to the hospital-specific rates is not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of the Act, which only mentions adjusting "the standardized

amount" under section 1886(d) of the Act and does not mention adjusting the hospital-specific rates.

In the FY 2009 IPPS proposed rule (73 FR 23540), we indicated that we continued to have concerns about this issue. Because hospitals paid based on the hospital-specific rate have their Medicare claims grouped using the same MS-DRG system as other IPPS hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. In section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rates should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. The special exceptions and adjustment provision authorizes us to provide "for such other exceptions and adjustments to [IPPS] payment amounts … as the Secretary deems appropriate." In the FY 2009 IPPS final rule (73 FR 48448 through 48449), we indicated that, for the FY 2010 rulemaking, we planned to examine our FY 2008 claims data for

hospitals paid based on the hospital-specific rate. We further indicated that if we found evidence of significant increases in case-mix for patients treated in these hospitals that do not reflect real changes in case-mix, we would consider proposing application of the documentation and coding adjustments to the FY 2010 hospital-specific rates under our authority in section 1886(d)(5)(I)(i) of the Act.

In response to public comments received on the FY 2009 IPPS proposed rule, we stated in the FY 2009 IPPS final rule that we would consider whether such a proposal was warranted for FY 2010. To gather information to evaluate these considerations, we indicated that we planned to perform analyses on FY 2008 claims data to examine whether there has been a significant increase in case-mix for hospitals paid based on the hospital-specific rate. If we found that application of the documentation and coding adjustment to the hospital-specific rates for FY 2010 was warranted, we indicated that we would propose to make such an adjustment in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule.

8. Documentation and Coding Adjustment to the Hospital-Specific Rates for FY 2011 and Subsequent Fiscal Years

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule and final rule, we discussed our retrospective evaluation of the FY 2008 claims data for SCHs and MDHs using the same methodology described earlier for other IPPS hospitals. We found that, independently for both SCHs and MDHs, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 slightly exceeded the proposed 2.5 percent result discussed earlier for other IPPS

hospitals, but did not significantly differ from that result. We refer readers to those FY 2010 proposed and final rules for a more complete discussion (74 FR 24098 through 24100 and 74 FR 43775 through 43776, respectively).

As we have noted previously, because hospitals paid on the basis of their hospital-specific rate, including SCHs (and MDHs until the end of FY 2012), use the same MS-DRG system as all other IPPS hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. Therefore, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS-DRGs to all other hospitals. We believe the documentation and coding estimates for all subsection (d) hospitals should be the same. While the findings for the documentation and coding effect for all IPPS hospitals are similar to the effect for SCHs (and were slightly different to the effect for MDHs), we continue to believe that this is the appropriate policy so as to neither advantage or disadvantage different types of providers. Our best estimate, based on the most recently available data, is that a cumulative adjustment of -5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments to hospitals paid on the basis of their hospital-specific rate. We note that, for FY 2013, this adjustment would only apply to the SCHs because the MDH program expires in FY 2012 (as discussed in section IV.G. of this preamble). Unlike the case of standardized amounts paid to IPPS hospitals, prior to FY 2011, we had not made any previous adjustments to the hospital-specific rates paid to SCHs (and MDHs) to account for documentation and coding changes. Therefore,

the entire -5.4 percent adjustment needed to be made, as opposed to a -3.9 percent remaining adjustment for IPPS hospitals.

After finalizing a -2.9 percent prospective adjustment in FY 2011 (75 FR 50067 through 50071), we finalized a prospective adjustment to the hospital-specific rate of -2.0 percent for FY 2012 (76 FR 51499) instead of our proposed adjustment of -2.5 percent. Making this level of adjustment allowed CMS to maintain, for FY 2012, consistency in payment rates for different IPPS hospitals paid using the MS-DRG. We indicated in the final rule that because this -2.0 percent adjustment no longer reflects the entire remaining required adjustment amount of -2.5 percent, an additional -0.5 percent adjustment to the hospital-specific payment rates would be required in future rulemaking.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27889), we proposed to complete the remaining prospective adjustment to account for the documentation and coding effect that occurred in FY 2008 and FY 2009 by applying a -0.5 percent adjustment to the hospital-specific rate. We continue to believe that SCHs had the same opportunity to benefit from improvements in documentation and coding that did not reflect an increase in patient severity, and we continue to believe that any resulting adjustments should be applied similarly to all subsection (d) hospitals, when possible. For FY 2013, we proposed a prospective adjustment of -1.9 percent to the standardized amount. Therefore, we stated in the proposed rule (77 FR 27889) that we believed it was also appropriate to propose a -0.5 percent adjustment to the hospital-specific rate for FY 2013.

Comment: Commenters questioned CMS' statutory authority to apply documentation and coding adjustments to hospitals receiving the hospital-specific rate. The commenters stated that section 1886(d)(3)(A)(vi) of the Act specifically required the Secretary to determine if overpayments were made, and make appropriate adjustments to the standardized amount. The commenters contended that the broad authority granted under section 1886(d)(5)(I)(i) of the Act is not so broad as to permit CMS to extend the scope of a legislative directive that was specifically limited to hospitals paid under a prospective payment system.

Response: We continue to disagree that we do not have the authority to make prospective documentation and coding adjustments to the hospital-specific rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51499) for further discussion on our authority granted under section 1886(d)(5)(I)(i) of the Act. We do not believe that specific discretionary authority under section 1886(d)(3)(A)(iv) of the Act creates a limit on the broad authority granted under section 1886(d)(5)(I) of the Act. In this final rule, we are finalizing a prospective -0.5 percent adjustment to the hospital-specific rate to account for documentation and coding effects for discharges occurring in FY 2008 and FY 2009.

9. Application of the Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

a. Background

Puerto Rico hospitals are paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As noted

previously, the documentation and coding adjustment we adopted in the FY 2008 IPPS final rule with comment period relied upon our authority under section 1886(d)(3)(A)(vi) of the Act, which provides the Secretary the authority to adjust "the standardized amounts computed under this paragraph" to eliminate the effect of changes in documentation and coding that do not reflect real changes in case-mix. Section 1886(d)(3)(A)(vi) of the Act applies to the national standardized amounts computed under section 1886(d)(3) of the Act, but does not apply to the Puerto Rico-specific standardized amount computed under section 1886(d)(9)(C) of the Act.

While section 1886(d)(3)(A)(vi) of the Act is not applicable to the Puerto Rico-specific standardized amount, we believe that we have the authority to apply the documentation and coding adjustment to the Puerto Rico-specific standardized amount using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. Similar to SCHs that are paid based on the hospital-specific rate, we believe that Puerto Rico hospitals that are paid based on the Puerto Rico-specific standardized amount should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. Consistent with the approach described for SCHs and MDHs in the FY 2009 IPPS final rule (73 FR 48449), we indicated that we planned to examine our FY 2008 claims data for hospitals in Puerto Rico. We indicated in the FY 2009 IPPS proposed rule (73 FR 23541) that if we found evidence of significant increases in case-mix for patients treated in these hospitals, we would consider proposing to apply documentation and

coding adjustments to the FY 2010 Puerto Rico-specific standardized amount under our authority in section 1886(d)(5)(I)(i) of the Act.

b. Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate was that, for documentation and coding that occurred over FY 2008 and FY 2009, a cumulative adjustment of -2.6 percent was required to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments from the Puerto Rico-specific rate. As we stated above, we believe it is important to maintain both consistency and equity among all hospitals paid on the basis of the same MS-DRG system. At the same time, however, we recognize that the estimated cumulative impact on aggregate payment rates resulting from implementation of the MS-DRG system was smaller for Puerto Rico hospitals as compared to IPPS hospitals and SCHs. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50072 through 50073), we stated that we believed that a full prospective adjustment was the most appropriate means to take into full account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between hospitals paid on the basis of different prospective rates.

Because the Puerto Rico-specific rate received a full prospective adjustment of -2.6 percent in FY 2011, we proposed no further adjustment in the proposed rule for

FY 2012. For FY 2013, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27889), we also did not propose any adjustment to the Puerto Rico-specific rate.

10. Prospective Adjustments for FY 2010 Documentation and Coding Effect

Section 7(b)(1)(A) of Pub. L. 110-90 required CMS to make prospective documentation and coding adjustments under section 1886(d)(3)(A)(iv) of the Act if, based upon a review of FY 2008 and FY 2009 discharges, we determined that implementation of the MS-DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix during FY 2008 or FY 2009 and that were different than the prospective documentation and coding adjustments applied under section 7(a) of Pub. L. 110-90. However, section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts if the Secretary determines such adjustments to be necessary for any subsequent fiscal years in order to eliminate the effect of coding or classification changes that do not reflect real changes in case-mix. After review of comments and recommendations received in a FY 2012 comment letter from MedPAC (available on the Internet at: http://www.medpac.gov/documents/06172011_FY12IPPS_MedPAC_COMMENT.pdf), we analyzed claims data in FY 2010 to determine whether any additional adjustment would be required to ensure that the introduction of MS-DRGs was implemented in a budget neutral manner. While we expect that the impacts of documentation and coding behavior in response to the introduction of MS-DRGs in FY 2008 will eventually decline to insignificant levels, we analyzed FY 2010 data on claims paid through December 2011 using the same claims-based methodology as described in previous rulemaking

(73 FR 43768 and 43775). We determined a total prospective documentation and coding effect of 1.008 for FY 2010. Our actuaries have estimated that this 0.8 percentage point increase resulted in an increase in aggregate payments of approximately $1.19 billion in FY 2010. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27890), we proposed an additional -0.8 percent adjustment to account for the effects of documentation and coding changes that did not reflect real changes in case-mix in FY 2010.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27890), we stated that the combined total prospective adjustment to the standardized amount proposed for FY 2013 under Pub. L. 110-90 to account for documentation and coding effects in FY 2008 and FY 2009 and under section 1886(d)(3)(A)(vi) of the Act to account for documentation and coding effect in FY 2010 was -2.7 percent (-1.9 percent plus -0.8 percent). We indicated that the proposed adjustment would eliminate the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008, 2009, and 2010. While we did not make proposals regarding future fiscal years in the proposed rule, we plan to continue to monitor and analyze additional claims data and make adjustments, when necessary, as authorized under section 1886(d)(3)(A)(vi) of the Act. We noted that the proposed total adjustment to the proposed FY 2013 standardized amount would be +0.2 percent because these prospective adjustments will be offset by the completion of the recoupment adjustment under section 7(b)(1)(B) of Pub. L. 110-90, as discussed below.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27890), we noted that while we have decided to review FY 2010 claims data to determine whether additional prospective adjustments are necessary (as discussed earlier), section 7(b)(1)(B) of Pub. L. 110-90 does not authorize CMS to calculate any retrospective adjustment for overpayments made in FY 2010, nor to recover any related overpayments beyond FY 2012. The Secretary's authority under section 1886(d)(3)(A)(vi) of the Act is limited to prospective adjustments.

Consistent with our proposal for IPPS hospitals paid on the basis of the standardized amount, our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act, and based upon our review of FY 2010 claims data, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27890), we also proposed an additional -0.8 percent adjustment to the hospital-specific rate to account for documentation and coding changes in FY 2010 that did not reflect real changes in case-mix. We indicated that we believed that a full prospective adjustment for hospitals paid based on the hospital-specific rate is the most appropriate means to take into account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between hospitals paid on the basis of different prospective rates. Therefore, we proposed a combined adjustment of -1.3 percent (-0.5 percent + -0.8 percent) to the hospital-specific rate, accounting for all documentation and coding effects observed between FY 2008 though FY 2010.

Based upon our analysis of FY 2010 claims data, we found no significant additional effect of documentation and coding in FY 2010 that would warrant any additional adjustment to the Puerto Rico-specific rate.

Comment: Numerous comments objected to the CMS proposal to make an adjustment under section 1886(d)(3)(A)(vi) of the Act to account for payment increases due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2010. Commenters pointed to MedPAC's analysis in its public comment letter in response to the FY 2011 IPPS/LTCH PPS proposed rule that suggested that "negative documentation and coding" may have occurred under the CMS-DRGs, creating an overestimation of documentation and coding due to the introduction of MS-DRGs. MedPAC estimated that the magnitude of this effect could reach 0.36 percent in FY 2008, 0.36 percent in FY 2009, and 0.25 percent in FY 2010. CMS responded to these findings in the FY 2011 IPPS/LTCH PPS final rule by stating that MedPAC characterized this impact of any potential overestimate as "small" and could not be corroborated with any specific examples or analysis. Commenters indicated that they did not consider the potential impacts to be "small" and pointed out that if such estimates are true, hospitals would be due an additional +0.72 percent adjustment to account for overestimated recoupments (as well as similar positive adjustments to the hospital-specific and Puerto Rico-specific rate). Some commenters asserted that there are numerous examples of changes in documentation and coding that may have decreased the CMI under the CMS-DRGs, and provided five specific examples.

One commenter, compared the FY 2007 CC list to the FY 2008 CC list, identifying examples of chronic conditions that were CCs under the CMS-DRGs, but are no longer considered CCs or MCCs under the MS-DRGs, and that would also necessarily result in a lower MS-DRG assignment because more specific codes related to that condition were not developed. The commenter expressed surprise that CMS' medical coding experts were unable to do the same. The commenter identified the following common, chronic conditions which were CCs under the CMS-DRGs, but are not a CC or MCC under the MS-DRGs: atrial fibrillation; chronic blood loss anemia; mitral valve disorder; and aortic valve disorder. The commenter stated that removing these chronic conditions from the CC list under the MS-DRGs led to a substantial decrease in the reporting of these conditions as a secondary diagnosis when the MS-DRGs were implemented in FY 2008.

Specifically, after 10 years in which the proportion of IPPS cases that included atrial fibrillation as a secondary diagnosis increased each year, the proportion decreased by 20 percent immediately upon implementation of the MS-DRGs in FY 2008. This decrease in coding of atrial fibrillation would cause the CMI as measured by the FY 2007 DRG GROUPER to go down, while having no effect on the CMI as measured by the MS-DRG GROUPER. The commenter stated that if this negative documentation and coding effect is not taken into account in CMS' analysis, it will inappropriately increase

CMS' estimate of documentation and coding change. The commenter also found that the secondary diagnoses of chronic blood loss anemia, mitral valve disorder and aortic valve disorder decreased in proportion immediately upon implementation of the MS-DRGs in FY 2008.

In addition, the commenter stated that hyperpotassemia was a CC under the CMS-DRGs, but is not a CC or MCC under the MS-DRGs. Because of this, there was a substantial decrease in the reporting of hyperpotassemia as a secondary diagnosis when the MS-DRGs were implemented in FY 2008. Specifically, after 9 consecutive years in which the proportion of IPPS cases that included hyperpotassemia as a secondary diagnosis increased, the proportion decreased by 37 percent immediately upon implementation of the MS-DRGs in FY 2008.

In responding to MedPAC's analysis, the commenter stated that CMS concluded that it did not believe it would be appropriate to revise its estimates based solely on MedPAC's analysis without knowing of any specific examples. Given that the commenter is now providing such specific examples, the commenter urged the agency to revise its analysis to account for what the commenter believed to be overestimation of documentation and coding as identified by MedPAC and the AHA. Specifically, the commenter recommended that CMS subtract 0.25 percentage points from its estimate of a 6.2 percent cumulative documentation and coding effect; which yields a revised cumulative effect of 5.95 percent. Under this methodology, because CMS has already implemented documentation and coding cuts of 3.5 percent, the commenter stated that the

cut remaining is actually only 2.45 percent, instead of the 2.7 percent the agency proposed.

Response: We disagree with the commenter's suggestion that the removal of the codes for the chronic conditions of atrial fibrillation, chronic blood loss anemia, mitral valve disorder and aortic valve disorder from the CC list upon the implementation of MS-DRGs and the subsequent decrease in hospital reporting are examples of a "negative" documentation and coding effect. We note that what the commenter provided are examples of an immediate change in coding and reporting practices based on incentives under the MS-DRGs. It did not suggest that patients had fewer occurrences of the chronic conditions identified. They do suggest that hospitals were immediately aware of the incentives provided by the CC and MCC lists under MS-DRGs and began focusing on identifying and reporting codes on the MS-DRG CC and MCC lists.

We believe the commenters' suggestions of immediate changes in coding and reporting based on incentives provided by the MS-DRGs CC and MCC lists support our view that coding practices have changed in response to incentives, which we have shown lead to increases in the case-mix index that were not based on actual changes in patient severity.

We further believe that while the MedPAC analysis suggested that a potential overestimate could have, in theory, occurred in the methodology, the estimates are theoretical maximums. It is not clear at this time that, based on the information submitted, to what extent the five examples provided by commenters substantiate these theoretical maximums or any change in adjustments.

Nonetheless, we recognize that the methodological issues that surround this question are complex, and may merit further consideration. Therefore, we are not finalizing the proposed -0.8 percent adjustment to the standardized amount and the hospital-specific rate at this time until more analysis can be completed.

	Remaining Prospective Adjustment for FYs 2008-2009	**Prospective Adjustment for FY 2010**	**Prospective Adjustment for FY 2013**	**Removal of Onetime Recoupment Adjustment in FY 2013**	**Combined Documentation & Coding Adjustment for FY 2013**
Level of Adjustments	-1.9%	-0.0%	-1.9%	+2.9%	+1.0%

As in prior years, the FY 2008, FY 2009, and FY 2010 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effects. Interested individuals may still order these files through the Web site at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the file and provides directions and further detailed instructions for how to order.

Persons placing an order must send the following: a Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for $3,655 to:

Mailing address if using the U.S. Postal Service:

Centers for Medicare & Medicaid Services,

RDDC Account,

Accounting Division,

P.O. Box 7520,

Baltimore, MD 21207-0520.

Mailing address if using express mail:

Centers for Medicare & Medicaid Services,

OFM/Division of Accounting – RDDC,

7500 Security Boulevard, C3-07-11,

Baltimore, MD 21244-1850.

E. Refinement of the MS-DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS-DRGs.

As we implemented cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to "charge compression," which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single CCR is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to the Research Triangle Institute, International (RTI) to study the effects of charge

compression in calculating the relative weights and to consider methods to reduce the variation in the cost-to-charge ratios (CCRs) across services within cost centers. For a detailed summary of RTI's findings, recommendations, and public comments that we received on the report, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48452 through 48453).

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for "Medical Supplies Charged to Patients" and another line for "Implantable Devices Charged to Patients." We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS/LTCH PPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS-DRG relative weights could result from correcting charge compression for devices and implants. In determining the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals should use revenue codes established by the AHA's National Uniform Billing Committee to determine the items that should be reported in the "Medical Supplies Charged to Patients" and the "Implantable Devices Charged to Patients" cost centers. Accordingly, a new subscripted line 55.30 for "Implantable Devices Charged to Patients" was created in July 2009 as part of CMS' Transmittal 20 update to the cost report Form

CMS-2552-96. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

As we discussed in the FY 2009 IPPS final rule (73 FR 48458) and in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527), in addition to the findings regarding implantable devices, RTI also found that the costs and charges of computed tomography (CT) scans, magnetic resonance imaging (MRI), and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and the OPPS relative weights would better estimate the costs of those services if CMS were to add standard cost centers for CT scans, MRI, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the costs from charges on claims data. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRI, and cardiac catheterization, and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS 2552-10. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a detailed discussion of the reasons for the creation of standard cost centers for CT scans, MRI, and cardiac catheterization.) The new standard cost centers for CT scans, MRI, and cardiac catheterization are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS-2552-10.

2. Summary of Policy Discussion in FY 2012

In the FY 2009 IPPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new "Implantable Devices Charged to Patients" cost center to develop a CCR for Implantable Devices Charged to Patients in the FY 2012 or FY 2013 IPPS rulemaking cycle. However, as noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report CMS 2552-10, we determined that a new CCR for Implantable Devices Charged to Patients might not be available before FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for CT scans, MRI, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077).

Accordingly, during the FY 2012 IPPS rulemaking (76 FR 51502), we assessed the availability of data in the "Implantable Devices Charged to Patients" cost center. In order to develop a robust analysis regarding the use of cost data from the "Implantable Devices Charged to Patients" cost center, it was necessary to have a critical mass of cost reports filed with data in this cost center. We checked the availability of data in the "Implantable Devices Charged to Patients" cost center on the FY 2009 cost reports, but we did not believe that there was a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we did not propose to use data from the "Implantable Devices Charged to Patients" cost center to create a distinct CCR for "Implantable Devices Charged to Patients" for use in calculating the MS-DRG

relative weights for FY 2012. We indicated that we would reassess the availability of data for the "Implantable Devices Charged to Patients" cost center for the FY 2013 IPPS/LTCH PPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

3. Discussion for FY 2013

To calculate the MS-DRG relative weights, we use two data sources: the MedPAR file as the claims data source and the HCRIS as the cost data source. We adjust the charges from the claims to costs by applying the 15 national average CCRs developed from the cost reports. In the past several years, we have made progress in changing the cost report to add the "Implantable Devices Charged to Patients" cost center. At the time of development of the FY 2013 IPPS/LTCH PPS proposed rule, there was a sizeable number of hospitals in the FY 2010 HCRIS that had reported data for "Implantable Devices Charged to Patients" on their cost reports beginning during FY 2010. However, during the development of the proposed rule, we were able to access only those cost reports in the FY 2010 HCRIS with fiscal year begin dates on or after October 1, 2009, and before May 1, 2010. This is because cost reports with fiscal year begin dates of May 1, 2010, through September 30, 2010, were filed on the new cost report Form 2552-10, and cost reports filed on the Form 2552-10 were not accessible in the HCRIS. Normally, we pull the HCRIS dataset that is 3 years prior to the IPPS fiscal year (that is, for the FY 2013 relative weights, we would use the FY 2010 HCRIS, which includes data from cost reports that begin on or after October 1, 2009, and before October 1, 2010). However, because data from the Form 2552-10 cost reports were not available, to ensure

that the relative weights are calculated with a data set that is as comprehensive and accurate as possible, in the proposed rule, we proposed to calculate the FY 2013 relative weights with data from FY 2010 cost reports for providers with fiscal year begin dates of on or after October 1, 2009, and before May 1, 2010, and to back fill with data from FY 2009 cost reports for those providers that have fiscal year begin dates on or after May 1, 2010 through September 30, 2010. Further complicating matters was that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims was not yet available to us in the MedPAR file. Without the breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, we believed that we had no choice but to propose to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. We stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892) that when we do have the necessary supplies and implantable device data on the claims in the MedPAR file to create distinct CCRs for supplies and implantable devices, perhaps for FY 2014, we also hoped that we would have data for an analysis of creating distinct CCRs for MRI, CT scans, and cardiac catheterization. Prior to proposing to create these CCRs, we would first thoroughly analyze and determine the impacts of the data. Distinct CCRs for implantable devices, MRIs, and CT scans would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

Comment: Commenters expressed concern that CMS had proposed not to use the data available from the new "Implantable Devices Charged to Patients" cost center for FY 2013. The commenters were concerned about the continued delays in the utilization of the new cost center data, and stated that such delays only prolong the payment inaccuracies associated with charge compression. Two commenters suggested a short-term fix to account for the lack of data and to create a CCR for implantable devices. The commenters suggested that CMS calculate a DRG-by-DRG estimate of the split of standardized supplies charges into implantable devices and routine supplies. They stated that once supplies charges are apportioned in each DRG, separate national average CCRs for implantable devices and other supplies could be applied, based on the existing cost reports. The commenters recommended using the CY 2010 Inpatient Standard Analytic File (SAF) to calculate the DRG-level factors for apportioning the supplies charges, as the file has information on charges by revenue center, allowing implantable devices to be split from routine supplies. They further suggested that CMS could calculate the CY 2010 ratios of routine supply charges to implantable device charges by DRG, apply those ratios to the FY 2011 MedPAR supplies charges, and then utilize the separate CCRs for supplies and implantable devices to estimate costs within each DRG. The commenters added that the remainder of the DRG weight calculation would proceed at this point, now with 16 CCRs, including the implantable devices CCR. The commenters stated that CMS has information required for DRG assignment, and could run the data through the latest MS-DRG GROUPER if MS-DRG definition changes are an issue.

Several commenters requested that CMS adopt a regression-based CCR for implantable devices due to the delay in using the cost report and claims data to calculate an implantable device CCR. The commenters suggested that CMS implement this approach, which was a recommendation made by RTI and MedPAC, to the statistical disaggregation of CCRs in the "Medical Supplies Charged to Patients" cost center, as it would immediately address charge compression until data from the new cost centers become available.

One commenter requested that CMS use the data from the hospitals that are compliant in using the "Implantable Devices Charged to Patients" cost center data to establish an implantable device CCR for establishing FY 2013 relative weights. The commenter suggested that, despite data limitations of the current data, CMS continue to revise this CCR in subsequent years, as the agency does for all cost centers as more robust data are available, without further delaying needed improvements in the interim period.

Response: We acknowledge the commenters' concern that we did not propose a distinct CCR for implantable devices charged to patients for FY 2013. Nevertheless, we believe it would be inappropriate to finalize a specific CCR for implantable devices charged to patients for FY 2013 (using SAF data, a regression-based methodology, or the limited implantable devices cost report data that we do have), without an opportunity for the public to review and comment on our analysis. Rather, we believe that it is appropriate to wait until FY 2014, when we hope to be able to provide a proper impact analysis of the addition of a CCR for implantable devices charged to patients in the

relative weights calculation. Accordingly, we are not implementing a regression-based CCR for implantable devices at this time, nor are we implementing any new CCRs for use in the relative weights calculation for FY 2013.

Comment: Several commenters expressed concern that CMS may not have sufficient data to establish an implantable device cost center to use in the calculation of the relative weights for FY 2014. Two commenters requested that CMS develop and discuss in this FY 2013 IPPS final rule an action plan for ensuring that FY 2011 HCRIS and MedPAR data will be available for allowing the "Implantable Devices Charged to Patients" cost center to be used for calculating MS-DRG relative weights for FY 2014. Another commenter requested that, rather than waiting for the next rulemaking cycle, CMS should determine if it will have the necessary data available prior to the FY 2014 proposed rule and inform stakeholders if there continues to be administrative issues with the data. The commenter believed that this will allow stakeholders to weigh in on potential solutions to avoid another year of delay in establishing the implantable device CCR.

Response: We understand the commenters' desire for reassurance that the FY 2014 rulemaking cycle will not present further unanticipated delays in the availability of both HCRIS and MedPAR data required to create distinct CCRs for implantable devices charged to patients and supplies charged to patients, respectively. We expect to have the necessary data available to begin modeling the additional CCRs before the end of calendar year 2012. Therefore, we are optimistic that, for the FY 2014 proposed rule, we will be able to provide a detailed impact analysis of the relative weights using distinct

CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. If, for some reason, additional delays are encountered toward the end of calendar year 2012, we will consider informing stakeholders of this delay, if appropriate, and hosting a national conference call, so that alternative solutions to establishing additional CCRs can be considered in a timely fashion.

Comment: Some commenters supported our proposal of not making major refinements in the MS-DRG relative weight methodology.

Response: We appreciate the commenters' support for our proposal of not making major refinements to the MS-DRG relative weights.

Comment: One commenter recommended that, despite the delay in the implementation of the "Implantable Devices Charged to Patients" cost center for the IPPS relative weights, CMS should proceed with the implementation of the implantable devices cost center in the calculation of OPPS rates for CY 2013. The commenter requested that CMS work toward a solution to combine data from the two different cost reporting forms in the HCRIS data so that OPPS rates can be calculated using the cost difference reported in the "Implantable Devices Charged to Patients" cost center.

Response: We note that the CY 2013 OPPS/ASC proposed rule, which went on public display at the Office of the Federal Register on July 6, 2012 (available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1589-P.html), in fact, includes a proposal to use data from the "Implantable

Devices Charged to Patients" cost center to create a distinct CCR for use in calculating the OPPS relative weights for CY 2013.

Comment: Two commenters expressed continued concern about the accuracy of establishing new CT and MRI cost centers using cost report and claims data. The commenters were concerned that the data reported in the CT and MRI cost centers will not represent hospitals' full cost of providing CT and MRI for some time. The commenters stated that a large portion of the capital costs for CT and MRI equipment may have been allocated across the entire hospital, rather than to the radiology cost center, which would result in the understatement of costs of CT and MRI reported in the radiology cost center.

Response: We received similar comments regarding the allocation of capital costs for radiology equipment on the FY 2011 IPPS/LTCH PPS proposed rule. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50078), we provided a detailed response for CMS' longstanding policy on the proper reporting of such capital costs. Specifically, we stated that "section 104 of the PRM-I contains definitions of buildings (section 104.2), building equipment (section 104.3), major moveable equipment (section 104.4), and minor equipment (section 104.5) that apply for purposes of cost report completion. We believe that it is clear that CT and MRI equipment are 'major moveable equipment' and are neither a building cost nor a building equipment cost. Specifically, section 104.4 of the PRM-I defines 'major moveable equipment' as follows: 'The general characteristics of this equipment are: (a) a relatively fixed location in the building; (b) capable of being moved, as distinguished from building equipment; (c) a unit cost sufficient to justify

ledger control; (d) sufficient size and identity to make control feasible by means of identification tags; and (e) a minimum life of approximately three years. Major moveable equipment includes such items as accounting machines, beds, wheelchairs, desks, vehicles, x-ray machines, etc.' In addition to this longstanding instruction, we believe that our view that CT scanning and MRI equipment are major moveable equipment is supported by the 2008 edition of 'Estimated Useful Lives of Depreciable Hospital Assets,' which states that the estimated useful life of a CT scanner is 5 years, an MRI is 5 years, and an X-ray unit is 7 years. Therefore, we believe that our longstanding policy makes it clear that CT scanning and MRI equipment [are] major moveable equipment and should be reported as such on the cost report. As major moveable equipment, the costs should be reported together with the rest of the hospital's major moveable equipment cost in the 'Capital Related Costs-Moveable Equipment' cost center(s) on Worksheet A (lines 2 and 4 [on the CMS Form 2552-96 and line 2 on the CMS Form 2552-10]). The costs in this cost center are allocated to all the hospital's cost centers that use major moveable equipment (including CT and MRI) using 'dollar value' or 'square feet' if the provider obtained the contractor's approval under Provider Reimbursement Manual Part II (PRM-II), Section 3617, to use the simplified cost allocation methodology. However, a hospital that is concerned that this method of allocation may result in inaccurate CCRs (on Worksheet C, Part I) for the CT scan, MRI, and other ancillary cost centers may request contractor approval under Section 2307 of the PRM-I to directly assign the cost of moveable equipment to all of the hospital's cost centers that use moveable equipment, including CT scans and MRIs. If the hospital meets all of the criteria in Section 2307 of

the PRM-I, the contractor may approve the direct assignment method. This would ensure that the high cost of the CT scanning and MRI equipment would be reflected in the CCR that would be calculated for those departments and that would be used to estimate the cost of CT scanning and MRI services. In any case, hospitals with accounting systems that include the cost of CT scanning and MRI equipment in the 'Capital Related Costs – Building and Fixtures' cost center should correct their cost reporting practices to come into compliance with CMS' longstanding policy in this regard. Reporting of costs and charges on the Medicare cost report must be compliant with Medicare cost reporting principles, regardless of differing payment structures and incentives of other payers or State reporting requirements" (75 FR 50078). Hospitals that still need to correct their cost reporting practices in this regard should do so soon, so that when we propose distinct CCRs for MRI and CT scans, hopefully for FY 2014, these CCRs will represent fairly accurately the costs of these radiology services.

In summary, in this final rule, we are finalizing our proposal to continue to use the existing 15 CCRs to calculate the MS-DRG relative weights for FY 2013. For this final rule, as we did for the proposed rule, because data from the CMS Form 2552-10 continue to be unavailable, we are using data from FY 2010 cost reports for providers with fiscal year begin dates of on or after October 1, 2009, and before May 1, 2010, and we are backfilling with data from FY 2009 cost reports for those providers that have fiscal year begin dates on or after May 1, 2010 through September 30, 2010. Depending on the availability of necessary data, we hope to be able to propose, if appropriate, for FY 2014 to use distinct CCRs for implantable devices charged to patients and supplies charged to

patients, and possibly distinct CCRs for MRI, CT scans, and cardiac catheterization as well.

F. Preventable Hospital-Acquired Conditions (HACs), Including Infections

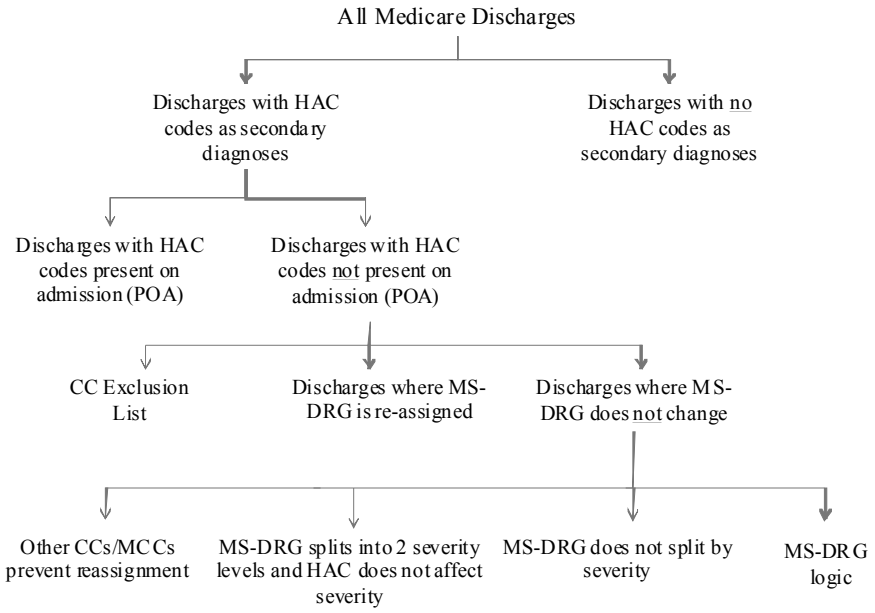
1. Background

Section 1886(d)(4)(D) of the Act addresses certain hospital-acquired conditions (HACs), including infections. This provision is part of an array of Medicare tools that we are using to promote increased quality and efficiency of care. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications.

However, the treatment of certain conditions can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may generate an outlier payment. Because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS-DRG system that took effect in FY 2008 and that has been refined through rulemaking in subsequent years, certain conditions can generate higher payments even if the outlier payment requirements are not met. Under the MS-DRG system, there are currently 261 sets of MS-DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or an MCC. The presence of a CC or an MCC generally results in a higher payment.

Section 1886(d)(4)(D) specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) are high cost, high volume, or both; (b) are assigned to a higher paying MS-DRG when present as a secondary diagnosis (that is, conditions under the MS-DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions.

Effective for discharges occurring on or after October 1, 2008, pursuant to the authority of section 1886(d)(4)(D) of the Act, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS-DRG if a selected condition is not present on admission (POA). Thus, if a selected condition that was not POA manifests during the hospital stay, it is considered a HAC and the case is paid as though the secondary diagnosis was not present. However, even if a HAC manifests during the hospital stay, if any nonselected CC/MCC appears on the claim, the claim will be paid at the higher MS-DRG rate. In addition, Medicare continues to assign a discharge to a higher paying MS-DRG if a selected condition is POA. When a HAC is not POA, payment can be effected in a manner shown in the diagram below.



2. HAC Selection

Beginning in FY 2007, we have set forth proposals, and solicited and responded to public comments, to implement section 1886(d)(4)(D) of the Act through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, including a detailed discussion of the collaborative interdepartmental process and public input regarding selected and potential candidate HACs, we refer readers to the following rules: the FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547) and final rule (73 FR 48471); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080); and the FY 2012 IPPS/LTCH

PPS proposed rule (76 FR 25810 through 25816) and final rule (76 FR 51504 through 51522). A complete list of the 10 current categories of HACs is included on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25813 through 25814) and FY 2012 IPPS/LTCH PPS final rule (76 FR 51507 through 50509), we proposed but did not finalize the candidate condition Contrast-Induced Acute Kidney Injury. Instead, we deferred the decision making on this condition as a selected HAC until future rulemaking and such a time when improved coding for the condition is available.

3. Present on Admission (POA) Indicator Reporting

Collection of POA indicator data is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision as well as for broader public health uses of Medicare data. In previous rulemaking, we provided both CMS and CDC Web site resources that are available to hospitals for assistance in this reporting effort. For detailed information regarding these sites and materials, including the application and use of POA indicators, we refer the reader to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 through 51507).

As discussed in previous IPPS proposed and final rules, there are five POA indicator reporting options, as defined by the ICD-9-CM Official Guidelines for Coding and Reporting. Under the HAC policy, we treat HACs coded with "Y" and "W" indicators as POA and allow the condition on its own to cause an increased payment at the CC/MCC level. We treat HACs coded with "N" and "U" indicators as Not Present on

Admission (NPOA) and do not allow the condition on its own to cause an increased payment at the CC/MCC level. We refer readers to the following rules for a detailed discussion: the FY 2009 IPPS proposed rule (73 FR 23559) and final rule (73 FR 48486 through 48487); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43784 through 43785); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23881 through 23882) and final rule (75 FR 50081 through 50082); and the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25812 through 25813) and final rule (76 FR 51506 through 51507).

Indicator	Descriptor
Y	Indicates that the condition was present on admission.
W	Affirms that the hospital has determined that, based on data and clinical judgment, it is not possible to document when the onset of the condition occurred.
N	Indicates that the condition was not present on admission.
U	Indicates that the documentation is insufficient to determine if the condition was present at the time of admission.
1	Signifies exemption from POA reporting. CMS established this code as a workaround to blank reporting on the electronic 4010A1. A list of exempt ICD-9-CM diagnosis codes is available in the ICD-9-CM Official Guidelines for Coding and Reporting.

Beginning on or after January 1, 2011, hospitals were required to begin reporting POA indicators using the 5010 electronic transmittal standards format. The 5010 format removes the need to report a POA indicator of "1" for codes that are exempt from POA reporting. We have issued CMS instructions on this reporting change as a One-Time Notification, Pub. No. 100-20, Transmittal No. 756, Change Request 7024, effective on August 13, 2010, which can be located at the following link on the CMS Web site:

http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R756OTN.pdf. However, for claims that continue to be submitted using the 4010 electronic transmittal standards format, the POA indicator of "1" is still necessary because of reporting restrictions from the use of the 4010 electronic transmittal standards format.

In addition, as discussed in section II.G.9. of the preamble of this final rule, the 5010 format allows the reporting and, effective January 1, 2011, the processing of up to 25 diagnoses and 25 procedure codes. As such, it is necessary to report a valid POA indicator for each diagnosis code, including the principal and all secondary diagnoses up to 25.

4. HACs and POA Reporting in ICD-10-CM and ICD-10-PCS

As we stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 and 51507) and in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27894), in preparation for the transition to the ICD-10-CM and ICD-10-PCS code sets, further information regarding the use of the POA indicator with the ICD-10-CM/ICD-10-PCS classifications as they pertain to the HAC policy will be discussed in future rulemaking.

At the March 5, 2012 meeting of the ICD-9-CM Coordination and Maintenance Committee, an announcement was made with regard to the availability of the ICD-9-CM HAC list translation to ICD-10-CM and ICD-10-PCS code sets. Participants were informed that the list of the current ICD-9-CM selected HACs has been translated into codes using the ICD-10-CM and ICD-10-PCS classification system. It was recommended that the public review this list of ICD-10-CM/ICD-10-PCS code

translations of the current selected HACs. The translation list is available on the CMS Web page at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html. We encourage the public to submit comments on these translations through the HACs Web page using the CMS ICD-10-CM/PCS HAC Translation Feedback Mailbox that has been set up for this purpose under the Related Links section titled "CMS HAC Feedback." The final HAC list translation from ICD-9-CM to ICD-10-CM/ICD-10-PCS will be subject to formal rulemaking.

In the meantime, we continue to encourage readers to review the educational materials and draft code sets currently available for ICD-10-CM/ICD-10-PCS on the CMS Web site at: http://www.cms.gov/Medicare/Coding/ICD10/index.html. In addition, the draft ICD-10-CM/ICD-10-PCS coding guidelines can be viewed on the CDC Web site at: http://www.cdc.gov/nchs/icd/icd10cm.html.

Comment: Commenters expressed appreciation for CMS' decision to make this crosswalk available. Commenters noted that they would continue to review the crosswalk and provide additional comments, as warranted.

Response: We appreciate the commenters' support and continued feedback.

5. Changes to the HAC Policy for FY 2013

a. Additional Diagnosis Codes to Existing HACs

As discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27894), as changes to diagnosis codes and new diagnosis codes have been proposed and finalized for the list of CCs and MCCs, we have modified the list of selected HACs to reflect these

changes. While there were not any new diagnosis codes proposed for FY 2013, there were new and revised diagnosis codes effective October 1, 2011 (FY 2012) that were not finalized in time for inclusion in the FY 2012 IPPS rulemaking. Therefore, in the proposed rule (77 FR 27894), we proposed to add two of these codes to an existing HAC category. We proposed to add diagnosis codes 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the Vascular Catheter-Associated Infection HAC category for FY 2013. These codes were created in response to a request discussed at the March 9-10, 2011 ICD-9-CM Coordination and Maintenance Committee meeting to better identify specific types of infections (systemic versus local) that occur as a result of central venous catheter placement.

Previously, there was only one existing HAC code (999.31 (Infection due to central venous catheter)) in the Vascular Catheter-Associated Infection HAC category. With the creation of codes 999.32 and 999.33, effective October 1, 2011, the title for code 999.31 was revised to "Other and unspecified infection due to central venous catheter." Therefore, codes 999.32 and 999.33 provide further specificity as to the type of infection due to a central venous catheter. We refer readers to page 45 of the topic packet found at the following link on the CDC ICD-9-CM Web page at http://www.cdc.gov/nchs/data/icd9/TopicpacketforMarch2011_HA1.pdf for further information.

Shown in the table below are the two diagnosis codes that we proposed with their corresponding descriptions and their CC/MCC designations.

ICD-9-CM Code	Code Descriptor	CC/MCC Designation
999.32	Bloodstream infection due to central venous catheter	CC
999.33	Local infection due to central venous catheter	CC

We invited public comments on the proposed adoption of these two ICD-9-CM diagnosis codes designated as CC/MCCs that are listed above, to be added to the Vascular Catheter-Associated Infection HAC category as indicated for FY 2013.

Comment: Several commenters supported the addition of these two codes. One commenter, a State program, indicated that it uses these codes in a statewide HAC payment incentive program.

Response: We appreciate the commenters' support.

Comment: Some commenters opposed the addition of these two diagnosis codes. Commenters also urged CMS to remove the one existing HAC code (999.31) in the Vascular Catheter-Associated Infection HAC category. They stated that CMS is proposing to add a quality measure on central line associated bloodstream infection (CLABSI), which would capture vascular catheter-associated infections and asserted that "this could penalize hospitals twice for the same event." (We note that the commenters may be referring to two different CMS programs, the Hospital IQR Program and the Hospital VBP Program.) Commenters stated that their opposition to the proposed inclusion of the two codes is not specific to the particular codes that were proposed, but that their opposition is predicated on the "expansion of this HAC [Vascular Catheter-Associated Infection]." Commenters also stated that they supported reducing the incidence of CLABSI as a patient safety goal and urged CMS to "select only one

program in which to measure hospital performance for vascular catheter-associated infection."

Response: The HAC-POA Program is part of an array of tools used by the Medicare program to promote increased quality and efficiency of care. These tools include quality measurement as well as payment adjustments. Because of their importance, HACs have been included in multiple tools used by the Medicare program to measure quality of services provided and performance, and to determine payment adjustments. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, such as when any nonselected CC/MCC appears on the claim, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications and would not generally "penalize hospitals twice."

Because of their importance, measures of HACs have historically been included in the Hospital IQR Program and are simultaneously monitored by different CMS programs. The HAC/POA policy authorized under section 1886(D)(4)(d) of the Act is a claims-based payment policy, and in many cases, even if a HAC manifests during a hospital stay, if any nonselected CC/MCC appears on the claim, the claim will be paid at the higher MS-DRG rate.

Comment: One commenter supported the addition of diagnosis code 999.32, Bloodstream infection due to central venous catheter, to the Vascular Catheter-Associated Infection HAC category, however, the commenter expressed concern with the inclusion of diagnosis code 999.33, Local infection due to central venous catheter, as a condition under this same HAC category to be subject to the HAC payment policy. According to the commenter, diagnosis code 999.33 identifies and describes local infections related to the soft tissues versus infections in the central bloodstream. As such, the commenter asserted that the Vascular Catheter-Associated Infection HAC category should only include central bloodstream infections. Therefore, the commenter did not support the addition of code 999.33 to the Vascular Catheter-Associated Infection HAC category.

In addition, this same commenter recommended that CMS publish data analyses for the Vascular Catheter-Associated Infection HAC category. Specifically, the commenter requested that volume and cost data be made publicly available for diagnosis codes 999.31, Other and unspecified infection due to central venous catheter; 999.32, Bloodstream infection due to central venous catheter; and 999.33, Local infection due to central venous catheter. The commenter reiterated that they do not support the inclusion of code 999.33 as a condition under the Vascular Catheter-Associated Infection HAC category, however, the commenter stated the additional information would assist in identifying potential shifts in volume among the newer, more specific codes of 999.32 and 999.33.

Response: We appreciate the commenter's support for the addition of diagnosis code 999.32, Bloodstream infection due to central venous catheter, to the Vascular Catheter-Associated Infection HAC category. With respect to the concern expressed regarding diagnosis code 999.33, Local infection due to central venous catheter, we believe the commenter may be confused. The title of the HAC category is Vascular Catheter-Associated Infection; therefore, the emphasis is on the fact that the patient had a central venous catheter placed and subsequently developed an infection due to the presence of that catheter. We acknowledge there is widespread interest particularly in bloodstream infections due to central venous catheters, as several initiatives have been undertaken focusing on surveillance and prevention. However, for this HAC payment provision, it is our belief that local infections resulting from a central venous catheter are also of importance and deserve similar efforts among the provider community and healthcare industry with regard to surveillance and prevention, as do the other selected HAC conditions. While the condition being described by diagnosis code 999.33, Local infection due to central venous catheter is a local infection, it identifies the fact that a patient acquired the infection as a result of a central venous catheter. Therefore, we continue to believe it is appropriate to finalize this code for inclusion in this HAC category.

In response to the recommendation that CMS conduct and publish data analyses to provide further detailed information related to volume and cost for codes 999.31, 999.32 and 999.33, we note that we have provided the results for each selected condition within each HAC category beginning with FY 2009 data analysis presented in FY 2011.

We refer the commenter and readers to the RTI evaluation of the HAC-POA program for years FY 2009 through FY 2011 on the following website: http://www.rti.org/reports/cms/. As codes 999.32 and 999.33 became effective October 1, 2011 (FY 2012), results of the FY 2012 data analysis are not currently available.

After consideration of the public comments we received, we are finalizing our proposal to add diagnosis codes 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the Vascular Catheter-Associated Infection HAC category for discharges occurring on or after October 1, 2012.

b. New Candidate HAC Condition: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27894 through 27896), we discussed our rationale for proposing a new condition, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures, for selection for FY 2013 as a HAC under section 1886(d)(4)(D) of the Act. As described in more detail in section II.F.1. of this preamble, each HAC must be: (1) high cost, high volume, or both; (2) assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (3) could reasonably have been prevented through the application of evidence-based guidelines. We also discuss other considerations relating to the selection of a HAC, including any administrative or operational issues associated with a proposed condition. For example, the condition may only be able to be identified by multiple codes, thereby requiring the

development of special GROUPER logic to also exclude similar or related ICD–9–CM codes from being classified as a CC or an MCC. Similarly, a condition acquired during a hospital stay may arise from another condition that the patient had prior to admission, making it difficult to determine whether the condition was reasonably preventable. In the proposed rule, we invited public comment on the degree to which these conditions fulfill these statutory requirements, as well as clinical, coding, and prevention issues on our proposal to add SSI Following CIED Procedures as a condition subject to the HAC payment provision for discharges occurring on or after October 1, 2012.

CIED therapy reduces morbidity and mortality in selected patients with cardiac rhythm disturbances.[1] More than 500,000 CIEDs are implanted each year in the United States and 70 percent of CIED recipients are age 65 or older.[2] However, this benefit with regard to the treatment of cardiac rhythm disturbances is somewhat reduced by complications following device placement, including infections. Patients can present with early or late infections because of CIED placement.[3] Two-thirds of these infections are caused by Staphylococcus aureus and coagulase-negative Staphylococcus species. Treatment of these infections usually entails surgical explantation of the device,

---

[1] Epstein, A. E., J. P. DiMarco, et al. (2008). "ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons." Circulation **117**(21): e350-408.

[2] Zhan, C., W. B. Baine, et al. (2007). "Cardiac device implantation in the United States from 1997 through 2004: a population-based analysis." J Gen Intern Med, 23 Suppl 1: 13-19.

[3] Baddour, L. M., A. E. Epstein, et al. (2010). "Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association." Circulation, 121(20048212): 458-477.

Baddour, L. M., A. E. Epstein, et al. (2010). "Update on Cardiovascular Implantable Electronic Device Infections and Their Management: A Scientific Statement From the American Heart Association." Circulation, 121(3): 458-477.

sometimes under general anesthesia and a prolonged course of intravenous antibiotics, along with external electrical support in a monitored intensive care setting. The rate of CIED infection is increasing faster than the rate of CIED implantation,[4] and there are published data on the mortality and cost associated with CIED infection or the relationship of these outcomes to different CIED types.

There is not a unique code that identifies SSI Following CIED Procedures. However, the condition can be identified as a subset of discharges with ICD–9–CM diagnosis code 996.61 (Infection and inflammatory reaction due to cardiac device, implant and graft) or 998.59 (Other postoperative infection). Our clinical advisors believe that diagnosis code 996.61 or 998.59, in combination with the associated procedure codes below, can accurately identify SSI Following CIED Procedures. The procedure codes are:

- 00.50 (Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system [CRT-P]);
- 00.51 (Implantation of cardiac resynchronization defibrillator, total system [CRT-D]);
- 00.52 (Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system);
- 00.53 (Implantation or replacement of cardiac resynchronization pacemaker pulse generator only [CRT-P]);

---

[4] Greenspon, A. J., J. D. Patel, et al. (2011). "16-Year Trends in the Infection Burden for Pacemakers and Implantable Cardioverter-Defibrillators in the United States 1993 to 2008." Journal of the American College of Cardiology 58(10): 1001-1006.

- 00.54 (Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only [CRT-D]);
- 37.80 (Insertion of permanent pacemaker, initial or replacement, type of device not specified);
- 37.81 (Initial insertion of single-chamber device, not specified as rate responsive);
- 37.82 (Initial Insertion of single-chamber device, rate responsive);
- 37.83 (Initial insertion of dual-chamber device);
- 37.85 (Replacement of any type pacemaker device with single-chamber device, not specified as rate responsive);
- 37.86 (Replacement of any type of pacemaker device with single-chamber device, rate responsive);
- 37.87 (Replacement of any type pacemaker device with dual-chamber device);
- 37.94 (Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]);
- 37.96 (Implantation of automatic cardioverter/defibrillator pulse generator only);
- 37.98 (Replacement of automatic cardioverter/defibrillator pulse generator only);
- 37.74 (Insertion or replacement of epicardial lead [electrode] into epicardium);
- 37.75 (Revision of lead [electrode]);

- 37.76 (Replacement of transvenous atrial and/or ventricular lead(s) [electrode]);
- 37.77 (Removal of lead(s) [electrode] without replacement);
- 37.79 (Revision or relocation of cardiac device pocket); and
- 37.89 (Revision or removal of pacemaker device).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27894 through 27896), we proposed to identify SSI Following CIED Procedures with diagnosis code 996.61 or 998.59 in combination with one or more of the above associated procedure codes. We believe the condition meets the three criteria for inclusion on the HAC list, as discussed in greater detail below.

First, the condition is one that is high cost and high volume. We reviewed Medicare claims data in the FY 2011 MedPAR file. For FY 2011, we found that there were 859 inpatient discharges coded with SSI Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure codes submitted through Medicare claims. The cases had an average cost of $51,795 for the entire hospital stay. We found that there were 583 inpatient discharges coded with SSI Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure codes submitted through Medicare claims reported as POA. These POA cases had an average cost of $41,999. We also found that there were 276 inpatient discharges coded with SSI Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure

codes submitted through Medicare claims reported as NPOA. These NPOA cases had an average cost of $72,485. We note that these data are consistent with other data presented for current HACs. Therefore, we believe this condition is high cost and high volume.

In addition, we reviewed the literature regarding this condition. Infection associated with CIED procedures resulted in a substantial incremental increase in admission mortality and long-term mortality and varies with the type of CIED. For the purposes of the proposal, we considered CIED procedures in the aggregate. Several large studies showed CIED infection associated with an approximately 5 percent to 8 percent inhospital mortality as well as a 17.5 percent to 35.1 percent one year mortality.[5] Additionally, there is a significant cost impact for patients who suffer infections after CIED implantation. A recent large analysis of 2007 data on over 200,000 Medicare beneficiaries demonstrated the mean hospital cost of CIED infections ranges from $28,676 to $53,349, compared with a mean hospital cost ranging from $12,468 to $36,851 for beneficiaries without infection.[6] This additional information supports our conclusion from our analysis of data in the MedPAR file that this condition is high cost.

Second, the condition of SSI Following CIED Procedures, as specified in our proposal, is a CC under the MS-DRG system. We did not identify any additional administrative or operational difficulties associated with proposing this condition as a HAC.

---

[5] Tarakji, K. G., E. J. Chan, et al. (2010). "Cardiac implantable electronic device infections: Presentation, management, and patient outcomes." Heart Rhythm **7**(8): 1043-1047.

[6] Sohail, M. R., C. A. Henrikson, et al. (2011). "Mortality and cost associated with cardiovascular implantable electronic device infections." Arch Intern Med **171**(20): 1821-1828.

Third, because there are widely recognized guidelines for the prevention of SSI Following CIED Procedures, we believe the condition is reasonably preventable through application of evidence-based guidelines. A large randomized controlled trial demonstrated that prophylactic preoperative antibiotics reduced CIED infection by 81 percent in patients who received them.[7] Well-accepted guidelines for the prevention and prophylaxis of CIED infection now exist supporting the use of prophylactic antibiotics.

In the proposed rule, we invited public comment on whether SSI Following CIED Procedures meets the requirements set forth under section 1886(d)(4)(D) of the Act, as well as other coding and prevention issues associated with our proposal to add this condition as a proposed condition subject to the HAC payment provision for FY 2013 (for discharges occurring on or after October 1, 2012). We indicated that we were particularly interested in receiving comments on the degree to which SSI Following CIED Procedures is reasonably preventable through the application of evidence-based guidelines.

Comment: The majority of commenters supported SSI Following CIED Procedures as a new addition to the HAC/POA condition list, citing its clinical relevance to the Medicare beneficiary population and concerns about the increasing incidence of these infections in conjunction with increased morbidity and mortality, and the associated costs with these infections. One commenter, a State program, indicated that it uses these codes in a statewide HAC payment incentive program.

Response: We appreciate the commenters' support.

---

[7] de Oliveira, J. C., M. Martinelli, et al. (2009). "Efficacy of Antibiotic Prophylaxis Before the Implantation of Pacemakers and Cardioverter-Defibrillators: Results of a Large, Prospective, Randomized, Double-Blinded, Placebo-Controlled Trial." Circ Arrhythm Electrophysiol, 2(1): 29-34.

Comment: Some commenters raised concerns that the inclusion of SSI Following CIED Procedures as a HAC candidate does not meet the statutory conditions of section 1886(d)(4)(D) of the Act because "CMS points out that there were only 859 cases of SSI Following CIED Procedures during FY 2011. This constitutes only 0.25 percent of all CIED cases." These commenters asserted that the HAC candidate condition does not meet the high-volume criterion and, therefore, should not be included as a HAC.

Response: We appreciate the commenters' concern regarding whether this candidate condition meets the standards of the statutory criteria. We note that we consider all cases where HAC codes are on the claim as a secondary diagnosis, regardless of their POA indicator, in evaluating conditions based on cost and volume and also use external data sources when available. With regard to cost, the proposed rule included data analyses that showed that the average cost per case of SSI Following CIED Procedures is $51,795 and also included literature that describes the increase in the mean cost of admissions with CIED infection to those CIED placements without infection. Therefore, we reiterate our belief that this condition meets the high-cost criterion. As discussed previously, section 1886(d)(4)(D) of the Act specifies that a condition on the HAC list may be high-volume or high-cost or both. It does not require the condition to be both, and a condition that is only high-cost would meet this statutory criterion. Therefore, we believe that the statutory criterion has been met.

In the proposed rule, we characterized this condition as "high-cost and high-volume" and described an analysis that showed 859 cases. While 859 cases may seem like a small number of cases as the commenters pointed out, we note that, in past

rules, we have had similar numbers for HACs, such as in FY 2008, where we stated that there were "764 cases reported of Medicare patients who had an object left in during surgery reported as a secondary diagnosis" (72 FR 24720). Therefore, a volume of 859 cases is not as high as the volume for some other HACs and is higher than the volume for some HACs.

Comment: Some commenters were opposed to the SSI Following CIED Procedures becoming a HAC because they believed that this HAC selection "will result in hospitals dedicating time and effort to avoiding this extremely low-incidence adverse event (when resources could have been devoted to more highly prevalent safety concerns)."

Response: We appreciate and understand the concern of the commenters. We note that SSIs are an established HAC category and that a similar condition has been identified by public commenters in prior rulemaking. In the FY 2008 IPPS final rule with comment period (72 FR 47213), SSIs were identified as a broad category for consideration. However, at the time, we determined that coding of SSI with only ICD-9-CM code 998.59 (Other postoperative infection) did not meet the statutory criteria for being subject to the provision because it does not uniquely identify SSIs. We stated that we would explore ways to identify SSIs and would reevaluate the condition in FY 2009. In response to public comment in the FY 2008 final rule with comment period, we finalized one SSI, mediastinitis after coronary artery bypass graft (CABG) surgery, and continued to ask for public input so that further specific SSIs could be identified.

In FY 2009, we expanded our selection of the SSI for elective procedures as HACs. In the FY 2009 IPPS final rule (73 FR 48477 through 48479), we discussed how, in response to commenters' suggestions, we selected certain orthopedic procedures in the HAC SSI category using ICD-9-CM diagnosis code 996.67 (Infection and inflammatory reaction due to other orthopedic device and implant graft) or 998.59 (Other postoperative infection) and selected 81.XX orthopedic ICD-9-CM procedure codes. Another SSI condition that was proposed and finalized during FY 2009 based on public comment was "Surgical Site Infection Following Bariatric Surgery for Obesity." The ICD-9-CM codes that are used to describe "Surgical Site Infection Following Bariatric Surgery for Obesity" are: 278.01 (Morbid Obesity) and 998.59 (Other postoperative infection), and procedure code 44.38 (Laparoscopic gastroenterostomy) or 44.39 (Other gastroenterostomy), or 44.95 (Laparoscopic gastri restrictive procedure).

As discussed in that same final rule for FY 2009 (73 FR 48478 through 48479), a commenter recommended adding Surgical Site Infection following Implantation of Cardiac Devices as a HAC. The commenter provided the following information regarding this recommended HAC:

- A recent estimate that approximately 300,000 pacemaker implants had been performed in 2007.
- A reference stating that the estimated rate of infection following cardiac device implantation is 4 percent and that the cost to treat each pacemaker infection is approximately $25,000.
- Evidence-based guidelines for preventing these infections.

Our response in that FY 2009 final rule was that "surgical site infection following certain cardiac device procedures is a strong candidate HAC." We stated the condition is high-cost, high-volume, triggers a higher-paying MS-DRG, and may be considered reasonably preventable through the application of evidence-based guidelines. We further explained that we did not propose this specific condition in the FY 2009 IPPS proposed rule; however, we expect to propose surgical site infection following certain cardiac device procedures, as well as surgical site infection following other types of device procedures, as future candidates. We also stated that we looked forward to working with stakeholders to identify additional procedures, such as device procedures, in which SSIs could be considered reasonably preventable through the application of evidence-based guidelines. We continue to agree with public commenters from FY 2009 that SSI Following Implantation of Cardiac Device Procedures is a strong candidate and made this specific proposal for FY 2013 for that reason.

In light of the public comments we received, and given our prior establishment of a broad HAC category for SSIs in relation to HACs and historical discussion of SSI following certain cardiac device procedures as a strong candidate, in this final rule, we are modifying our proposal so that, rather than this procedure being a new HAC category, we are finalizing SSI Following CIED Procedures as a new subcategory under SSIs (for example, HAC 9D Surgical Site Infection Following Cardiac Implantation).

Comment: Some commenters opposed the use of administrative/claims data to identify HAIs in the HAC/POA Program and noted that the proposed rule stated that there is no unique code that identifies SSI Following CIED procedures, and thus CMS

proposed to use a combination of codes to capture these data. The commenters believed the use of claims data for the determination of HAIs/HACs has limited value in improving patient care because claims data do not provide precise identification of HAIs, nor do they provide information in a timely manner to provide effective treatment.

Response: We appreciate the commenters' concern that administrative data may not provide the most precise identification of HAIs and their comments about the codes used to identify the conditions proposed for addition to the HAC list. However, we point out that the statute establishes this policy as a payment policy, which is implemented on a per claim basis by adjusting the MS-DRG assignment. The statute further requires that the conditions on the HAC list must be identifiable through ICD-9-CM codes. The conditions identified on the HAC list and the corresponding codes or combinations of codes used to make a payment adjustment are not intended to provide information in a timely manner to provide treatment to any particular individual. The statute establishes a payment adjustment that can encourage hospitals to make improvements with regard to a limited number of conditions that, if they did not occur, could have otherwise resulted in an increased payment for a reasonably avoidable complication.

Comment: One commenter did not believe that punitive payment mechanisms coupled with the lack of risk adjustment for the conditions on the HACs list is the most appropriate or effective method to reduce complications. Commenters also asserted that CMS is expanding the HAC program "without fully understanding the impact of appropriate risk adjustment."

Response: We appreciate the commenters' response, but disagree with their assumptions. We received similar comments regarding the addition of two new codes to another existing HAC category. We note that our response is similar. The HAC/POA Program is part of an array of tools used by the Medicare program to promote increased quality and efficiency of care. These tools include quality measurement, as well as payment adjustments. Because of their importance, HACs have been included in multiple tools used by Medicare to measure quality of services provided and performance, and to determine payment adjustments. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, such as when a nonselected CC/MCC appears on a claim, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications.

With regard to risk adjustment, risk adjustment is not a requirement under section 1886(d)(4)(D) of the Act for inclusion of a condition on the HAC list for payment adjustment. We believe the commenters may be confusing the HAC payment adjustment policy with quality measurement policies, where risk adjustment is sometimes used. We believe meeting the statutory criteria as specified encourages hospitals to promote measures to protect all patients from reasonably preventable HACs.

Comment: One commenter stated: "It is inappropriate for CMS to deny payment for HAC related complications without taking into consideration whether a patient did, in

fact, receive optimal evidence-based care given that the rates of many of the HACs cannot reach zero."

Response: We appreciate the commenter's response. We believe that, although it may be difficult to reduce the incidence of conditions on the HAC list to zero, the incidence of conditions can be significantly reduced in cases where evidence-based guidelines for the prevention of the condition exist and are used. Additionally, we point out that payment is not denied, but could be made at a lower paying MS-DRG rate. If any nonselected CC/MCC appears on the claim when a HAC is not present on admission, the claim will be paid at the higher MS-DRG rate, so the hospital would not receive a lower payment. Finally, in accordance with 42 CFR 412.60(d), hospitals may appeal the DRG assignment on a claim within 60 days of the initial notice of the DRG assignment. This may be of interest to the public, as the commenter expressed concern about those cases where a HAC occurs and a lower paying MS-DRG assignment is made.

After consideration of the public comments we received, in this final rule, we are modifying our proposal to add SSI Following CIED Procedures as a HAC condition. Our final policy makes SSI following CIED Procedures a sub-HAC condition within the SSI HAC category subject to the HAC payment provision for discharges occurring on or after October 1, 2012.

c. New Candidate HAC Condition: Iatrogenic Pneumothorax with Venous Catheterization

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27896 through 27897), we discussed our rationale for proposing a new condition, Iatrogenic Pneumothorax with Venous Catheterization, for selection as a HAC for FY 2013 under section 1886(d)(4)(D)

of the Act. We previously proposed Iatrogenic Pneumothorax more generally as a HAC in the FY 2009 IPPS rulemaking (73 FR 48485).

In the FY 2009 IPPS final rule (73 FR 48485), we considered Iatrogenic Pneumothorax as a condition but did not finalize it due to commenters' concerns about the preventability of the condition when following the evidence-based guidelines. Most commenters opposed the selection of Iatrogenic Pneumothorax as a HAC and indicated that the evidence-based guidelines often acknowledge that Iatrogenic Pneumothorax is a known relatively common risk for certain procedures. Further, with regard to evidence-based guidelines, many commenters opposed designation of this condition as a HAC due to a lack of consensus within the medical community regarding its preventability.[8] Some commenters offered suggestions to exclude certain procedures or situations, including central line placement, thoracotomy, and the use of a ventilator, if Iatrogenic Pneumothorax were to be selected as a HAC. In that rule, we noted that we would continue to review the development of evidence-based guidelines for the prevention of Iatrogenic Pneumothorax if evidence warranted and consider Iatrogenic Pneumothorax as a HAC in the future. We refer readers to that final rule for a more detailed discussion (73 FR 48485). To address concerns raised by commenters in FY 2009, we reviewed changes in the standard of care and evidence-based guidelines to identify specific situations where Iatrogenic Pneumothorax would be considered reasonably preventable and identified venous catheterization as one such instance.

[8] Ahan, et al.: Accidental Iatrogenic Pneumothorax in Hospitalized Patients, *Medical Care,* 44(2):182-6, Feb. 2006.

Pneumothorax is defined as the presence of air or gas in the pleural cavity, which is the space between the covering of the tissue of the lung and parietal pleura, or the part of the pleura that lines the chest wall. The presence of air in this space partially or completely collapses the lung and is life threatening. Air can enter the intrapleural space through a passage through the chest wall. Iatrogenic Pneumothorax is a type of traumatic pneumothorax that results from incursion into the pleural space secondary to diagnostic or therapeutic medical intervention, such as needle placement for central line catheter guidance.

There is no unique code that identifies Iatrogenic Pneumothorax with Venous Catheterization. However, Iatrogenic Pneumothorax with Venous Catheterization can be identified as a subset of discharges with ICD–9–CM diagnosis code 512.1 (Iatrogenic pneumothorax). Our clinical advisors believe that diagnosis code 512.1, in combination with the associated procedure code 38.93 (Venous catheterization NEC), can accurately identify Iatrogenic Pneumothorax with Venous Catheterization. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27896 through 27897), we proposed to identify Iatrogenic Pneumothorax with Venous Catheterization reported in combination with diagnosis code 512.1 (Iatrogenic pneumothorax) and procedure code 38.93 (Venous catheterization NEC). We recognize that, in quality measurement such as with the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) Number 6 (Iatrogenic Pneumothorax Rate), exclusion criteria are used to increase the accuracy of identifying these cases. We believe that, by limiting our proposal to include Iatrogenic Pneumothorax as a HAC only in the context of venous catheterization, we

have improved our ability to accurately identify these cases. While we did not propose exclusion criteria, we welcomed public comment in this regard. In addition, we believe this more narrowly tailored condition meets the three criteria for inclusion on the HAC list, as discussed in greater detail below.

First, the condition is one that is high cost and high volume. We reviewed Medicare claims data in the FY 2011 MedPAR file. We found that there were 4,467 inpatient discharge cases coded for Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93. The cases had an average cost of $39,128 for the entire hospital stay. We found that there were 612 inpatient discharge cases coded for Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93 submitted through Medicare claims reported as POA. These POA cases had an average cost of $26,693. We also found that there were 3,855 inpatient discharge cases coded for Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93 submitted through Medicare claims reported as NPOA. These NPOA cases had an average cost of $41,102. We note that these data are consistent with other data presented for current HACs. Therefore, we believe this condition is high cost and high volume.

In addition, we reviewed the literature regarding this condition. The cannulation of veins (that is, insertion of a catheter) with central venous catheterization is an important aspect of patient care for the administration of fluids and medications and for monitoring purposes. Eight percent of hospitalized patients receive a central venous

catheter, and more than 5 million central venous catheters are inserted in the United States each year. Indwelling catheters have several known complications and side effects associated with their use, such as infections or vessel damage. Additionally, there are risks associated with the placement of central venous catheters including the risk of pneumothorax for central catheters placed in the upper area of the patient's neck or chest when placed in the internal jugular or subclavian veins. Mechanical complications associated with Iatrogenic Pneumothorax are reported to occur in 5 to 19 percent of patients.[9]

Second, the condition of Iatrogenic Pneumothorax with Venous Catheterization as specified in our proposal is a CC under the MS-DRGs.

Third, there are widely recognized guidelines that address the prevention of Iatrogenic Pneumothorax with Venous Catheterization, and we believe that Iatrogenic Pneumothorax in the context of venous catheterization is reasonably preventable through application of these evidence-based guidelines.

In terms of guidelines, the AHRQ, in a 2001 report "Making Health Care Safer: A Critical Analysis of Patient Safety Practices" (AHRQ Publication No. 01-EO58) recommended the use of ultrasound for the placement of all central venous catheters as one of its 11 practices aimed at improving patient care. Current standard placement techniques for these venous catheters rely on the knowledge of anatomic landmarks and other indicators to guide the initial cannulation of the vein. The increase in the number of small, advanced and portable 2D ultrasound devices has inspired the use of these newer

[9] McGee, D. C. and M. K. Gould (2003). "Preventing Complications of Central Venous Catheterization." New England Journal of Medicine, 348(12): 1123-1133.

ultrasound devices in central venous line placement, as now direct visualization of the target vessel can be achieved, making it easier to avoid these complications. Recommendations for the use of ultrasound as an adjunct to central venous line placement now exist and are based on supportive literature Category A (Randomized controlled trials report statistically significant ($P > .01$) differences between clinical interventions for a specified clinical outcome) with a Level 1 weight of scientific evidence (multiple randomized controlled trials with the aggregated findings supported by meta-analysis).[10] Several studies have shown a decrease in the mechanical complication rate with the use of ultrasound during line placement.[11] Guidelines for performing ultrasound guided vascular cannulation have been recently published.[12]

We believe new evidence-based guidelines provide substantial clinical guidance for reasonable prevention when this condition occurs in the context of venous catheterization. In the proposed rule, we invited public comment on whether Iatrogenic Pneumothorax with Venous Catheterization meets the requirements set forth under section 1886(d)(4)(D) of the Act, as well as other coding and prevention issues associated with our proposal to add this proposed condition, as a condition subject to the HAC payment provision for discharges occurring on or after October 1, 2012. We stated that

---

[10] Echoc, A. U. R. b. t. A. S. o. A. a. t. S. o. C. A. T. F. o. T. (2010). "Practice Guidelines for Perioperative Transesophageal Echocardiography." Anesthesiology, 112(5): 1084-1096 1010.1097/ALN.1080b1013e3181c1051e1090.

[11] Hind, D.: "Ultrasonic device for central venous cannulation: Meta-analysis." BJM, 2003, vol. 327, 7411:361-364; and
Troianos, C. A., G. S. Hartman, et al. (2012). "Guidelines for Performing Ultrasound Guided Vascular Cannulation: Recommendations of the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists." Anesthesia and Analgesia, 114(1): 46-72.

[12] Troianos, C. A., G. S. Hartman, et al. (2012). "Guidelines for Performing Ultrasound Guided Vascular Cannulation: Recommendations of the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists." Anesthesia and Analgesia, 114(1): 46-72.

we were particularly interested in public comment on how limiting the condition to situations in which it occurs in conjunction with venous catheterization influences preventability, and whether additional limits should be considered in the context of venous catheterization.

Comment: Some commenters supported CMS' proposal to include Iatrogenic Pneumothorax with Venous Catheterization as a candidate condition for the HAC list. Some commenters noted that this proposal aligns with and encourages use of "widely recognized" guidelines based in research evidence, including AHRQ's 2001 published report, "Making Healthcare Safer: A Critical Analysis of Patient Safety Practices" (AHRQ Publication No. 01-E058), that shows iatrogenic pneumothorax can be a reasonably preventable complication when performing the venous catheterization using an ultrasound. One commenter stated, "Recent studies have highlighted the cost savings and increased quality of care that ultrasound guided catheterization can provide…[and that] fewer complications from needle placement result in improved patient outcomes and greater clinician efficiency."Another commenter listed additional guidelines, such as the 2002 guidance from CDC regarding the use of ultrasound and the prevention of intravascular catheter-related complications, the 2002 guidance from the National Institute for Health and Clinical Excellence (NICE) on the use of ultrasound for placing central venous catheters, the 2001 (revised in 2008) guidance from the American College of Emergency Physicians which represents the first specialty specific comprehensive guidelines for the use of ultrasound in emergency medicine, and the 2012 practice guideline from the American Society of Anesthesiologists (ASA) Taskforce on Central

Venous Access for central venous access defined as placement of a catheter such that the catheter is inserted into a venous great vessel.

Another commenter noted that "Since 2001, controlled trials have been published evaluating ultrasound guided central venous catheterization in various types of patient populations...and found significantly higher success rates and reduced complication rates in all studies."

Response: We agree with commenters' input and appreciate the commenters' support.

Comment: One commenter encouraged CMS to add exclusion criteria "to prevent reporting errors" of the Iatrogenic Pneumothorax with Venous Catheterization HAC. Another commenter recommended that CMS add the following exclusion codes to distinguish iatrogenic and spontaneous pneumothorax; pneumothorax and air leaks: ICD-9-CM codes 512.2 (Postoperative air leak), 512.81 (Primary Spontaneous Pneumothorax), 512.82 (Secondary spontaneous pneumothorax), 512.83 Chronic pneumothorax), 512.84 (Other air leak), and 512.89 (Other Pneumothorax). One of the commenters noted that Iatrogenic Pneumothorax does not have an ICD-9-CM code.

Response: We thank the commenters for their response. At this time, we continue to believe that, by limiting our proposal to include Iatrogenic Pneumothorax as a HAC only in the context of venous catheterization, we have improved our ability to accurately identify these cases and that no further exclusion criteria are needed. We believe that the commenter may have misunderstood our proposed policy in offering the specific suggestions for exclusion codes. First, the commenter is mistaken about there

not being a code for Iatrogenic Pneumothorax in ICD-9-CM. The condition is indexed clearly to diagnosis code 512.1 (Iatrogenic pneumothorax). Also, as specified, this HAC would not include the codes for spontaneous pneumothorax because it is not a complication as a result of a medical intervention and, therefore, is not iatrogenic. ICD-9-CM diagnosis code 512.1 is specific enough to capture those complications that have been caused through medical intervention in the context of venous catheterization.

Comment: Some commenters opposed the addition of the Iatrogenic Pneumothorax with Venous Catheterization condition "because it puts hospitals at risk of being penalized twice for the same event." Commenters pointed out that CMS proposed to add a patient safety composite measure that includes Iatrogenic Pneumothorax with Venous Catheterization to the Hospital VBP Program. In the commenters' view, this penalizes hospitals twice for the same event. The commenters noted that they supported reducing iatrogenic pneumothorax as a patient safety goal for CMS, and urged CMS to "select only one program in which to measure hospitals' performance on IPs with venous catheterization." In addition, the commenters stated that "CMS has continued to add additional components to the HAC list without fully understanding the impact of appropriate risk adjustment."

Response: We received similar public comments regarding our proposal to include SSI Following CIED Procedures in the existing HAC category, and, similarly, we appreciate the commenters' response but disagree with their assumptions. As we responded above with regard to the SSI Following CIED Procedures condition, the HAC/POA program is part of an array of tools used by the Medicare program to promote

increased quality and efficiency of care. These tools include quality measurement, as well as payment adjustments. Because of their importance, HACs have been included in multiple tools used by the Medicare program to measure quality of services provided and performance, and to determine payment adjustments. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, such as when a nonselected CC/MCC appears on a claim, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications and would not generally "penalize hospitals twice."

With regard to risk adjustment, risk adjustment is not a requirement under section 1886(d)(4)(D) of the Act for inclusion of a condition on the HAC list for payment adjustment. We believe the commenters may be confusing the HAC payment adjustment policy with quality measurement policies, where risk adjustment is sometimes used. We believe meeting the statutory criteria as specified encourages hospitals to promote measures to protect all patients from reasonably preventable hospital-acquired conditions.

Comment: Some commenters opposed the inclusion of Iatrogenic Pneumothorax with Venous Catheterization as a HAC candidate condition because they did not believe that this proposed HAC condition is high-volume.

Response: We received similar comments with regard to our proposal to include SSI Following CIED Procedures as a HAC candidate condition. We similarly point out

that our proposal characterized this condition as "high-cost and high-volume" and described analysis that showed 4,467 cases and an average cost of $39,128. Furthermore, as discussed previously, section 1886(d)(4)(D) of the Act specifies that a condition on the HAC list may be high-volume or high-cost or both. It does not require the condition to be both and a condition that was only high-cost would still meet this statutory criterion.

Comment: Other commenters "recommended that CMS work with CDC and other quality organizations to identify more robust measures for HAC[s] prior to implementing these two proposed conditions, as their inclusion is not currently endorsed by national quality organizations."

Response: In establishing the HAC payment policy under section 1886(d)(4)(D) of the Act, our experts have worked closely with the public health and infectious disease professionals from across the Department of Health and Human Services to identify the candidate preventable HACs. New HAC proposals are made in consultation with the CDC to ensure the clinical soundness of the proposal.

Comment: A few commenters stated that "For many conditions on the HAC list, occurrence rates cannot be reduced to zero or near zero even when the evidence-based guidelines are followed." In addition, one commenter stated "We believe that effective preventive measures make Iatrogenic Pneumothorax reducible but not 100 percent preventable. However, the same report states that these prevention strategies may reduce the incidence but not necessarily eliminate it. CMS should recognize the reality that a target rate of zero ("never event") is perhaps not attainable with this condition at this time."

Response: We appreciate the commenters' response. We believe that, although it may be difficult to reduce the incidence of conditions on the HAC list to zero, the incidence of conditions can be significantly reduced in cases where evidence-based guidelines for the prevention of the condition exist and are used. For Iatrogenic Pneumothorax with Venous Catheterization, the use of the improved newly published evidence-based guidelines has shown the complication rate can be markedly reduced in the placement of the venous catheter into the internal jugular vein.

Comment: A few commenters expressed that the inclusion of the Iatrogenic Pneumothorax with Venous Catheterization condition may have unintended and deleterious consequences, which may lead providers toward using alternative sites for central line placement that are less prone to pneumothorax, but carry increased risk of mechanical and infectious complications. They indicated that alternative sites could be the internal jugular or femoral veins. Because of these consequences, these commenters did not support the addition of Iatrogenic Pneumothorax with Venous Catheterization to the HAC list.

Response: We believe the commenters may have misunderstood our proposal. The new HAC condition will apply to a population of patients who have iatrogenic pneumothorax as a complication of central venous placement of a catheter in the internal jugular vein. We do not believe hospitals will be led to consider alternative, suboptimal sites for central venous access because of this new addition to the HAC list.

Comment: Some commenters expressed concerns regarding the use of ultrasound in academic medical centers and Level 1 Trauma Centers for venous catheter placement

versus the use of ultrasound for venous catheter placement in small community hospitals. They stated that "there is little to no data on how often ultrasound guidance is used in small community medical centers." Furthermore, they stated that "ultrasound guidance is less commonly used in procedures involving central venous access via the subclavian vein, and is often impossible to use in trauma cases."

Response: We believe that, in applying evidence-based guidelines, hospitals will have appropriately trained hospital personnel. Also, we point out that the lesser paying MS-DRG is not assigned when additional nonselected CC/MCCs appear on a claim, and that trauma cases may likely involve additional nonselected CC/MCCs.

As we indicated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27897), with the exception of the condition of Iatrogenic Pneumothorax with Venous Catheterization, at this time, we do not believe that additional analysis exists that would require us to change our previous determinations regarding the previously considered candidate HACs in the FY 2008 IPPS final rule with comment period (72 FR 47200 through 47218), the FY 2009 IPPS final rule (73 FR 48471 through 48491), the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782 through 43785), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51510 through 51511). We refer readers to these rules for a detailed discussion that supports our determination regarding each of the previously considered candidate HACs and continue to encourage public dialogue about refinements to the HAC list.

After consideration of the public comments we received, we are finalizing our proposal to add Iatrogenic Pneumothorax with Venous Catheterization with the codes

specified above as a condition subject to the HAC payment provision for discharges occurring on or after October 1, 2012.

6. RTI Program Evaluation Summary

On September 30, 2009, a contract was awarded to Research Triangle Institute, International (RTI) to evaluate the impact of the Hospital-Acquired Condition-Present on Admission (HAC-POA) provisions on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. This is an intra-agency project with funding and technical support coming from CMS, the Office of Public Health and Science (OPHS), AHRQ, and CDC. The evaluation will also examine the implementation of the program and evaluate additional conditions for future selection.

RTI's evaluation of the HAC-POA provisions is divided into several parts. The evaluation includes conditions that are currently treated as HACs and also previously considered candidate conditions. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50085 through 50101) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51512 through 51522) for a fuller description of this evaluation and findings to date regarding analysis of FY 2009 and FY 2010 data, respectively. Summary and detailed data were made publicly available on the CMS Web site at: http://www.cms.gov/HospitalAcqCond/01_Overview.asp and the RTI Web site at: http://www.rti.org/reports/cms/.

RTI's analysis of the FY 2011 MedPAR data file for the HAC-POA program evaluation is included as follows in this FY 2013 IPPS/LTCH PPS final rule. These

summary and detailed data are available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html and the RTI Web site at: http://www.rti.org/reports/cms/.

a. RTI Analysis of FY 2011 POA Indicator Reporting Across Medicare Discharges

To better understand the impact of HACs on the Medicare program, it is necessary to first examine the incidence of POA indicator reporting across all eligible Medicare discharges. As mentioned previously, only IPPS hospitals are required to submit POA indicator data for all diagnosis codes on Medicare claims. Therefore, all non-IPPS hospitals were excluded, as well as providers in waiver States (Maryland) and territories other than Puerto Rico.

Using MedPAR claims data from October 2010 through September 2011, RTI found a total of approximately 89.3 million secondary diagnoses across approximately 8.94 million discharges. As shown in Chart A below, the majority of all secondary diagnoses (77.57 percent) were reported with a POA indicator of "Y," meaning the condition was POA.

CHART A.—POA CODE DISTRIBUTION ACROSS ALL SECONDARY DIAGNOSES

		Number	**Percentage**
Total Discharges in Final File		8,941,507	
Total Number of Secondary Diagnoses Across Total Discharges		89,252,194	100.00
POA	**Indicator Description**		
Y	Condition present on admission	69,231,189	77.57

W	Status cannot be clinically determined	21,796	0.02
N	Condition not present on admission	5,748,769	6.44
U	Documentation not adequate to determine if condition was present on admission	207,258	0.23
1	Exempted ICD-9-CM code	14,043,182	15.73

SOURCE: RTI Analysis of MedPAR IPPS Claims, October 2010 through September 2011.

b. RTI Analysis of FY 2011 POA Indicator Reporting of Current HACs

Following the initial analysis of POA indicator reporting for all secondary diagnoses, RTI evaluated POA indicator reporting for specific HAC-associated secondary diagnoses. The term "HAC-associated secondary diagnosis" refers to those diagnoses that are on the selected HAC list and were reported as a secondary diagnosis. Chart B below shows a summary of the HAC categories with the frequency in which each HAC was reported as a secondary diagnosis and the corresponding POA indicators assigned on the claims. It is important to note that, because more than one HAC-associated diagnosis code can be reported per discharge (that is, on a single claim), the frequency of HAC-associated diagnosis codes may be more than the actual number of discharges that have a HAC-associated diagnosis code reported as a secondary diagnosis. Below we discuss the frequency of each HAC-associated diagnosis code and the POA indicators assigned to those claims.

RTI analyzed the frequency of each reported HAC-associated secondary diagnosis (across all 8.94 million discharges) and the POA indicator assigned to the claim. Chart B below shows that the most frequently reported conditions were in the Falls and Trauma HAC category, with a total of 181,157 HAC-associated diagnosis codes being reported for that HAC category. Of these 181,157 diagnoses, 4,738 reported a

POA indicator of "N" for not POA and 175,831 diagnoses reported a POA indicator of "Y" for POA. The lowest frequency appears in the Blood Incompatibility HAC category with only 22 HAC-associated secondary diagnosis codes reported.

CHART B.—POA STATUS OF CURRENT HACS: OCTOBER 2010 THROUGH SEPTEMBER 2011

Selected HAC	Frequency as a Secondary Diagnosis	Not Present on Admission				Present on Admission			
		POA = N		POA = U		POA = Y		POA = W	
		No.	Percent	No.	Percent	No.	Percent	No.	Percent
1. Foreign Object Retained After Surgery (CC)	606	283	46.7	1	0.2	321	53.0	1	0.2
2. Air Embolism (MCC)	45	34	75.6	0	0.0	11	24.4	0	0.0
3. Blood Incompatibility (CC)	22	10	45.5	1	4.5	11	50.0	0	0.0
4. Pressure Ulcer Stages III & IV (MCC)	102,172	1,742	1.7	75	0.1	100,328	98.2	27	0.0
5. Falls and Trauma (MCC & CC)	181,157	4,738	2.6	510	0.3	175,831	97.1	78	0.0
6. Catheter-Associated UTI (CC)	16,807	3,906	23.2	32	0.2	12,835	76.4	34	0.2
7. Vascular Catheter-Associated Infection (CC)	11,324	5,910	52.2	25	0.2	5,366	47.4	23	0.2
8. Poor Glycemic Control (MCC)	15,360	612	4.0	7	0.0	14,734	95.9	7	0.0
9A. Surgical Site Infection Mediastinitis CABG (CC)	58	50	86.2	0	0.0	8	13.8	0	0.0
9B. Surgical Site Infection Following Certain Orthopedic Procedures (CC)	356	247	69.4	0	0.0	109	30.6	0	0.0

Selected HAC	Frequency as a Secondary Diagnosis	Not Present on Admission				Present on Admission			
		POA = N		POA = U		POA = Y		POA = W	
		No.	Percent	No.	Percent	No.	Percent	No.	Percent
9C. Surgical Site Infection Following Bariatric Surgery for Obesity (CC)	25	24	96.0	0	0.0	1	4.0	0	0.0
10. Pulmonary Embolism & DVT Orthopedic (MCC)	3,368	2,715	80.6	20	0.6	611	18.1	22	0.7
Total *	331,300	20,271	6.1	671	0.2	310,166	93.6	192	0.1

*More than one HAC-associated diagnosis code can be reported per discharge; therefore, frequency of HAC-associated diagnosis codes may be more than the actual number of discharges that have a HAC-associated diagnosis code reported as a secondary diagnosis.

In the FY 2009 IPPS final rule (73 FR 48486 through 48487), we adopted as final our proposal to: (1) pay the CC/MCC MS-DRGs for those HACs coded with "Y" and "W" indicators; and (2) not pay the CC/MCC MS-DRGs for those HACs coded with "N" and "U" indicators. We also discussed the comments we received urging CMS to strongly consider changing the policy and to pay for those HACs assigned a POA indicator of "U" (documentation is insufficient to determine if the condition was present at the time of admission). We stated we would monitor the extent to which and under what circumstances the "U" POA reporting option is used. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we also discussed and responded to comments regarding HACs coded with the "U" indicator (74 FR 43784 and 43785). As shown in Chart B above, RTI's analysis provides data on a total of 671 HAC-associated secondary diagnoses reported with a POA indicator of "U." Of those diagnoses, 510 (0.3 percent) were assigned to the Falls and Trauma HAC category.

We continue to believe that better documentation will result in more accurate public health data. We did not propose to change our policy under which CMS does not pay at the higher CC/MCC amount when a selected HAC diagnosis code is reported with a POA indicator of "U."

We encourage readers to further review the RTI detailed report which demonstrates the frequency of each individual HAC-associated diagnosis code within the HAC categories. For example, in the Foreign Object Retained After Surgery HAC category, there are two unique ICD-9-CM diagnosis codes to identify that condition: code 998.4 (Foreign body accidentally left during a procedure) and code 998.7 (Acute reaction to foreign substance accidentally left during a procedure). In the detailed RTI report, readers can view that code 998.4 was reported 591 times and code 998.7 was reported 15 times, across all MS-DRGs, for a total of 606 times. The RTI detailed report is available at the following Web site: http://www.rti.org/reports/cms/.

c. RTI Analysis of FY 2011 Frequency of Discharges and POA Indicator Reporting for Current HACs

RTI further analyzed the effect of the HAC provision by studying the frequency in which a HAC-associated diagnosis was reported as a secondary diagnosis with a POA indicator of "N" or "U" and, of that number, how many resulted in MS-DRG reassignment. In Chart C below, Column A shows the number of discharges for each HAC category where the HAC-associated diagnosis was reported as a secondary diagnosis. For example, there were 45 discharges that reported Air Embolism as a secondary diagnosis. Column C shows the number of discharges for each HAC reported

with a POA indicator of "N" or "U." Continuing with the example of Air Embolism, the chart shows that, of the 45 reported discharges, 34 discharges (75.56 percent) had a POA indicator of "N" or "U" and were identified as a HAC discharge. There were a total of 34 discharges to which the HAC policy applied and that could, therefore, have had an MS-DRG reassignment. Column E shows the number of discharges where an actual MS-DRG reassignment occurred. As shown in Column E, the number of discharges with an Air Embolism that resulted in actual MS-DRG reassignments was 14 (41.18 percent of the 34 discharges with a POA indicator of "N" or "U"). Thus, while there were 34 discharges (75.56 percent of the original 45) with an Air Embolism reported with a POA indicator of "N" or "U" identified as a HAC discharge that could have caused MS-DRG reassignment, the end result was 14 (41.18 percent) actual MS-DRG reassignments. There are a number of reasons why a selected HAC reported with a POA indicator of "N" or "U" will not result in MS-DRG reassignment. These reasons were illustrated with the diagram in section II.F.1. of the preamble of this final rule and will be discussed in further detail in section II.F.3.e. of this preamble.

Chart C below also shows that, of the 287,993 discharges with a HAC-associated diagnosis as a secondary diagnosis, 3,006 discharges ultimately resulted in MS-DRG reassignment. As will be discussed below, there were 15 claims that resulted in MS-DRG reassignment where 2 HACs were reported on the same admission. The four HAC categories that had the most discharges resulting in MS-DRG reassignment were: (1) Falls and Trauma; (2) Pulmonary Embolism and DVT Orthopedic (Orthopedic PE/DVT); (3) Pressure Ulcer Stages III & IV; and (4) Catheter-Associated Urinary Tract

Infection (CAUTI). Codes falling under the Falls and Trauma HAC category were the most frequently reported secondary diagnoses with 143,920 discharges. Of these 143,920 discharges, 4,555 (3.16 percent) were coded as not POA and identified as HAC discharges. This category also contained the greatest number of discharges that resulted in an MS-DRG reassignment. Of the 4,555 discharges within this HAC category that were not POA, 1,241 (27.24 percent) resulted in an MS-DRG reassignment.

Of the 287,993 total discharges reporting HAC-associated diagnoses as a secondary diagnosis, 3,044 discharges were coded with a secondary diagnosis of Orthopedic PE/DVT. Of these 3,044 discharges, 2,473 (81.24 percent) were coded as not POA and identified as HAC discharges. This category contained the second greatest number of discharges resulting in an MS-DRG reassignment. Of the 2,473 discharges in this HAC category that were not POA, 1,082 discharges (43.75 percent) resulted in an MS-DRG reassignment.

The Pressure Ulcer Stages III & IV category had the second most frequently coded secondary diagnoses, with 96,646 discharges. Of these discharges, 1,770 (1.83 percent) were coded as not POA and identified as HAC discharges. This category contained the third greatest number of discharges resulting in an MS-DRG reassignment. Of the 1,770 discharges in this HAC category that were not POA, 286 discharges (16.16 percent) resulted in an MS-DRG reassignment.

The Catheter-Associated UTI category had the third most frequently coded secondary diagnoses, with 16,807 discharges. Of these discharges, 3,918 (23.31 percent) were coded as not POA and identified as HAC discharges. This category contained the

fourth greatest number of discharges resulting in an MS-DRG reassignment. Of the 3,918 discharges in this HAC category that were not POA, 160 discharges (4.08 percent) resulted in an MS-DRG reassignment.

The remaining 6 HAC categories only had 237 discharges that ultimately resulted in MS-DRG reassignment. We note that, even in cases where a large number of HAC-associated secondary diagnoses were coded as not POA, this finding did not necessarily translate into a large number of discharges that resulted in MS-DRG reassignment. For example, only 20 of the 5,921 Vascular Catheter-Associated Infection secondary diagnoses that were coded as not POA and identified as HAC discharges resulted in an MS-DRG reassignment.

There were a total of 431 discharges with a HAC-associated secondary diagnosis reporting a POA indicator of "N" or "U" that were excluded from acting as a HAC discharge (subject to MS-DRG reassignment) due to the CC Exclusion List logic within the GROUPER. The CC Exclusion List identifies secondary diagnosis codes designated as a CC or an MCC that are disregarded by the GROUPER logic when reported with certain principal diagnoses. For example, a claim with a principal diagnosis code of 250.83 (Diabetes with other specified manifestations, type 1 [juvenile type], uncontrolled) and a secondary diagnosis code of 250.13 (Diabetes with ketoacidosis, type 1, [juvenile type], uncontrolled) with a POA indicator of "N" would result in the HAC-associated secondary diagnosis code 250.13 being ignored as a CC. According to the CC Exclusion List, code 250.13 is excluded from acting as a CC when code 250.83 is the principal diagnosis. As a result, the HAC logic would not be applicable to that case.

For a detailed discussion on the CC Exclusion List, we refer readers to section II.G.9. of this preamble.

Discharges where the HAC logic was not applicable due to the CC Exclusion List occurred among the following 5 HAC categories: Pressure Ulcer Stages III and IV (30 cases), Falls and Trauma (303 cases), Catheter-Associated UTI (20 cases), Vascular Catheter-Associated Infection (14 cases), and Manifestations of Poor Glycemic Control (64 cases). Further information regarding the specific number of cases that were excluded for each HAC-associated secondary diagnosis code within each of the above mentioned HAC categories is also available. We refer readers to the RTI detailed report at the following Web site: http://www.rti.org/reports/cms/.

In summary, Chart C below demonstrates that there were a total of 287,993 discharges with a reported HAC-associated secondary diagnosis. Of the total 287,993 discharges, 19,839 (6.54 percent) discharges were HACs reported with a POA indicator of "N" or "U" that were identified as a HAC discharge. Of these 19,839 discharges, the number of discharges resulting in MS-DRG reassignments was 3,006 (15.96 percent).

CHART C.—DISCHARGE FREQUENCIES OF CURRENT CMS HACS OCTOBER 2010 THRUGH SEPTEMBER 2011

Selected HAC Category	Discharges With This Condition as Secondary Diagnosis		Discharges Identified as a HAC		Discharges That Change MS-DRG Due to HAC	
	Number (Column A)	Percent[2] (Column B)	Number (Column C)	Percent[3] (Column D)	Number (Column E)	Percent[4] (Column F)
1. Foreign Object Retained After Surgery	606	0.01	284	46.86	37	13.03

Selected HAC Category	Discharges With This Condition as Secondary Diagnosis		Discharges Identified as a HAC		Discharges That Change MS-DRG Due to HAC	
	Number (Column A)	Percent[2] (Column B)	Number (Column C)	Percent[3] (Column D)	Number (Column E)	Percent[4] (Column F)
2. Air Embolism	45	0.00	34	75.56	14	41.18
3. Blood Incompatibility	22	0.00	11	50.00	1	9.09
4. Pressure Ulcer Stages III & IV	96,646	1.08	1,770	1.83	286	16.16
5. Falls and Trauma	147,684	1.65	4.596	3.11	1,259	27.39
a. Fracture	128,065	1.43	3,829	2.99	996	26.01
b. Dislocation	1,014	0.01	22	2.17	2	9.09
c. Intracranial Injury	15,478	0.17	694	4.48	258	37.18
d. Crushing Injury	55	0.00	1	1.82	0	0.00
e. Burn	2,147	0.02	42	1.96	3	7.14
f. Electric Shock	925	0.01	8	0.86	0	0.00
Less: Discharges with multiple Falls & Trauma	3,764	0.04	41	1.09	18	43.90
5. Falls & Trauma: Unduplicated Total	143,920	1.61	4,555	3.16	1,241	27.24
6. Catheter-Associated UTI	16,807	0.19	3,918	23.31	160	4.08
7. Vascular Catheter-Associated Infection	11,324	0.13	5,921	52.29	20	0.34
8. Poor Glycemic Control	15,145	0.17	555	3.66	152	27.39
9a. SSI Mediastinitis CABG	58	0.07	50	86.21	5	10.00
9b. SSI Orthopedic	351	0.31	244	69.52	6	2.44
9c. SSI Bariatric	25	0.19	24	96.00	2	8.33
10. Pulmonary Embolism & DVT Orthopedic	3,044	0.76	2,473	81.24	1,082	43.75
Total[1]	287,993	3.22	19,839	6.54	3,006	15.96

[1] Discharges can appear in more than one row. The total figure is not adjusted for the 207 discharges with more than one HAC that appear as secondary diagnoses (15 of these resulted in MS-DRG reassignment).
[2] Percent computed relative to total discharges "at risk" for this HAC. For HACs 1-8, this is 8,941,507. For HAC 9a, this is 77,744. For HAC 9b, this is 112,951. For HAC 9c, this is 13,404. For HAC 10, this is 401,246.
[3] Percent computed relative to discharges with condition as a secondary diagnosis.
[4] Percent computed relative to discharges with this HAC (Column C).

SOURCE: RTI Analysis of MedPAR IPPS Claims, October 2010 through September 2011.

A small number of discharges had multiple HAC categories reported during the same stay. In reviewing the 8.94 million claims, RTI found 207 cases in which at least two different HAC categories were reported on the same discharge. Chart D below summarizes these cases. The Vascular Catheter-Associated Infection HAC category had the highest number of discharges involving another HAC category with 126 total discharges. Of these 126 discharges, 47 involved a code from the Pressure Ulcer Stages III & IV HAC category and 62 discharges involved a code from the Catheter-Associated UTI HAC category.

Some of these cases with multiple HACs reported had both HAC codes ignored in the MS-DRG assignment. Of these 207 claims, 15 did not receive higher payments based on the presence of these reported HACs and we describe these claims below in section II.F.3.f.(2) of this preamble. Depending on the MS-DRG to which the cases were originally assigned, ignoring the HAC codes would have led to a MS-DRG reassignment if there were no other MCCs or CCs reported, if the MS-DRG was subdivided into severity levels, and if the case were not already in the lowest severity level prior to ignoring the HAC codes.

CHART D.—CLAIMS WITH MORE THAN ONE HAC SECONDARY DIAGNOSIS OCTOBER 2010 THROUGH SEPTEMBER 2011

HAC	1. Foreign Object Retained After Surgery (CC)	4. Pressure Ulcer Stages III & IV (MCC)	5. Falls and Trauma (MCC & CC)	6. Catheter-Associated UTI (CC)	7. Vascular Catheter-Associated Infection (CC)	8. Poor Glycemic Control (MCC)	Total
3. Blood Incompatibility (CC)		1					1
5. Falls and Trauma (MCC & CC)		8					8
6. Catheter-Associated UTI (CC)	1	17	8				26
7. Vascular Catheter-Associated Infection (CC)	2	47	15	62			126
8. Poor Glycemic Control (MCC)	1	2	1	4	5		13
9A. Surgical Site Infection Mediastinities CABG (CC)		1	1		3		5
9B. Surgical Site Infection Following Certain Orthopedic Procedures (CC)		1		3	2		6
10. Pulmonary Embolism & DVT Orthopedic (MCC)			10	7		1	18
Total Discharges with 2 HACs *	4	77	35	76	10	1	203

*In total, there were 207 discharges with more than one HAC secondary diagnosis. However, there were 4 discharges involving 3 HAC secondary diagnoses. These discharges included the following HAC secondary diagnoses:
Discharge 1: Pressure Ulcer Stages III & IV (MCC & CC), Catheter-Associated Infection (CC), and Vascular Catheter-Associated Infection (CC);
Discharge 2: Pressure Ulcer Stages III & IV (MCC & CC), Catheter-Associated Infection (CC), and Vascular Catheter Associated Infection (CC);

Discharge 3: Pressure Ulcer Stages III & IV (MCC & CC), Catheter-Associated Infection (CC), and Vascular Catheter Associated Infection (CC);
Discharge 4: Catheter-Associated Infection (CC), Vascular Catheter Associated Infection (CC), and Poor Glycemic Control (MCC).

d. RTI Analysis of Circumstances When Application of HAC Provisions Would Not Result in MS-DRG Reassignment for Current HACs

As discussed in section II.F.1. and illustrated in the diagram in section II.F.1. of this preamble, there are instances when the MS-DRG assignment does not change even when a HAC-associated secondary diagnosis has a POA indicator of either "N" or "U." In analyzing our claims data, RTI identified four main reasons why an MS-DRG assignment would not change despite the presence of a HAC. Those four reasons are described below and are shown in Chart E below. Column A shows the frequency of discharges that included a HAC-associated secondary diagnosis. Column B shows the frequency of discharges where the HAC-associated secondary diagnosis was coded as not POA and identified as a HAC discharge. Column C shows the frequency of discharges in which the HAC-associated secondary diagnosis coded as not POA resulted in a change in MS-DRG. Columns D, E, F, and G show the frequency of discharges in which the HAC-associated secondary diagnosis coded as not POA did not result in a change in MS-DRG assignment. Columns D, E, F, and G are explained in more detail below.

(1) Other MCCs/CCs Prevent Reassignment

Column D (Other MCC/CCs that Prevent Reassignment) in Chart E below indicates the number of cases reporting a HAC-associated secondary diagnosis code that did not have an MS-DRG reassignment because of the presence of other secondary diagnoses on the MCC or CC list. A claim that is coded with a HAC-associated

secondary diagnosis and a POA status of either "N" or "U" may have other secondary diagnoses that are classified as an MCC or a CC. In such cases, the presence of these other MCC and CC diagnoses will still lead to the assignment of a higher severity level, despite the fact that the GROUPER software is disregarding the ICD-9-CM code that identifies the selected HAC in making the MS-DRG assignment for that claim. For example, there were 175 cases in which the ICD-9-CM codes for the Foreign Object Retained After Surgery HAC category were present, but the presence of other secondary diagnoses that were MCCs or CCs resulted in no change to the MS-DRG assignment. Chart E shows that a total of 12,335 cases did not have a change in the MS-DRG assignment because of the presence of other reported MCCs and CCs.

(2) Two Severity Levels Where HAC Does Not Impact MS-DRG Assignment

Column E (Number of MS-DRGs with Two Severity Levels Where HAC Does Not Impact MS-DRG Assignment) shows the frequency with which discharges with a HAC as a secondary diagnosis coded as not POA did not result in an MS-DRG change because the MS-DRG is subdivided solely by the presence or absence of an MCC. A claim with a HAC and a POA indicator of either "N" or "U" may be assigned to an MS-DRG that is subdivided solely by the presence or absence of an MCC. In such cases, removing a HAC ICD-9-CM CC code will not lead to further changes in the MS-DRG assignment. Examples of these MS-DRG subdivisions are shown in the footnotes to the chart and include the following examples:

- MS-DRGs 100 and 101 (Seizures with or without MCC, respectively); and
- MS-DRGs 102 and 103 (Headaches with or without MCC, respectively).

The codes that fall under the HAC category of Foreign Object Retained After Surgery are CCs. If this case were assigned to an MS-DRG with an MCC subdivision such as MS-DRGs 100 and 101, the presence of the HAC code would not affect the MS-DRG severity level assignment. In other words, if the Foreign Object Retained After Surgery code was the only secondary diagnosis reported, the case would be assigned to MS-DRG 101. If the POA indicator was "N," the HAC Foreign Object Retained After Surgery code would be ignored in the MS-DRG assignment logic. Despite the fact that the code was ignored, the case would still be assigned to the same lower severity level MS-DRG. Therefore, there would be no impact on the MS-DRG assignment.

Column E in Chart E below shows that there were 1,922 cases where the HAC code was "N" or "U" and the MS-DRG assignment did not change because the case was already assigned to the lowest severity level.

(3) No Severity Levels

Column F (Number of MS-DRGs with No Severity Levels) shows the frequency with which discharges with a HAC as a secondary diagnosis coded as not POA did not result in an MS-DRG change because the MS-DRG is not subdivided by severity levels. A claim with a HAC and a POA of "N" or "U" may be assigned to an MS-DRG with no severity levels. For instance, MS-DRG 311 (Angina Pectoris) has no severity level subdivisions; this MS-DRG is not split based on the presence of an MCC or a CC. If a patient assigned to this MS-DRG develops a secondary diagnosis such as a Stage III pressure ulcer after admission, the condition would be considered to be a HAC. The code for the Stage III pressure ulcer would be ignored in the MS-DRG assignment because the

condition developed after the admission (the POA indicator was "N"). Despite the fact that the ICD-9-CM code for the HAC Stage III pressure ulcer was ignored, the MS-DRG assignment would not change. The case would still be assigned to MS-DRG 311. Chart E below shows that 2,570 cases reporting a HAC-associated secondary diagnosis did not undergo a change in the MS-DRG assignment based on the fact that the case was assigned to an MS-DRG that had no severity subdivisions (that is, the MS-DRG is not subdivided based on the presence or absence of an MCC or a CC, rendering the presence of the HAC irrelevant for payment purposes).

(4) MS-DRG Logic

Column G (MS-DRG Logic Issues) shows the frequency with which a HAC as a secondary diagnosis coded as not POA did not result in an MS-DRG change because of MS-DRG assignment logic. There were six discharges where the HAC criteria were met and the HAC logic was applied, however, due to the structure of the MS-DRG logic, these cases did not result in MS-DRG reassignment. These cases may appear similar to those discharges where the MS-DRG is subdivided into two severity levels by the presence or absence of an MCC and did not result in MS-DRG reassignment; however, these discharges differ slightly in that the MS-DRG logic also considers specific procedures that were reported on the claim. In other words, for certain MS-DRGs, a procedure may be considered the equivalent of an MCC or CC. The presence of the procedure code dictates the MS-DRG assignment despite the presence of the HAC-associated secondary diagnosis code with a POA indicator of "N" or "U."

For example, a claim with a principal diagnosis code of 724.02 (Spinal stenosis, lumbar region, without neurogenic claudication) with a HAC-associated secondary diagnosis code of 996.64 (Infection and inflammatory reaction due to indwelling urinary catheter) and diagnosis code 599.0 (Urinary tract infection, site not specified), having POA indicators of "Y," "N," and "N," respectively, and procedure code 84.80 (Insertion or replacement of interspinous process device(s)) results in an assignment to MS-DRG 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator). In this case, the disc device (code 84.80) is what dictated the MS-DRG assignment and the presence of the HAC-associated secondary diagnosis code, 996.64, did not affect the MS-DRG assigned. Other examples of MS-DRGs that are subdivided in this same manner are as follows:

- MS-DRG 029 (Spinal procedures with CC or Spinal Neurostimulators);
- MS-DRG 129 (Major Head & Neck Procedures with CC/MCC or Major Device); and
- MS-DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents).

Column G in the chart below shows that three of the six cases that did not result in MS-DRG reassignment due to the MS-DRG logic were in the Catheter-Associated UTI HAC category, two cases were in the Falls and Trauma HAC Category, and one case was in the Vascular Catheter-Associated Infection HAC Category.

In conclusion, a total of 16,833 cases (12,335 + 1,922 +2,570 + 6) did not have a change in MS-DRG assignment, regardless of the presence of a HAC. The reasons

described above explain why only 3,006 cases had a change in MS-DRG assignment despite the fact that there were 19,839 HAC cases with a POA of "N" or "U."

CHART E.—REASONS HAC DID NOT CHANGE MS-DRG ASSIGNMENT OCTOBER 2010 THROUGH SEPTEMBER 2011

Selected HAC Category	Number of Discharges with This Condition as Secondary Diagnosis (Column A)	Number of Discharges Identified as a HAC (Column B	Number of HAC Discharges That Change MS-DRG Due to HAC (Column C)	HAC Discharges That Do Not Change MS-DRG			
				Number of Other MCCs/CCs That Prevent Reassign-ment (Column D)	Number of MS-DRGs with Two Severity Levels Where HAC Does Not Impact MS-DRG Assignment* (Column E)	Number of MS-DRGs with No Severity Levels (Column F)	Other MS-DRG Logic Issues ** (Column G)
1. Foreign Object Retained After Surgery – CC	606	284	37	175	56	16	0
2. Air Embolism – MCC	45	34	14	17	0	3	0
3. Blood Incompatibility-CC	22	11	1	7	1	2	0
4. Pressure Ulcer Stages III & IV – MCC	96,646	1,770	286	991	0	493	0
5. Falls and Trauma – MCC & CC	143,920	4,555	1,241	2,449	488	375	2
6. Catheter-Associated UTI- CC	16,807	3,918	160	2,952	424	379	3
7. Vascular Catheter-Associated Infection – CC	11,324	5,921	20	4,551	158	1,191	1
8. Poor Glycemic Control – MCC & CC	15,145	555	152	358	0	45	0

Selected HAC Category	Number of Discharges with This Condition as Secondary Diagnosis (Column A)	Number of Discharges Identified as a HAC (Column B	Number of HAC Discharges That Change MS-DRG Due to HAC (Column C)	HAC Discharges That Do Not Change MS-DRG			
				Number of Other MCCs/CCs That Prevent Reassign-ment (Column D)	Number of MS-DRGs with Two Severity Levels Where HAC Does Not Impact MS-DRG Assignment* (Column E)	Number of MS-DRGs with No Severity Levels (Column F)	Other MS-DRG Logic Issues ** (Column G)
9A. Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG) – MCC	58	50	5	28	0	17	0
9B. Surgical Site Infection Following Certain Orthopedic Procedures – CC	351	244	6	155	67	16	0
9C. Surgical Site Infection Following Bariatric Surgery for Obesity – CC	25	24	2	19	0	3	0
10. Pulmonary Embolism & DVT Orthopedic – MCC & CC	3,044	2,473	1,082	633	728	30	0
Total[1]	287,993	19,839	3,006	12,335	1,922	2,570	6

[1] Discharges can appear in more than one row. The total figure is not adjusted for the 207 discharges with more than one HAC that appear as secondary diagnoses (15 of these resulted in MS-DRG reassignment).
*Examples where an HAC classified as a CC would not impact the DRG assignment if it were removed. The MS-DRG is subdivided by the presence or absence of an MCC. A CC would not impact this DRG assignment.
MS-DRGs 100 and 101 (Seizures with or without MCC, respectively)
MS-DRGs 102 and 103 (Headaches with or without MCC, respectively)
**Cases where HAC did not change MS-DRG assignment because of the MS-DRG logic.
MS-DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators)
MS-DRG 129 (Major Head & Neck Procedures with CC/MCC or Major Device)
SOURCE RTI Analysis of MedPAR IPPS Claims, October 2010 through September 2011

e. RTI Analysis of Coding Changes for HAC-Associated Secondary Diagnoses for Current HACs

In addition to studying claims from October 2010 through September 2011 (FY 2011), RTI evaluated claims data from 4 years prior to determine if there were significant changes in the number of discharges with a HAC being reported as a secondary diagnosis. RTI examined claims from FY 2007 through FY 2010 and compared these data to the FY 2011 data.

We refer readers to the RTI detailed report for all the conditions in each fiscal year (FY 2007 through FY 2011) as described above at the following Web site: http://www.rti.org/reports/cms/.

f. RTI Analysis of Estimated Net Savings for Current HACs

RTI determined estimates of the net savings generated by the HAC payment policy based on MedPAR claims from October 2010 through September 2011.

(1) Net Savings Estimation Methodology

The payment impact of a HAC is the difference between the IPPS payment amount under the initially assigned MS-DRG and the amount under the reassigned MS-DRG. The amount for the reassigned MS-DRG appears on the MedPAR files. To construct this, RTI modeled the IPPS payments for each MS-DRG following the same approach that we use to model the impact of IPPS annual rule changes. Specifically, RTI replicated the payment computations carried out in the IPPS PRICER program using payment factors for IPPS providers as identified in various CMS downloaded files. The files used are as follows:

- Version 28 of the Medicare Severity GROUPER software (applicable to discharges between October 1, 2010 and September 30, 2011). IPPS MedPAR claims were run through this file to obtain needed HAC-POA output variables.

- The FY 2011 MS-DRG payment weight file. This file includes the weights, geometric mean length of stay (GLOS), and the postacute transfer payment indicators.

- CMS standardized operating and capital rates. Tables 1A through 1C, as downloaded from the Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/CMS1255464.html, include the full update and reduced update amounts, as well as the information needed to compute the blended amount for providers located in Puerto Rico.

- The IPPS impact files for FY 2011, also as downloaded from the Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/CMS1255464.html. This file includes the wage index and geographic adjustment factors in effect at the start of FY 2011, plus the provider type variable to identify providers qualifying for alternative hospital-specific amounts and their respective hospital-specific rates.

- The IPPS impact files for FY 2012, as downloaded from the Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/CMS1255464.html. This file is created for a subsequent payment year, but the file

includes IME and DSH percent adjustments that were in effect as of March 2011. For providers that did not appear in the FY 2012 file, we defaulted to the IME and DSH rates from the FY 2011 file.

- CMS historical provider-specific files (PSF). This includes the indicator to identify providers subject to the full or reduced standardized rates and the applicable operating and capital CCRs. A SAS version was downloaded from the Web site at: http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/04_psf_SAS.asp.

There were three providers with discharges in the final HAC analysis file that did not appear in either of the impact files. For these providers, we identified the geographic CBSA from the historical PSF and assigned the wage index using values from Tables 4A and 4C as downloaded from the Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS2009/List.asp. These three providers were not eligible for IME or DSH adjustments.

The steps for estimating the HAC payment impact are as follows:

Step 1: Re-run the Medicare Severity GROUPER on all records in the analysis file. This is needed to obtain information on actual HAC-related MS-DRG reassignments in the file, and to identify the CCs and MCCs that contribute to each MS-DRG assignment.

Step 2: Model the base payment and outlier amounts associated with the initial MS-DRG (including all secondary diagnoses in the file) using the computations laid out in the CMS file "Outlier Example FY 2007 new.xls," as downloaded from the Web site at: http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-

Payment/AcuteInpatientPPS/index.html?redirect=/04_outlier/ASP#TopOfPage, and modified to accommodate FY 2011 factors. RTI's first round of computations treated all claims as though paid under standard IPPS rules without adjusting for short-stay transfers or HSP amounts.

Step 3: Model the base payment and outlier amounts associated with the final MS-DRG (excluding the HAC-related secondary diagnoses) using the computations laid out in the CMS file "Outlier Example FY 2007 new.xls," as downloaded from the Web site at: http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Payment/AcuteInpatientPPS/index.html?redirect=/04_outlier.asp#TopOfPage and modified to accommodate FY 2011 factors. RTI's first round of computations treated all claims as though paid under standard IPPS rules without adjusting for short-stay transfers or hospital-specific amounts.

Step 4: Compute MS-DRG base savings as the difference between the nonoutlier payments for the initial and final MS-DRGs. Compute outlier amounts as the difference in outlier amounts due under the initial and final reassigned MS-DRG. Compute net savings due to HAC reassignment as the sum of base savings plus outlier amounts.

Step 5: Adjust the model to incorporate short-stay transfer payment adjustments.

Step 6: Adjust the model to incorporate hospital-specific payments for qualifying rural providers receiving the hospital-specific payment rates.

It is important to mention that using the methods described above, the MS-DRG and outlier payment amounts that are modeled for the final assigned MS-DRG do not always match the DRG price and outlier amounts that appear in the MedPAR record.

There are several reasons for this. Some discrepancies are caused by using single wage index, IME and DSH factors for the full period covered by the discharges, when in practice these payment factors can be adjusted for individual providers during the course of the fiscal year. In addition, RTI's approach disregards any Part A coinsurance amounts owed by individual beneficiaries with greater than sixty covered days in a spell of illness. Ten percent of all FY 2011 HAC discharges showed at least some Part A coinsurance amount due from the beneficiary, although less than 2 percent of reassigned discharges (43 cases in the analysis file) showed Part A coinsurance amounts due. Any Part A coinsurance payments would reduce the actual savings incurred by the Medicare program.

There are also a number of less common special IPPS payment situations that are not factored into RTI's modeling. These could include new technology add-on payments, payments for blood clotting factors, reductions for replacement medical devices, adjustments to the capital rate for new providers, and adjustments to the capital rate for certain classes of providers who are subject to a minimum payment level relative to capital cost.

(2) Net Savings Estimate

Chart F below summarizes the estimated net savings of current HACs based on MedPAR claims from October 2010 through September 2011, based on the methodology described above. Column A shows the number of discharges where an MS-DRG reassignment for each HAC category occurred. For example, there were 14 discharges with an Air Embolism that resulted in an actual MS-DRG reassignment. Column B

shows the total net savings caused by MS-DRG reassignments for each HAC category. Continuing with the example of Air Embolism, the chart shows that the 14 discharges with an MS-DRG reassignment resulted in a total net savings of $124,620. Column C shows the net savings per discharge for each HAC category. For the Air Embolism HAC category, the net savings per discharge is $8,901.

CHART F.—ESTIMATED NET SAVINGS OF CURRENT HACs OCTOBER 2010 THROUGH SEPTEMBER 2011

Selected HAC	Number of Discharges That Change MS-DRG Due to HAC (Column A)	Net Savings (In Dollars) (Column B)	Net Savings Per Discharge (In Dollars) (Column C)
1. Foreign Object Retained After Surgery	37	$167,818	$4,536
2. Air Embolism	14	$124,620	$8,901
3. Blood Incompatibility	1	$7,115	$0
4. Pressure Ulcer Stages III & IV	286	$1,846,449	$6,456
5. Falls and Trauma			
a. Fracture	996	$6,232,020	$6,257
b. Dislocation	2	$9,075	$4,538
c. Intracranial Injury	258	$1,222,290	$4,738
d. Crushing Injury	0	$0	$0
e. Burn	3	$4,583	$1,528
f. Other injuries	0	$0	$0
Less: Discharges with multiple Falls & Trauma	-18	-$105,430	-$5,857
5. Falls & Trauma: Unduplicated Total	1,241	$7,362,538	$5,933
6. Catheter-Associated UTI	160	$491,053	$3,069
7. Vascular Catheter-Associated Infection	20	$92,100	$4,605
8. Poor Glycemic Control	152	$1,002,378	$6,595
9a. SSI Mediastinitis CABG	5	$60,438	$12,088
9b. SSI Orthopedic	6	$41,503	$6,917
9c. SSI Bariatric	2	$3,312	$0
10. Pulmonary Embolism & DVT Orthopedic	1,082	$8,313,098	$7,683

Selected HAC	Number of Discharges That Change MS-DRG Due to HAC (Column A)	Net Savings (In Dollars) (Column B)	Net Savings Per Discharge (In Dollars) (Column C)
Total[1]	3,006	$19,512,422	$6,491
Less: Discharges with Multiple HACs [2]	-15	-$136,645	-$9,110
Unduplicated Total	2,991	$19,375,777	$6,478

[1] Discharges can have more than one Falls and Trauma subcategory HAC and therefore appear in more than one row.
[2] Total net savings is adjusted by $136,645 for 15 claims that have multiple HACs.

SOURCE: RTI Analysis of MedPAR IPPS Claims, October 2010 through September 2011.

As shown in Chart F above, the total net savings calculated for October 2010 through September 2011 was roughly $19.4 million. The three HACs with the largest number of discharges resulting in MS-DRG reassignment, Falls and Trauma, Orthopedic PE/DVT, and Pressure Ulcer Stages III & IV, generated $17.5 million of net savings for the fiscal year. Estimated net savings for FY 2011 associated with the Falls and Trauma category were $7.4 million. Estimated net savings associated with Orthopedic PE/DVT for the fiscal year were $8.3 million and for Pressure Ulcer Stages III & IV were $1.85 million.

The mean net savings per discharge calculated for October 2010 through September 2011 was roughly $6,478. The HAC category of SSI, Mediastinitis, Following Coronary Artery Bypass Graft (CABG) had the highest net savings per discharge, but represented a small proportion of total net savings because the number of discharges that resulted in MS-DRG reassignment for this HAC was low. The HAC categories of Blood Incompatibility, where only one discharge resulted in MS-DRG reassignment, and SSI Following Bariatric Surgery for Obesity, where only two

discharges resulted in MS-DRG reassignment had the lowest net savings per discharge. We refer readers to the RTI detailed report available at the following Web site: http://www.rti.org/reports/cms/.

As we discuss in section II.F.1. of this preamble, implementation of this policy is part of an array of Medicare VBP tools that we are using to promote increased quality and efficiency of care. We point out that a decrease over time in the number of discharges where these conditions are not POA is a desired consequence. We recognize that estimated net savings would likely decline as the number of such discharges decline. However, we believe that the sentinel effect resulting from CMS identifying these conditions is critical. It is our intention to continue to monitor trends associated with the frequency of these HACs and the estimated net payment impact through RTI's program evaluation and possibly beyond.

As mentioned previously, a small number of cases analyzed by RTI for FY 2011 had multiple HACs during the same stay. In reviewing our 8.94 million claims, RTI found 207 cases where at least two HACs were reported on the same admission as noted in section II.F.3.g.(2) of this preamble. Of these 207 claims, 15 resulted in MS-DRG reassignment. Chart G below summarizes these cases. There were 15 cases that had two HACs not POA that resulted in an MS-DRG reassignment. Of these, seven discharges involved Orthopedic PE/DVT, while four discharges involved the Pressure Ulcer Stages III & IV and Falls and Trauma HAC categories.

CHART G.--CLAIMS WITH MORE THAN ONE HAC SECONDARY DIAGNOSIS WHERE MS-DRG REASSIGNMENT OCCURRED OCTOBER 2010 THROUGH SEPTEMBER 2011

Selected HAC	4. Pressure Ulcer Stages III & IV - MCC	5. Falls and Trauma – MCC & CC	10. Pulmonary Embolism & DVT Orthopedic (MCC)	Total
5. Falls and Trauma – MCC & CC	1		3	4
6. Catheter-Associated Urinary Tract Infection (UTI) – CC	2	3	3	8
7. Vascular Catheter-Associated Infection – CC	1	1		2
8. Poor Glycemic Control (MCC)			1	1
Total	4	4	7	15

g. Previously Considered Candidate HACs-- RTI Analysis of Frequency of Discharges and POA Indicator Reporting

RTI evaluated the frequency of conditions previously considered, but not adopted as HACs in prior rulemaking, that were reported as secondary diagnoses (across all 8.94 million discharges) as well as the POA indicator assignments for these conditions. Chart H below indicates that the three previously considered candidate conditions most frequently reported as a secondary diagnosis were: (1) Clostridium Difficile-Associated Disease (CDAD), which demonstrated the highest frequency, with a total of 90,347 secondary diagnoses codes being reported for that condition, of which 30,176 reported a POA indicator of "N"; (2) Methicillin Resistant Staphylococcus aureus, with a total of 83,976 secondary diagnosis codes being reported for that condition, with 3,498 of those reporting a POA indicator of "N"; and (3) Iatrogenic Pneumothorax, with a total of 20,309 secondary diagnoses codes being reported for that condition, with 17,828 of those

reporting a POA indicator of "N." As these three conditions had the most significant impact for reporting a POA indicator of "N," it is reasonable to believe that these same three conditions would have the greatest number of potential MS-DRG reassignments. The frequency of discharges for the previously considered HACs that could lead to potential changes in MS-DRG assignment is discussed in the next section. We take this opportunity to remind readers that, because more than one previously considered HAC diagnosis code can be reported per discharge (on a single claim), the frequency of these diagnosis codes may be more than the actual number of discharges with a previously considered candidate condition reported as a secondary diagnosis.

CHART H.--POA STATUS OF PREVIOUSLY CONSIDERED "CANDIDATE" HAC CONDITIONS--OCTOBER 2010 THROUGH SEPTEMBER 2011

Previously Considered HAC Condition	Frequency as a Secondary Diagnosis	Not Present on Admission				Present on Admission			
		POA = N		POA = U		POA =Y		POA = W	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
1. Clostridium Difficile-Associated Disease (CDAD)	90,347	30,176	33.40	354	0.39	59,700	66.08	117	0.13
2. Delirium	752	246	32.71	2	0.27	504	67.02	0	0.00
3. Legionnaire's Disease	520	29	5.58	3	0.58	488	93.85	0	0.00
4. Staphylococcus aureus Septicemia	18,844	4,043	21.46	37	0.20	14,736	78.20	28	0.15
5. Methicillin-Resistant Staphylococcus aureus	83,976	3,498	4.17	173	0.21	80,280	95.60	25	0.03
6. Iatrogenic Pneumothorax	20,309	17,828	87.78	5	0.02	1,476	7.27	0	0.00
7. Ventilator-Associated Pneumonia	4,715	3,634	77.07	4	0.08	1,074	22.78	3	0.06

In Chart I below, Column A shows the number of discharges for each previously considered candidate HAC category when the condition was reported as a secondary diagnosis. For example, there were 90,347 discharges that reported CDAD as a secondary diagnosis. Previously considered candidate HACs reported with a POA indicator of "N" or "U" may cause MS-DRG reassignment (which would result in reduced payment to the facility). Column C shows the discharges for each previously considered candidate HAC reported with a POA indicator of "N" or "U." Continuing with the example of CDAD, Chart I shows that, of the 90,347 discharges, 30,530 discharges (33.79 percent) had a POA indicator of "N" or "U." Therefore, there were a total of 30,530 discharges that could potentially have had an MS-DRG reassignment. Column E shows the number of discharges where an actual MS-DRG reassignment could have occurred; the number of discharges with CDAD that could have resulted in actual MS-DRG reassignments is 784 (2.57 percent). Thus, while there were 30,530 discharges with CDAD reported with a POA indicator of "N" or "U" that could potentially have had an MS-DRG reassignment, the result was 784 (2.57 percent) potential MS-DRG reassignments. As discussed above, there are a number of reasons why a condition reported with a POA indicator of "N" or "U" would not result in an MS-DRG reassignment.

In summary, Chart I below demonstrates there were a total of 219,397 discharges with a previously considered candidate HAC reported as a secondary diagnosis. Of those, 60,025 discharges were reported with a POA indicator of "N" or "U." The total number of discharges that could have resulted in MS-DRG reassignments is 3,544.

CHART I.--PREVIOUSLY CONSIDERED "CANDIDATE" HAC DISCHARGE FREQUENCIES--OCTOBER 2010 THROUGH SEPTEMBER 2011

Previously Considered HAC Condition	Discharges with this Condition as Secondary Diagnosis[2]		Discharges with this Condition Not Present on Admission (POA = "N" or "U")[3]		Cases that Could Change MS-DRG Due to Previously Considered Candidate HAC[4]	
	Number (Column A)	Percent (Column B)	Number (Column C)	Percent (Column D)	Number (Column E)	Percent (Column F)
1. Clostridium Difficile-Associated Disease (CDAD)	90,347	1.01	30,530	33.79	784	2.57
2. Delirium	752	0.01	248	32.98	18	7.26
3. Legionnaire's Disease	520	0.01	32	6.15	3	9.38
4. Staphylococcus aureus Septicemia	18,806	0.21	4,073	21.66	84	2.06
5. Methicillin-Resistant Staphylococcus aureus (MRSA)	83,948	0.94	3,671	4.37	1	0.03
6. Iatrogenic Pneumothorax	20,309	0.23	17,833	87.81	2,652	14.87
7. Ventilator-Associated Pneumonia	4,715	0.05	3,638	77.16	2	0.05
Total[1]	219,397	2.45	60,025	27.36	3,544	5.90

[1] Discharges can appear in more than one row.
[2] Percent computed relative to total cases "at risk," which is 8,941,507 for all candidate conditions.
[3] Percent computed relative to discharges with condition as a secondary diagnosis.
[4] Percent computed relative to discharges with condition as a secondary diagnosis and identified as a previously considered HAC (that is, coded as not present on admission).

SOURCE: RTI Analysis of MedPAR IPPS Claims, October 2010 through September 2011.

h. Current and Previously Considered Candidate HACs--RTI Report on Evidence-Based Guidelines

The RTI program evaluation includes a report that provides references for all evidence-based guidelines available for each of the selected and previously considered candidate HACs that provide recommendations for the prevention of the corresponding conditions. Guidelines were primarily identified using the AHRQ National Guidelines Clearing House (NGCH) and the CDC, along with relevant professional societies. Guidelines published in the United States were used, if available. In the absence of U.S. guidelines for a specific condition, international guidelines were included.

Evidence-based guidelines that included specific recommendations for the prevention of the condition were identified for each of the 10 selected conditions. In addition, evidence-based guidelines were also found for the previously considered candidate conditions.

RTI prepared a final report to summarize its findings regarding evidence-based guidelines, which can be found on the Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html.

i. Proposals Regarding Current HACs and Previously Considered Candidate HACs

We believe that the RTI analysis summarized above does not provide additional information that would require us to change our previous determinations regarding current HACs. We refer readers to section II.F.6. of the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218) and to section II.F.7. of the FY 2009 IPPS

final rule (73 FR 48474 through 48491) for detailed discussion supporting our determination regarding each of these conditions.

In the FY 2013 IPPS/LTCH PPS proposed rule, we discussed our rationale for proposing two new conditions, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) procedures (77 FR 27894 through 27896), and Iatrogenic Pneumothorax with Venous Catheterization (77 FR 27896 through 27897) for selection as HACs under section 1886(d)(4)(D) of the Act. (We previously proposed Iatrogenic Pneumothorax more generally as a HAC in the FY 2009 IPPS rulemaking (73 FR 48485).) We also discussed a proposal to revise the Vascular Catheter - Associated Infection HAC category with the addition of two new diagnosis codes 999.32 (Bloodstream infection due to central venous catheter), and 999.33 (Local infection due to central venous catheter) (77 FR 27894). Accordingly, we are finalizing those proposals as discussed in section II.F.5. of this preamble.

In addition to the evaluation of HAC and POA MedPAR claims data, RTI has conducted analyses on readmissions due to HACs and the incremental costs of HACs to the health care system, a study of spillover effects and unintended consequences, as well as an analysis on the accuracy of coding of HACs and POA indicators. Reports on these analyses are publicly available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html.

Comment: Commenters encouraged CMS to more carefully evaluate this program and its potential for unintended consequences, and to explore how information

learned from POA coding could be used to better understand and prevent HACs before it considers the inclusion of any additional categories of HACs.

Response: We appreciate the commenters' response. We routinely, either internally or through our contractors, review the significant aspects of the HAC/POA Program.

G. Changes to Specific MS-DRG Classifications

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27898), we invited public comment on each of the MS-DRG classification proposed changes described below, as well as our proposals to maintain certain existing MS-DRG classifications, which are also discussed below. In some cases, we proposed changes to the MS-DRG classifications based on our analysis of claims data. In other cases, we proposed to maintain the existing MS-DRG classification based on our analysis of claims data.

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2013, comments and suggestions should have been submitted by early December 2011. The comments that were submitted in a timely manner are discussed below in this section.

Below we summarize the public comments we received on the FY 2013 proposed rule, if any, present our responses, and state our final policies.

1. Pre-Major Diagnostic Categories (Pre-MDCs)

a. Ventricular Assist Devices (VADs)

A ventricular assist device (VAD) is a mechanical circulatory device or pump that is used to partially or completely support heart function and blood flow in patients with a damaged or weakened heart. The device takes blood from the ventricles of the heart and helps pump the blood to the rest of the body.

Some VADs are intended for short-term use, often for patients who are recovering from heart attacks or heart surgery, while other VADs are intended for long-term use (months to years and, in some cases, for life). VADs are not the same device as artificial hearts, which are designed to completely take over cardiac function and generally require the removal of the patient's native heart.

VADs are designed to assist the ventricles, either the right (RVAD) or the left (LVAD), and, in some cases, both ventricles at once (BiVAD). The type of VAD used depends on the patient's underlying heart disease and the pulmonary arterial resistance that determines the load on the right ventricle. LVADs are the most commonly used, but when pulmonary arterial resistance is high, right ventricular assistance becomes necessary and an RVAD may be inserted. Long-term VADs are normally used to help maintain a patient's quality of life while he or she awaits a heart transplant. This process is known as a "bridge to transplant." However, sometimes the insertion of an LVAD becomes the final treatment for the patient, which is known as "destination therapy." In this case, the VAD is a permanent implant, and no heart transplantation occurs. In a smaller number of cases, the implantation of a VAD, combined with pharmaceutical therapy, has enabled the native heart to recover sufficiently to allow the VAD to be explanted, a "bridge to recovery."

CMS has issued a national coverage determination (NCD) entitled "Artificial Hearts and Related Devices" under Section 20.9 of the Medicare Coverage Manual (Pub. No. 100-3). This NCD, which describes CMS' requirements for coverage of medical services provided to Medicare beneficiaries for the insertion of VADs, can be

found at the CMS Web site at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=5&NCAId=211&ver=20&NcaName=Artificial+Hearts&bc=ACAAAAAAIAAA&. We refer readers to this Web page for the complete viewing of the NCD for the insertion of VADs.

The assignment of procedure codes used to describe the insertion of VADs has been discussed repeatedly in IPPS rulemaking, for the CMS-DRGs (in effect prior to FY 2008) and more recently for the MS-DRGs (FY 2008 to present). We refer readers to the FY 2003 IPPS final rule (67 FR 49989) for a complete discussion of the assignment of these procedure codes up to that date. In addition, the topic was discussed in FY 2005; we refer readers to the FY 2005 IPPS final rule (69 FR 48927 through 48930) for a complete discussion regarding the assignment of these procedure codes for FY 2005. Specifically, for FY 2005, we moved ICD-9-CM procedure code 37.66 (Insertion of implantable heart assist system) from CMS-DRG 525 (Other Heart Assist System Implant) to CMS-DRG 103 (Heart Transplant). When we adopted the MS-DRG classification system in FY 2008, former CMS-DRG 103 remained in the Pre-MDC section but was renamed and subdivided into MS-DRG 001 (Heart Transplant or Implant of Heart Assist System with MCC) and MS-DRG 002 (Heart Transplant or Implant of Heart Assist System without MCC).

For FY 2013, we received a request to restructure MS-DRGs 001 and 002 by removing all of the procedure codes that describe the insertion of a device, leaving only procedure codes 33.6 (Combined heart-lung transplantation) and 37.51 (Heart

transplantation) in the heart transplant DRGs. The requestor further asked that the remaining device codes be assigned to newly created MS-DRGs. The requestor believed that, within the existing MS-DRG grouping, CMS is underpaying for services to patients who have a VAD implanted and overpaying for services to patients who have heart transplantations. The requestor believed that the recommended restructuring "would allow defined grouping of cases with the higher level of resource [sic] required reflected in payment."

In the FY 2013 IPPS/LTCH PPS proposed rule, we indicated that we had reviewed data in the September 2011 update of the FY 2011 MedPAR file and found that the average length of stay for heart transplantations and VAD implantation cases are very similar (35.1 days for heart transplantations and 36.63 days for VAD implantations). We also found that the average cost for VAD implantation cases alone is higher than the average cost of heart transplantation cases. The table below includes our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Cost
MS-DRG 001 - All Cases	1,235	36.97	$164,846
MS-DRG 001 - Cases with Heart Transplant without VAD	384	35.1	$123,472
MS-DRG 001 - Cases with VAD Insertion Alone	811	36.85	$181,915
MS-DRG 002 - All Cases	313	19.66	$89,818
MS-DRG 002 - Cases with Heart Transplant without VAD	172	15.1	$58,890
MS-DRG 002 - Cases with VAD Insertion Alone	140	25.31	$128,069

We believe that this higher average cost could be attributable to the cost of the device itself. There are very few VADs approved by FDA; therefore, we believe this

small group of manufacturers is able to set their own charges in the market. We pointed out that the IPPS is not designed to pay solely for the cost of devices. The MS-DRG classification system (and more importantly, the IPPS) is not based solely on the cost of devices.

Rather, the MS-DRG system is a patient classification system that provides an average means of relating the type of patients a hospital treats (that is, case-mix) to the costs incurred by the hospital. We have previously stated that, "Central to the success of the Medicare inpatient hospital prospective payment system is that DRGs have remained a clinical description of why the patient required hospitalization. We believe it would be undesirable to transform DRGs into detailed descriptions of the technology and processes used by the hospital to treat the patient. If such a transformation were to happen, the DRGs would become largely a repackaging of fee-for-service without the management and communication benefits. The separation of the clinical and payment weight methodologies allows a stable clinical methodology to be maintained, while the payment weights evolve in response to changing practice patterns. The packaging of all services associated with the care of a particular type of patient into a single payment amount provides the incentive for efficiency inherent in a DRG-based prospective payment system. Substantial disaggregation of the DRGs into smaller units of payment, or a substantial number of cases receiving extra payments, would undermine the incentives and communication value in the DRG system." (66 FR 46904)

The results of our review of the claims data for MS-DRGs 001 and 002 are summarized in the following table.

MS-DRG 001 (Heart Transplant or Implant of Heart Assist System with MCC)		
Code	**Description of code(s)**	**No. of Cases**
All codes		1,235
33.6 or 37.51	Combined heart-lung transplantation or Heart transplantation	384
33.6 or 37.51 with 37.66	Combined heart-lung transplantation or Heart transplantation with Insertion of implantable heart assist system (VAD)	11
37.52	Implantation of total internal biventricular heart replacement system (Artificial heart)	2
37.66	Insertion of implantable heart assist system (VAD)	811
37.60 with 37.64	Implantation or insertion of biventricular external heart assist system + Removal of external heart assist system(s) or device(s)	1
37.63 with 37.64	Repair of heart assist system + Removal of external heart assist system(s) or device(s)	0
37.64 with 37.65	Removal of external heart assist system(s) or device(s) + plant of single ventricular (extracorporeal) external heart assist system	22
	Multiple VADs without heart transplant	22
MS-DRG 002 (Heart Transplant or Implant of Heart Assist System without MCC)		
Code	**Description of code(s)**	**No. of Cases**
All codes		313
33.6 or 37.51	Combined heart-lung transplantation or Heart transplantation	172
33.6 or 37.51 with 37.66	Combined heart-lung transplantation or Heart transplantation with Insertion of implantable heart assist system (VAD)	0
37.52	Implantation of total internal biventricular heart replacement system (Artificial heart)	0
37.66	Insertion of implantable heart assist system (VAD)	140
37.60 with 37.64	Implantation or insertion of biventricular external heart assist system plus Removal of external heart assist system(s) or device(s)	0
37.63 with 37.64	Repair of heart assist system + Removal of external heart assist system(s) or device(s)	0
37.64 with 37.65	Removal of external heart assist system(s) or device(s) + plant of single ventricular (extracorporeal) external heart assist system	1
	Multiple VADs without heart transplant	4

In the proposed rule, we stated that we believe that the IPPS should accurately recognize differences in utilization for clinically distinct procedures. However, we also reiterated the language in the FY 2009 IPPS final rule that the payments under a prospective payment system are predicated on averages (73 FR 48443). We believe that to create a new MS-DRG specific to VAD implantation would require basing that MS-DRG almost exclusively on the presence of procedure code 37.66, representing a single procedure and currently one manufacturer with FDA approval. Currently, other manufacturers are reported to be in clinical trials with their VADs. We indicated that this approach negates our longstanding method of grouping like procedures and diminishes the concept of averaging. Further, we are concerned that ignoring the structure of the MS-DRG system solely for the purpose of increasing payment for one device would set an unwarranted precedent for defining all of the other MS-DRGs in the system (73 FR 48497 and 48498).

The commenter requested that we create two new MS-DRGs for the VADs and that the requested MS-DRGs be divided based on the presence or absence of an MCC. We pointed out that the final rule establishing the MS-DRGs sets forth five criteria, all five of which are required to be met in order to warrant creation of a CC or an MCC subgroup within a base MS-DRG. The criteria can be found in the FY 2008 IPPS final rule with comment period (72 FR 47169). The original criteria were based on average charges; we now use average costs (FY 2007 IPPS final rule (71 FR 47882)). To reiterate, these criteria are as follows:

- A reduction in variance of costs of at least 3 percent.

- At least 5 percent of the patients in the MS-DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.
- There is a $2,000 difference in average cost between subgroups.

As procedure code 37.66 predominates in our claims data for VAD implantations, as we did in the proposed rule, we are including the following table to demonstrate the cost difference between MS-DRG 001 and MS-DRG 002.

MS-DRG	Number of Cases	Average Cost
001 - Cases with procedure code 37.66	811	$181,915
002 - Cases with procedure code 37.66	140	$128,069

As stated in the FY 2008 IPPS final rule with comment period, all five criteria must be met in order to subdivide an MS-DRG into MCC and non-MCC severity levels. In this instance, the number of cases in MS-DRG 002 containing procedure code 37.66 is 140, not the minimum number of 500 cases as established by the MS-DRG severity criteria. Therefore, even if we were to create a new MS-DRG for VAD implantation, unless we further divided the MS-DRG based on the presence of an MCC, we would substantially overpay approximately 15 percent of total VAD cases. However, we could not create multiple MS-DRGs for VAD implantation without ignoring our rules for subdividing MS-DRGs.

For these reasons, for FY 2013, we did not propose to make any changes to the structure of MS-DRGs 001 and 002. We invited public comment on our proposal.

Comment: Several commenters stated that they had no objections to CMS' proposal to maintain the current structure of MS-DRG 001 and MS-DRG 002 and not create separate MS-DRGs for VAD and heart transplants. The commenters stated that this proposal seems reasonable given the data and information provided.

One commenter stated that MS-DRG weights should reflect the overall costs of all of the services involved in an admission and that it would be inappropriate to bifurcate these MS-DRGs solely due to the cost of a single device, especially when that device is currently distributed by a single manufacturer. The commenter agreed with our proposal to maintain the existing structure of MS-DRGs 001 and 002, but urged CMS to continue to monitor the composition and costs of these MS-DRGs moving forward, especially as new VAD devices are approved for implantation.

Response: We appreciate the commenters' support for our proposal to maintain the existing structure of MS-DRG 001 and MS-DRG 002 for FY 2013. We will continue to monitor the composition and costs of these MS-DRGs as new VAD devices are approved for implantation.

Comment: One commenter stated that keeping the existing MS-DRG 001 and MS-DRG 002 structure may ultimately be a deterrent for appropriate provision of care to Medicare beneficiaries because of the discrepancy of cost between cardiac transplantation and implantation of VADs. The commenter stated that the cost of the VAD implantation is commonly more than $50,000 greater than the cost of a cardiac transplantation. The commenter stated that providing two MS-DRGs for heart transplants and two for VAD implantations will assure access to the best available technology.

Response: We acknowledge the commenter's concern about the potential for problems with future beneficiary access to VAD implantations and heart transplants. There are currently a limited number of FDA-approved VADs on the market. We will continue to monitor these MS-DRGs as additional VADs come onto the market and technologies change. We believe that creating separate MS-DRGs for VAD implantations and heart transplants could lead to significant reductions in the payment for heart transplants. Considering the limited number of FDA-approved VADs and the negative impact that creating separate MS-DRGs for VAD implantations and heart transplants would have on heart transplant cases, we do not believe the creation of separate MS-DRGs for VAD implantations and heart transplants is appropriate at this time.

After consideration of the public comments we received, we are finalizing our proposal to make no changes to MS-DRG 001 and MS-DRG 002 for FY 2013.

b. Allogeneic Bone Marrow Transplant

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50101), we deleted MS-DRG 009 (Bone Marrow Transplant) and created two new MS-DRGs: MS-DRG 014 (Allogeneic Bone Marrow Transplant) and MS-DRG 015 (Autologous Bone Marrow Transplant). We created MS-DRGs 014 and 015 because of differences in costs associated with the procedures in these two MS-DRGs. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51525 through 51526), we further subdivided MS-DRG 015 into two severity levels, by deleting MS-DRG 015 and creating MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC); and MS–DRG 017 (Autologous Bone Marrow

Transplant without CC/MCC). We created MS-DRGs 014 and 015 as these groups meet all five criteria for subdivision by severity level that we established in the FY 2008 IPPS final rule with comment period (72 FR 47169). As we discussed in the FY 2012 IPPS/LTCH PPS final rule, MS-DRG 014 did not meet the criteria for subdivision by severity level.

During the comment period for the FY 2012 IPPS/LTCH PPS proposed rule, we received a public comment regarding related and unrelated allogeneic bone marrow transplants (which are captured in MS-DRG 014) that had not been the subject of a proposal in that proposed rule. This issue was referred to briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), but we did not address the issue because we considered the comment to be out of the scope of provisions of the proposed rule. However, we addressed this issue in the FY 2013 proposed rule. The commenter recommended that MS-DRG 014 be subdivided into two MS-DRGs based on related and unrelated transplant donor source.

Allogeneic bone marrow transplantation utilizes the blood stem cells in bone marrow, umbilical cord blood, or peripheral blood from a donor that is either biologically related (sibling or other biologically close family member) or biologically unrelated (not a biologically close family member of the recipient) in the treatment of certain cancers and bone marrow diseases. Allogeneic transplant recipients must have a tissue type that matches the donor. According to the commenter, a related donor will typically be managed by the transplant facility from human leukocyte antigen (HLA) molecular typing through mobilization and collection, while an unrelated donor requires the use of

donor registry for searching and collection process. According to the commenter, the unrelated donor setting adds significant costs to the transplant that would not be incurred in the related transplant setting.

Currently, there are three ICD-9-CM procedure codes that identify the transplant donor source:

- 00.91 (Transplant from live related donor)
- 00.92 (Transplant from live non-related donor)
- 00.93 (Transplant from cadaver)

In our analysis of data in the FY 2011 MedPAR file, we found 467 cases assigned to MS-DRG 014 with average costs of approximately $64,403 and an average length of stay of approximately 24.8 days. There were 125 cases that reported procedure code 00.91 on the claim as the related transplant donor source with average costs of approximately $55, 969 and an average length of stay of approximately 24.1 days. In our analysis of the unrelated donor source, we included the cases reported with the transplant from a cadaver donor source (code 00.93) with the transplant from a live nonrelated donor source (code 00.92). There were 213 cases that reported either code 00.92 or 00.93 as the transplant donor source with average costs of approximately $64, 837 and an average length of stay of approximately 23 days. There were 129 cases that did not report a transplant donor source with average costs of approximately $71, 859 and an average length of stay of approximately 28.5 days. The following table illustrates our findings:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 014 – All cases	467	24.8	$64,403
MS-DRG 014 - Live related donor (code 00.91)	125	24.1	$55,969
MS-DRG 014 - Live nonrelated donor (code 00.92) or cadaver (code 00.93)	213	23	$64,837
MS-DRG 014 – No donor source	129	28.5	$71,859

As we noted in the proposed rule, one quarter of the cases (129 out of 467 cases) that did not report a transplant donor source code had the highest average costs of approximately $71,859, compared to $55,969 for live related donors and $64,837 for live nonrelated or cadaver donors and $64,403 for the overall average cost of cases within MS-DRG 014. The cases without a transplant donor source code also had a longer length of stay (28.5 days) than the live-related donor cases (24.1 days), the live nonrelated or cadaver cases (23 days), and the overall cases (24.8 days) assigned to MS-DRG 014.

Based on these findings, we stated that we believe that it would not be advisable to include cases without a transplant donor source code with the live nonrelated or cadaver donor cases, as we believe it would encourage providers not to report the transplant donor source code. All possible options must be included in any MS-DRG reconfiguration. Therefore, cases with no reported transplant donor source code must be included in the updated logic because this is the group with the highest average costs. Our clinical advisors reviewed this issue and do not support splitting MS-DRG 014 into two MS-DRGs because a quarter of the cases did not provide a transplant donor source. Therefore, we concluded that the cases reported with a transplant donor source code are appropriately assigned to MS-DRG 014 and that MS-DRG does not warrant further

subdivision. Without more complete information on donor source, we did not propose that MS-DRG 014 be subdivided in the proposed rule. We invited public comment on our proposal not to subdivide MS-DRG 014 into two MS-DRGs based on related and unrelated donor source.

Comment: Several commenters stated that they had no objections to CMS' proposal to maintain the current structure of MS-DRG 014. The commenters stated that the proposal seems reasonable based on the data and information provided. One commenter supported the subdivision to distinguish between related and unrelated allogeneic bone marrow transplants. However, the commenter stated that if CMS continues to believe that there is not sufficient data to support a split, CMS should require data collection of search and procurement costs. The commenter suggested that CMS establish a specific revenue code or line item on the hospital cost report to require hospitals to document the search and procurement costs in order to receive payment.

Response: We agree with the commenters that stated that, based on data and our analysis, we should not subdivide MS-DRG 014 without more complete information on the donor source. As stated previously, one quarter of the cases (129 out of 467 cases) did not report a transplant donor source code. We believe that we have sufficient methods of reporting donor source on the claim by reporting ICD-9-CM code 00.91, 00.92, or 00.93 and associated costs.

After consideration of the public comments we received, we are not making any changes to MS-DRG 014 for FY 2013.

2. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat): Influenza with Pneumonia

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), we discussed a public comment that we considered out of the scope of the FY 2012 proposed rule. Therefore, we did not address the issues in the final rule. The commenter requested that we consider reassigning cases with a combined diagnosis of influenza with pneumonia from a set of simple pneumonia MS-DRGs to a set of MS-DRGs that captures a more severe type of pneumonia. The specific request involves cases now assigned to MS-DRGs 193 (Simple Pneumonia and Pleurisy with MCC), 194 (Simple Pneumonia and Pleurisy with CC), and 195 (Simple Pneumonia and Pleurisy without MCC/CC) being moved to MS-DRGs 177 (Respiratory Infections and Inflammations with MCC), 178 (Respiratory Infections and Inflammations with CC), and 179 (Respiratory Infections and Inflammations without MCC/CC).

For the FY 2013 proposed rule, we examined data in the FY 2011 MedPAR file on cases that reported diagnosis code 487.0 (Influenza with pneumonia) as the principal diagnosis with an additional secondary diagnosis code for one of the following types of pneumonia:

- 482.0 (Pneumonia due to Klebsiella pneumoniae)
- 482.1 (Pneumonia due to Pseudomonas)
- 482.40 (Pneumonia due to Staphylococcus, unspecified)
- 482.41 (Methicillin susceptible pneumonia due to Staphylococcus aureus)
- 482.42 (Methicillin resistant pneumonia due to Staphylococcus aureus)

- 482.49 (Other Staphylococcus pneumonia)
- 482.81 (Pneumonia due to anaerobes)
- 482.82 (Pneumonia due to Escherichia coli [E. coli])
- 482.83 (Pneumonia due to other gram-negative bacteria)
- 482.84 (Pneumonia due to Legionnaires' disease)
- 482.89 (Pneumonia due to other specified bacteria)

Currently, when one of the pneumonia codes listed above is reported as a principal diagnosis, the case is assigned to MS-DRG 177, 178, or 179. However, when the patient has been diagnosed with one of these types of pneumonia and also has influenza, the ICD-9-CM coding book directs the coder to report diagnosis code 487.0 as the principal diagnosis and to assign an additional secondary code to describe the specific type of pneumonia. This reporting results in cases with diagnoses of both influenza and specific types of pneumonia being assigned to MS-DRG 193, 194, or 195 (Simple Pneumonia and Pleurisy with MCC, with CC, or without CC/MCC, respectively), instead of MS-DRG 177, 178, or 179. The commenter requested that we reassign cases reporting code 487.0 as the principal diagnosis with one of the specific pneumonia codes listed above as a secondary diagnosis to MS-DRGs 177, 178, and 179.

We analyzed data from the MedPAR file on cases with patients with pneumonia and found the following:

MS-DRG	Number of Cases	Average Length of Stay	Average Cost
MS-DRG 177 - All cases	69,128	8.20	$13,002
MS-DRG 178 - All cases	59,559	6.40	$9,193
MS-DRG 179 - All cases	14,108	4.65	$6,365

MS-DRG	Number of Cases	Average Length of Stay	Average Cost
MS-DRG 193 - All cases	125,892	6.28	$9,589
MS-DRG 193 - Cases with principal diagnosis code 487.0 and with a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	57	9.3	$15,867
MS-DRG 193 - Cases with principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	1,320	6.93	$10,416
MS-DRG 194- All cases	191,030	4.73	$6,524
MS-DRG 194 - Cases with principal diagnosis code 487.0 and with a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	59	6.9	$9,752
MS-DRG 194 - Principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	2,088	5.16	$6,871
MS-DRG 195 - All cases	80,253	3.53	$4,660
MS-DRG 195 - Cases with a principal diagnosis code 487.0 and a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	12	4.8	$5,842
MS-DRG 195 - Cases with principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	1,065	3.78	$4,580

The data showed that cases reporting a principal diagnosis code 487.0 with one of the pneumonia codes listed above as a secondary diagnosis have significantly higher average costs ($15,867 in MS-DRG 193, $9,752 in MS-DRG 194, and $5,842 in MS-DRG 195) than those cases reported without one of the pneumonia codes listed above as a secondary diagnosis ($10,416 in MS-DRG 193, $6,871 in MS-DRG 194, and

$4,580 in MS-DRG 195), and also the overall average costs for all cases in MS-DRGs 193, 194, and 195 ($9,589, $6,524, and $4,660, respectively). The influenza and pneumonia cases had average costs that more closely align with the average costs of cases currently assigned to MS-DRGs 177, 178, and 179 ($13,002, $9,193, and $6,365, respectively).

As a result of our analysis, the data support the commenter's request that we reassign cases reporting a principal diagnosis code 487.0 and an additional secondary diagnosis code for one of the pneumonia codes listed above, from MS-DRGs 193, 194, and 195 to MS-DRGs 177, 178, and 179. Our clinical advisors also support reassigning these cases to MS-DRGs 177, 178, and 179. Therefore, for FY 2013, we proposed to reassign cases with a principal diagnosis code 487.0 and an additional secondary diagnosis code of one of the following pneumonia codes listed as a secondary diagnosis codes from MS-DRGs 193, 194, and 195 to MS-DRGs 177, 178, and 179: 482.0; 482.1; 482.40; 482.41; 482.42; 482.49; 482.81; 482.82; 482.83; 482.84; and 482.89.

We invited public comment on our proposal for FY 2013.

Comment: Commenters supported our proposal to reassign cases with a principal diagnosis code of 487.0 with an additional secondary diagnosis code for the specified types of pneumonia from MS-DRGs 193 and 195 to MS-DRGs 177, 178, and 179. The commenters stated that these proposed reassignments better capture the more severe type of pneumonia that results in significantly higher average costs. Other commenters stated the proposed reassignments were reasonable, given the data and information provided.

Response: We appreciate the commenters' support of our proposals.

After consideration of the public comments we received, we are finalizing our proposal of reassigning cases with a principal diagnosis code of 487.0 and an additional secondary diagnosis code of one of the following pneumonia codes as a secondary diagnosis codes from MS-DRGs 193, 194, and 195 to MS-DRGs 177, 178, and 179: 482.0; 482.1, 482.40, 482.41, 482.42; 482.49; 482.81; 482.82; 482.83, 482.84; and 482.89.

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Mitral Valve Repair with Implant

We received a request to reassign procedure code 35.97 (Percutaneous mitral valve repair with implant) to the following MS-DRGs:

- MS-DRG 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac with MCC);
- MS-DRG 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac with CC);
- MS-DRG 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac without CC/MCC);
- MS-DRG 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with MCC);
- MS-DRG 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with CC); and
- MS-DRG 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac without CC/MCC).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51528 through 51529), we discussed reassigning procedure code 35.97 from MS-DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively) and MS-DRGs 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents), 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC), 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents), 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC), 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with MCC), and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI without MCC). In that final rule, we stated that we did not have sufficient claims data on which to base and evaluate any proposed changes to the current MS-DRG assignment. Procedure code 35.97 was created for use beginning October 1, 2010 (FY 2011) after the concept of percutaneous valve repair was presented at the March 2010 ICD-9-CM Coordination and Maintenance Committee meeting. Procedure code 35.97 was created at that time to describe the MitraClip™ device and any other percutaneous mitral valve repair devices currently on the market. This procedure code was assigned to the following MS-DRGs: 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively); 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents); 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC); 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents); 249 (Percutaneous Cardiovascular Procedure with

Non-Drug-Eluting Stent without MCC); 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with MCC); and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI without MCC).

According to the Food and Drug Administration's (FDA's) terms of the clinical trial for MitraClip™, the device is to be implanted in patients without any additional surgeries performed. Therefore, based on these terms, we stated that while the procedure code is assigned to MS-DRGs 246 through 251, the most likely MS-DRG assignments would be MS-DRGs 250 and 251, as described above. As we stated in the FY 2012 IPPS/LTCH PPS final rule, because procedure code 35.97 had only been in use since October 1, 2010, there were no claims data in the most recent update of the MedPAR file at that time to evaluate any alternative MS-DRG assignments. Therefore, we did not make any MS-DRG assignment changes for procedure code 35.97 for FY 2012.

For the FY 2013 proposed rule, we analyzed claims data from the FY 2011 MedPAR file on the procedure that describes mitral valve repair with implant and found the following:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 216 - All Cases	9,624	16.44	$61,015
MS-DRG 217 - All Cases	5,655	10.24	$41,324
MS-DRG 218 - All Cases	995	7.43	$34,587
MS-DRG 219 - All Cases	15,336	12.53	$50,176
MS-DRG 220 - All Cases	18,455	7.53	$34,150
MS-DRG 221 - All Cases	4,719	5.59	$29,082
MS-DRG 231 - All Cases	1,170	12.17	$49,728
MS-DRG 231 - Cases with Procedure Code 35.97	4	13.75	$35,409
MS-DRG 232 - All Cases	1,010	9.16	$37,820
MS-DRG 232 - Cases with Procedure Code 35.97	9	13.56	$46,008
MS-DRG 246 - All Cases	29,299	5.20	$20,725
MS-DRG 247 - All Cases	109,661	2.39	$13,014

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 248 - All Cases	13,562	6.35	$19,785
MS-DRG 248 - Cases with Procedure Code 35.97	1	32.00	$110,262
MS-DRG 249 - All Cases	35,100	2.86	$11,806
MS-DRG 250 - All Cases	8,313	7.07	$19,673
MS-DRG 250 - Cases with Procedure Code 35.97	39	9.77	$29,753
MS-DRG 251 - All Cases	31,316	2.92	$12,658
MS-DRG 251 - Cases with Procedure Code 35.97	98	2.69	$18,651

We note that most of the cases were found in MS-DRGs 250 and 251, as we predicted in the FY 2012 IPPS/LTCH PPS final rule based on FDA's terms of the clinical trial for MitraClip™. As stated earlier, the device is to be implanted in patients without any additional surgeries performed. There were 39 cases in MS-DRG 250 with average costs of $29,753 (which includes cases with an MCC). These average costs are significantly lower than the average costs of $61,015 for cases in MS-DRG 216, and the average costs of $50,176 for cases in MS-DRG 219 (which includes cases with an MCC). There were 98 cases in MS-DRG 251(without MCC) with average costs of $18,651. These average costs also are lower than the average costs of comparable cases in MS-DRGs 217, 218, 220, and 221, whose average costs range from a high of $41,324 to a low of $29,082. While the average costs of mitral valve repair cases are higher than the average costs of other cases assigned to MS-DRGs 250 and 251, they are significantly less than the average costs of cardiac valve replacement cases assigned to MS-DRGs 216 through 221. Our analysis of the claims data does not support reassigning the procedure that describes percutaneous mitral valve repair with implant from MS-DRGs 250 and 251 to MS-DRGs 216 through 221. Our clinical advisors also support maintaining the current assignment of this procedure in MS-DRGs 250 and 251. Therefore, based on our

findings, we did not propose to reassign procedure code 35.97 from MS-DRGs 250 and 251 to MS-DRGs 216 through 221.

We invited public comment on our proposal to maintain the current assignment of procedure code 35.97 in MS-DRGs 250 and 251 and not to reassign the procedure code to MS-DRGs 217 through 221.

Comment: Several commenters supported our proposal not make any MS-DRG modifications for procedure code 35.97 cases, which are currently assigned to MS-DRGs 250 and 251. The commenters stated that the proposal was reasonable, given the data and information provided.

Response: We appreciate the commenters' support for our proposal for FY 2013.

Comment: A number of commenters recommended that CMS reassign code 35.97 to MS-DRGs 216, 217, and 218. The commenters stated that percutaneous mitral valve repair offers an alternative to open surgery and is used in high risk patients. The commenters believed that the current payment is too low and that their hospitals may decide not to perform these procedures if the payment is not increased. The commenters stated that MS-DRGs 216, 217, and 218 more accurately reflect the associated comorbidities and the intensity of resources required to perform percutaneous mitral valve repairs with implant. Commenters also stated that the procedure is complex and requires a complex team of surgeon, imaging specialist, anesthesiologist, and interventionalist. Given this team approach, complexity, and lengthy procedure time, the commenters stated that MS-DRGs 216, 217, and 218 were more appropriate MS-DRG assignments.

One commenter, a manufacturer of a mitral valve repair device, echoed the comments above. The manufacturer also expressed concern that CMS' claims data may not fully reflect the costs of the mitral valve repair devices. The manufacturer stated that the data analyzed may have included some mitral valve repair cases that were performed in clinical trials and reflected trial-only device prices that were much lower than the planned commercial device prices.

Response: We note that MS-DRGs 216, 217, 218 currently include the requirement that a cardiac catheterization be performed during the hospital stay. We assume that the commenters meant to include the complete range of MS-DRGs for cardiac valve and other major cardiothoracic procedures (that is, MS-DRG 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with MCC), MS-DRG 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with CC), and MS-DRG 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac without CC/MCC), in addition to MS-DRGs 216, 217, and 218). MS-DRGs 216, 217, and 218 include the provision of cardiac catheterizations, while MS-DRGs 219, 220, and 221 do not include the use of a cardiac catheterization.

The claims data do not support adding percutaneous mitral valve repairs with implant to MS-DRGs 216, 217, and 218 (those with cardiac catheterizations) or to the complete range of DRGs that includes both those with and without cardiac catheterization (MS-DRGs 216 through 221). As stated earlier, there were 39 cases in MS-DRG 250 with average costs of $29,753 (which includes an MCC). These average costs are significantly lower than the $61,015 average costs for cases in MS-DRG 216 and the

$50,176 average costs for cases in MS-DRG 219, which includes an MCC. There were 98 cases in MS-DRG 251(without MCC) with average costs of $18,651. These average costs are also lower than the average costs of comparable cases in MS-DRG 217, 218, 220, and 221 whose average costs range from a high of $41,324 to a low of $29,082. While the average costs for these cases are higher than for others in MS-DRGs 250 and 251, they are significantly less than those cardiac replacement valve cases assigned to MS-DRGs 216 through 221. Our data indicate that the average cost for this procedure, including the significant cost of the devices, is much closer to the average cost of the percutaneous procedures that comprise the remaining 99 percent of the claims in the MS-DRGs 250 and 251 than it is to the proposed MS-DRGs, where payments are twice the reported cost of this procedure.

In this case it is true that costs of the percutaneous mitral valve implantations are more than the average for MS-DRGs 250 and 251. However it is a fundamental principle of an averaged payment system that half of the procedures in a group will have above average costs. It is expected that there will be higher cost and lower cost subsets, especially when a subset has low numbers. In this case the other ninety-nine percent of the claims that make up the assigned DRG will be expected to continue to include cases with similar costs but also include many cases with below average costs. In an average payment system, the “profit” of low-cost cases balances the “loss” of the high-cost cases, and hospitals and manufacturers cannot expect to see “profit” on every possible subset of cases in a DRG.

Our clinical advisors state that the current MS-DRG assignment is reasonable because the operating room resource utilizations of percutaneous procedures, such as those found in MS-DRGs 250 and 251, tend to group together, and are generally less costly than open procedures, such as those found in MS-DRGs 216 through 221. Percutaneous procedures by organ system represent groupings that are reasonably clinically coherent. More significantly, our clinical advisors state that postoperative resource utilization is significantly higher for open procedures with the much greater morbidity and consequent recovery needs. Because the equipment, technique, staff, patient populations and physician specialty all tend to group by type of procedure (percutaneous versus open), separately grouping percutaneous and open procedures is more clinically consistent. Therefore, our clinical advisors recommend that we not move percutaneous mitral valve repairs with implants into MS-DRGs 216 through 221. Based on the claims data and the advice of our clinical advisors, we do not believe the findings warrant moving code 35.97 from to MS-DRGs 250 and 251 to MS-DRGs 216 though 221.

After consideration of the public comments we received, we are finalizing our proposal to not make any MS-DRG modifications for procedure code 35.97 cases, which currently are assigned to MS-DRGs 250 and 251, for FY 2013.

b. Endovascular Implantation of Branching or Fenestrated Grafts in Aorta

The fenestrated (with holes) graft device is designed to treat patients with abdominal aortic aneurysms (AAA). Current treatment options for patients with AAAs

include open surgical repair, endovascular repair using stent-grafts, or medical management.

Aneurysmal disease that extends proximally to the level of the renal arteries is usually indicative of more extensive aortic disease and comorbidities. As a result, many of these patients are at a higher overall risk when undergoing open surgical repair. In addition, these patients are often not suitable for endovascular treatment with currently available endografts because the length of healthy aorta is insufficient to provide an adequate seal at the proximal end. The indications for use for many of the standard endografts call for an aortic neck length greater than or equal to 15 millimeters.

Published industry reports estimate that 8 percent to 30 percent of patients with AAAs that need repair have aortic necks of less than 15 millimeters in length. One institution has reported that over half of its patients with AAAs were considered ineligible for endovascular aneurysm repair or endovascular aortic repair (EVAR) due to an inadequate length of nondiseased aorta. These patients also were predominantly contraindicated for open repair.

Prior to the development of a fenestrated graft device, the only treatment option available to a large number of these high-risk patients would have been medical management. Open surgical repair is too challenging to frail patients, as it requires supraceliac clamping of the aorta and may result in renal ischemia, mesenteric ischemia, or atheroembolization of the visceral vessels of the aorta. EVAR with a standard endograft is not a viable option either because the shortened neck precludes an adequate proximal end seal, which can lead to type I endoleaks (leaking of blood around the device

into the aneurysm resulting in continued pressurization of the aneurysm). Medical management alone leaves these patients at high risk for AAA-related morbidity and mortality. These suboptimal choices led to the creation of fenestrated endografts that can seal above the renal arteries while maintaining access and uninterrupted blood flow to branch vessels of the aorta.

The fenestrated graft is currently under clinical trial in the United States. Effective April 4, 2012, the Zenith® Fenestrated AAA Endovascular Graft (Cook® Medical) received FDA approval. Another manufacturer of fenestrated grafts expects to receive FDA approval for its device within 3 years.

At the September 15, 2010 meeting of the ICD-9-CM Coordination and Maintenance Committee, the topic of fenestrated graft was presented with a request for a unique procedure code. As a result of that meeting, and additional meetings with manufacturers throughout the year, procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) was created for use beginning October 1, 2011 (FY 2012). This code is assigned to MS-DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively).

We have received a request from a manufacturer to reassign procedure code 39.78 from MS-DRGs 252, 253, and 254 to MS-DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively). The requestor stated that the assignment to MS-DRGs 252, 253, and 254 violates both of CMS' stated principles regarding assigning new codes to MS-DRGs that reflect both clinical coherence and similar consumption of resources.

From the standpoint of clinical coherence, the requestor noted that, while procedures in MS-DRGs 252, 253, and 254 are vascular procedures, the procedures do not involve the aorta. The requestor further noted that AAA repairs, both open and endovascular, are assigned to MS-DRGs 237 and 238. From the standpoint of similar consumption of resources, the requestor included anticipated device costs of $17,424 to $21,824 for a fenestrated endovascular procedure. The requestor noted that these costs only represent the device and do not include any additional resources required during the hospitalization. The requestor believed that the device costs are more similar to devices used in MS-DRGs 237 and 238.

CMS' practice is to assign new codes to MS-DRGs where similar procedures are also located. In terms of clinical coherence, CMS assigned the new code to the vascular procedure MS-DRGs (252, 253, and 254) where other noncoronary endovascular procedures for blood vessel repair also are assigned. This decision was based on our practice to group similar procedures together, in this case repairs to blood vessels, especially for new codes when CMS has no data history.

With regard to resource consumption, we point out that procedure code 39.78 was created for use effective with discharges on or after October 1, 2011. Our review of data in the MedPAR file shows no utilization of this code because it is too new. That is, we have no claims data that would either prove or disprove the requestor's supposition that procedure code 39.78 is not adequately paid under MS-DRGs 252, 253, and 254. As discussed elsewhere in this preamble, the MS-DRG system is not a device classification system. Therefore, because there are very few companies currently marketing their

fenestrated graft devices, we are concerned that these companies are able to set their own charges in the market.

In addition, the requestor opined that "an argument could possibly be made that the increased device costs and longer procedural times for [procedure code] 39.78 suggest assignment into MS-DRG 237 alone would be appropriate," although the requestor further stated that, without a significant volume of actual claims data, it might be more reasonable [for CMS] to take a conservative approach and assign these procedures to either MS-DRG 237 or MS-DRG 238. We note that MS-DRGs 237 and 238 are paired MS-DRGs, with both MS-DRGs containing the same procedure codes, but which have been subdivided based on the formula for the presence or absence of comorbid or complicating conditions. It is not an inherent part of the GROUPER logic to assign a code to only one DRG in a set of paired or triplicate MS-DRGs.

Because there is no data history for procedure code 39.78 that would justify a reassignment based on either clinical coherence or resource consumption, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27903 and 27904), we did not propose to make a change to the MS-DRG assignment of procedure code 39.78 for FY 2013. We stated our belief that procedure code 39.78 has been appropriately placed within the MS-DRG structure. We also stated that we would continue to evaluate the clinical coherence and resource consumption costs that impact this code and the current MS-DRG assignment. We invited public comment on our proposal.

Comment: Many commenters agreed or did not have any specific objections regarding our proposal to not reassign procedure code 39.78 from MS-DRGs 252, 253, and 254 to MS-DRGs 237 and 238 for FY 2013 based on the information we provided.

Response: We appreciate the commenters' support for our proposal for FY 2013.

Comment: Numerous commenters representing various professional organizations and device manufacturers disagreed with our proposal to maintain the current MS-DRG structure for procedure code 39.78. The commenters urged CMS to reevaluate the proposal and reassign procedure code 39.78 to MS-DRGs 237 and 238 for FY 2013.

The commenters stated that the proposed MS-DRG assignment for procedure code 39.78 is not clinically correct. Specifically, the commenters stated that the association of a fenestrated graft procedure to peripheral arterial endovascular interventions is not representative of the complexities involved in performing the fenestrated graft surgery, nor does it adequately depict a hospital's utilization of resources. The commenters further noted that the implantation of fenestrated grafts is more similar, from a clinical and resource consumption perspective, to the other endovascular graft procedures within MS-DRGs 237 and 238 than it is to the vascular procedures assigned to MS-DRGs 252, 253, and 254.

One commenter provided detailed information outlining the specific FDA-approved indications for both the standard and fenestrated endovascular graft procedures for treatment of aneurysms to further demonstrate how clinically similar the procedures actually are. Other commenters clarified that fenestrated grafts require all the

resources of a standard endovascular graft procedure *in addition to* all the resources required for placement of stents in the renal and visceral arteries to maintain perfusion. Another commenter reported that the devices required to perform a fenestrated graft procedure are "(1) more complicated, more numerous, and, in aggregate, significantly more expensive than those required for the predecessor [standard] procedures; and (2) the fenestrated/branch procedure itself is more complex and time consuming, requiring significantly greater hospital operating room time and resources." Therefore, according to the commenters, the resources required to perform implantation of a fenestrated graft are far more extensive in comparison to the resources utilized to perform procedures assigned to MS-DRGs 252, 253, and 254.

Some commenters also believed that CMS may have misunderstood some of the aspects of the fenestrated graft procedure. The commenters indicated that if the *standard* endovascular graft procedure (for example, procedure code 39.71 (Endovascular implantation of other graft in abdominal aorta) is currently assigned to MS-DRGs 237-238 and the *fenestrated* endovascular graft procedure requires greater utilization of resources, logically procedure code 39.78 should be assigned to MS-DRGs 237 and 238.

Other commenters reiterated the benefits of fenestrated graft procedures to those patients who are not candidates for standard endovascular grafts or open surgical repair. These commenters indicated that the patients necessitating fenestrated grafts are a complex patient population. Some commenters also stated that, despite the lack of sufficient MedPAR claims data for procedure code 39.78, CMS should consider the

clinical similarities between fenestrated graft procedures and the other procedures that currently group to MS-DRGs 237 and 238.

The commenters stated that, by reassigning procedure code 39.78 to MS-DRGs 237 and 238, patients would no longer be restricted access to this technology for treatment of juxtarenal/pararenal (next to or at renal arteries) aneurysms and hospitals would be more appropriately paid for the services they are providing.

Response: Although we did not propose to reassign procedure code 39.78 from MS-DRGs 252, 253, and 254 to MS-DRGs 237 and 238 for FY 2013, upon further review and consideration of the comments received, we agree with the commenters that the fenestrated grafts are more similar from a clinical and resource consumption perspective to the other endovascular graft procedures within MS-DRGs 237 and 238.

Therefore, as final policy for FY 2013, we are reassigning procedure code 39.78 from MS-DRG 252, 253, and 254 to MS-DRGs 237 and 238.

4. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders): Disorders of Porphyrin Metabolism

We received a request for the creation of a new MS-DRG to better identify cases where patients with disorders of porphyrin metabolism exist, to recognize the resource requirements in caring for these patients, to ensure appropriate payment for these cases, and to preserve patient access to necessary treatments. Porphyria is defined as a group of rare disorders ("porphyrias") that interfere with the production of hemoglobin that is needed for red blood cells. While some of these disorders are genetic (inborn) and others can be acquired, they all result in the abnormal accumulation of hemoglobin building blocks, called porphyrins, which can be deposited in the tissues where they particularly interfere with the functioning of the nervous system and the skin.

Treatment for patients suffering from disorders of porphyrin metabolism consists of an intravenous injection of Panhematin® (hemin for injection). In 1984, this pharmaceutical agent became the first approved drug for a rare disease to be designated under the Orphan Drug Act. It is the only FDA-approved prescription treatment for acute intermittent porphyria, being approved for manifestations temporarily related to the menstrual cycle in susceptible women.

ICD-9-CM diagnosis code 277.1 (Disorders of porphyrin metabolism) describes these cases, which are currently assigned to MS-DRG 642 (Inborn and Other Disorders of Metabolism). We analyzed data from the FY 2011 MedPAR file for cases assigned to this MS-DRG. As shown in the table below, we found a total of 1,447 cases in MS-DRG 642 with an average length of stay of 4.63 days and average costs of $7,400. We then

analyzed the data for cases reporting diagnosis code 277.1 as the principal diagnosis in this same MS-DRG. We found a total of 330 cases, with an average length of stay of 6.12 days and average costs of $11,476.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 642 – All cases	1,447	4.63	$7,400
MS-DRG 642– Cases with principal diagnosis code 277.1	330	6.12	$11,476

While the average costs for the 330 cases reporting a principal diagnosis code of 277.1 were higher than all cases in MS-DRG 642 ($11,476 versus $7,400), the volume of affected cases is small, representative of approximately 20 percent of all of the cases in MS-DRG 642. Under our existing policy (76 FR 51487 and 51488), in deciding whether to make modifications to the MS-DRGs, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different from the remaining patients in the MS-DRG. We evaluate the utilization of resources related to patient care using average costs and length of stay and rely on the judgment of our medical advisors to decide whether patients are clinically distinct or similar to other patients in the MS-DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we selected for review and the reminder of cases in the MS-DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that were extreme in terms of costs or length of stay. Further, we consider the number of patients who have a given set of characteristics and

generally prefer not to create a new MS-DRG unless it would include a substantial number of cases. Therefore, in the FY 2013 proposed rule, we determined that the findings do not support the creation of a new MS-DRG.

We acknowledge the importance of ensuring that patients diagnosed with a disorder of porphyrin metabolism have adequate access to care and receive the necessary treatment. Despite the fact that our data analysis did not demonstrate support for the creation of a new MS-DRG at this time, we also explored an alternative option. In reviewing the medical MS-DRGs in terms of resources and clinical coherence that are also located within MDC 10, we found three MS-DRGs that we believe are similar to MS-DRG 642. We analyzed data from the MedPAR file on cases in MS-DRGs 643, 644, and 645 (Endocrine Disorders with MCC, with CC, and without CC/MCC, respectively) to determine if the cases reporting a principal diagnosis code of 277.1 would be more appropriately reassigned from MS-DRG 642 to MS-DRGs 643, 644, and 645. Upon examination of the data, we found that the average costs of these cases were $10,835, $6,816, and $4,762, respectively, as shown in the table below.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 643 – Cases with principal diagnosis code 277.1	6,562	7.11	$10,835
MS-DRG 644 – Cases with principal diagnosis code 277.1	12,769	4.89	$6,816
MS-DRG 645 – Cases with principal diagnosis code 277.1	5,979	3.40	$4,762

Based on these findings, if we were to reassign cases where disorders of porphyrin metabolism (diagnosis code 277.1) were reported as the principal diagnosis

with a secondary diagnosis designated as a CC (MS-DRG 644) or with a secondary diagnosis that was not a CC/MCC (MS-DRG 645), Medicare would pay significantly less for these cases than they are now paid under MS-DRG 642. Therefore, it would not be appropriate to reassign cases reporting a principal diagnosis code of 277.1 from MS-DRG 642 to MS-DRGs 643, 644, and 645. In addition, our clinical advisors did not support this reassignment. The MS-DRG classification system on which the IPPS is based comprises a system of averages. As such, it is understood that, in any particular MS-DRG, it is not unusual for a small number of cases to demonstrate higher than average costs, nor is it unusual for a small number of cases to demonstrate lower than average costs. Upon review of the MedPAR data and the alternative option discussed, our clinical advisors agree that the current MS-DRG assignment for diagnoses of disorders of porphyrin metabolism (diagnosis code 277.1) to MS-DRG 642 is most appropriate at this time.

In the proposed rule, we acknowledged and recognized the severity of symptoms that patients diagnosed with disorders of porphyrin metabolism may experience. We also stated that we are sensitive to concerns about access to care and treatment for these patients. We further indicated that we would continue to monitor this issue and determine how to better account for the variation in resource utilization within the IPPS for these cases.

In summary, we did not propose to create a new MS-DRG or to reassign cases reporting a principal diagnosis code of 277.1 to MS-DRGs 643, 644, and 645 for FY 2013. We invited public comment on our proposal.

Comment: Several commenters agreed with our proposal to not create a new MS-DRG or to reassign cases reporting a principal diagnosis code of 277.1 from MS-DRG 642 to MS-DRGs 643, 644, and 645 for FY 2013.

Response: We appreciate the commenters' support for our proposal.

Comment: Two commenters, representing organizations dedicated to the treatment, education, and study of patients diagnosed with disorders of porphyrin metabolism, appreciated the attention that CMS devoted to this issue. However, these commenters expressed concern that CMS' proposal to not create a new MS-DRG for these cases would negatively impact beneficiary access to necessary treatments. For example, according to one of the commenters, certain facilities are unable to provide the needed Panhematin® therapy as a result of the costs incurred and the present MS-DRG assignment. The commenters believed that for beneficiaries who experience an acute porphyric attack, there are not any alternative therapies compared to the effectiveness of Panhematin®.

One of the commenters also submitted data from its own analysis indicating that not only are the average costs of porphyria cases greater than the average costs of all cases in MS-DRG 642, but also that the average costs of porphyria cases are greater than the average costs of other cases that contain the top 10 principal diagnoses (by volume of discharges) assigned to MS-DRG 642. The commenter asserted that, based on its analysis, as well as the analysis conducted and presented by CMS in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27904 through 27905), porphyria cases undoubtedly satisfy the criteria to create a new MS-DRG.

Additionally, the commenters opposed CMS' position regarding the inadequate number of cases in which to establish a new MS-DRG for porphyria cases. One of the commenters reported that, based on its own analysis, the number of porphyria cases demonstrated a significant subset of the total cases that grouped to MS-DRG 642. The other commenter acknowledged that the number of porphyria cases is small; however this commenter maintained that CMS may inadvertently be sending the message that rare diseases affecting smaller populations are not as significant as those diseases affecting larger populations by not creating a new MS-DRG for porphyria cases. The commenters urged CMS to reconsider the proposal and create a new MS-DRG for cases with a principal diagnosis of porphyria to ensure these beneficiaries have access to treatment for this potentially life-threatening disease.

Response: We acknowledge the commenters' concerns. CMS is committed to improving the lives and quality of care for Medicare beneficiaries. We take this opportunity to note that it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased costs. The MS-DRG system is a system of averages and it is expected that across the 571 diagnostic related groups that within certain groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs.

As discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27904 through 27905), we recognize the average costs of the small number of porphyria cases are greater than all the cases in MS-DRG 642. While the commenter's analysis found that approximately 50 percent of porphyria cases were more expensive than the average

cost of the other cases in this MS-DRG, it is not alarming and, in fact, is what we would expect (as the remaining percent of cases are *less* expensive than the average). The data provided by the commenter demonstrates that it is a subset of the porphyria cases that has the significantly higher cost exactly as it is a subset of the MS-DRG that has significantly higher costs. An averaged payment system depends on aggregation of similar cases with a range of costs, and these data are not unusual. In fact, it is usually possible to define subsets with higher values and subsets with lower values. We continue to follow our usual practice of identifying sufficiently large sets of claims data with a resource/cost similarity and clinical similarity and do not wish to abandon our use of diagnostic related groups in favor of smaller "single diagnosis payments" or even, as suggested by the commenter's data, subsets within a single diagnosis.

We disagree with the commenter that our proposal to not create a new MS-DRG for porphyria cases sends the message that rare diseases and patient access to treatment are not a significant cause for concern to the Agency in comparison to other well known and publicly recognized conditions. Although it was not included as part of the commenter's initial request for a new MS-DRG, we also explored an alternative option to reassign cases with a principal diagnosis of porphyria as was discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27904 through 27905). Furthermore, we indicated our intent to continue to monitor this issue.

As mentioned previously, we are sensitive to the commenters' concerns and access to treatment for beneficiaries who have been diagnosed with this condition. However, for the reasons summarized above, we are finalizing our proposal for FY 2013

to not create a new MS-DRG or to reassign cases with a principal diagnosis of porphyria (code 277.1) from MS-DRG 642 to MS-DRGs 643, 644, and 645.

5. Medicare Code Editor (MCE) Changes

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS-DRG.

a. MCE New Length of Stay Edit for Continuous Invasive Mechanical Ventilation for 96 Consecutive Hours or More

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27905 and 27906), we proposed to make a change to the MCE edits which included the creation of a new length of stay edit for continuous invasive mechanical ventilation for 96 consecutive hours or more.

It was brought to our attention that a number of hospitals reporting ICD-9-CM procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) may be inaccurately reporting this code. As the title of the procedure code implies, a patient must have received continuous mechanical ventilation for 96 hours or more in order for this code to be assigned. This equates to a patient being hospitalized for at least a 4-day length of stay and having received continuous invasive mechanical ventilation for a minimum of 4 days. Therefore, a patient with a length of

stay less than 4 days who received continuous invasive mechanical ventilation should not have procedure code 96.72 reported on the claim.

The ICD-9-CM classification system contains three procedure codes that identify and describe continuous invasive mechanical ventilation: procedure code 96.70 (Continuous invasive mechanical ventilation of unspecified duration); procedure code 96.71 (Continuous invasive mechanical ventilation for less than 96 consecutive hours); and procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more). To assist in the accurate assignment of these codes, guidance in the form of a "Note" is provided within the designated procedure section of ICD-9-CM. This "Note" describes the calculation of the number of hours during a hospitalization in which a patient receives continuous invasive mechanical ventilation. In addition, coding advice pertaining to appropriate code assignment for mechanical ventilation has been published in various editions of the American Hospital Association's (AHA's) *Coding Clinic for ICD-9-CM.*

For the proposed rule, we analyzed the FY 2011 MedPAR data to determine how many cases reported procedure code 96.72 with a length of stay less than 4 days. Specifically, we reviewed cases reporting procedure code 96.72 with a length of stay of 1 day, 2 days, or 3 days. We found a total of 595 cases meeting those criteria. The data analysis showed there were 89 cases reporting procedure code 96.72 with a length of stay of 1 day and average costs of $5,948, 134 cases reporting procedure code 96.72 with a length of stay of 2 days and average costs of $7,776, and 372 cases reporting procedure code 96.72 with a length of stay of 3 days and average costs of $11,613.

The data also demonstrated that the 595 cases found were distributed across a wide range of MS-DRGs, with the top two (in terms of volume) being MS-DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours) and MS-DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation 96+ hours). We note that the two MS-DRGs with the highest volume of cases reporting procedure code 96.72 and having a length of stay less than 4 days are the two MS-DRGs that specifically reference "96+ hours" in their titles. More importantly, a large percentage of these cases reporting procedure code 96.72 in error are being grouped to the incorrect MS-DRGs, resulting in significant overpayments. For example, of the 89 cases reporting procedure code 96.72 with a length of stay of 1 day, 31 cases were grouped to MS-DRGs 207 and 870. Of the 134 cases reporting procedure code 96.72 with a length of stay of 2 days, 54 cases were grouped to MS-DRGs 207 and 870. Lastly, of the 372 cases reporting procedure code 96.72 with a length of stay of 3 days, 160 cases were grouped to MS-DRGs 207 and 870. Therefore, the data show that a total of 245 cases (41 percent) were grouped to MS-DRGs 207 and 870 in error, resulting in approximately $25,000 in increased payments for each case (or approximately $6 million in increased payments for all 245 cases). Based on the results of these figures for that portion of the total 595 cases found, there is an even larger dollar amount that is being overpaid to hospitals. These overpayments justify corrective actions.

However, we also noted that the presumed amount of overpayments for claims having a length of stay less than 4 days, as discussed above, is merely an estimate based on the data analysis that has been conducted at this time. We are aware that, for

particular circumstances such as those patients who may require observation services, it is possible to have procedure code 96.72 reported on the claim with a length of stay less than 4 days. Although unlikely, a patient might be briefly ventilated in an extended outpatient stay following a toxic ingestion with loss of protective reflexes or following outpatient procedures with a prolonged effect of anesthesia. A subsequent conversion to an inpatient stay would cause the costs to be attributable to the stay, while the days themselves were not reported in the inpatient date span on the claim. Similar effects could occur following an observation stay for a patient on chronic home or skilled nursing facility ventilation. It is for this reason that we proposed a new edit in which claims found to have procedure code 96.72 with a length of stay less than 4 days would be returned to the provider for validation and resubmission. We indicated in the proposed rule that we would issue instructions in the form of a Change Request (CR) prior to the implementation date. We invited the public to comment on our proposal to create this edit, effective for FY 2013.

Comment: Commenters urged CMS to reconsider the proposed new edit for claims reporting procedure code 96.72 with a length of stay less than 4 days that would result in these claims being returned to the provider for validation and resubmission. Although several commenters agreed with the concept of the edit, the commenters expressed concern that the proposed process would be administratively burdensome to hospitals that may be accurately reporting the code according to established coding rules. For example, the commenters noted that coding rules allow the counting of hours a patient is on mechanical ventilation to begin from the time ventilation is initiated in the

emergency room department or upon admission. The commenters also stated that for those instances where patients may require observation services, as CMS noted in the proposed rule, it is possible that procedure code 96.72 can be reported on a claim with a length of stay less than 4 days. These commenters recommended that CMS work with the Medicare administrative contractors (MACs) to develop a less burdensome process for providers to implement this edit.

Response: We appreciate and acknowledge the commenters' concerns. In developing systems requirements, we will continue to work with MACs. Recent programming enhancements now allow the use of data fields that were not previously available for claims processing. We believe that these enhancements will eliminate the concern regarding additional administrative burden to hospitals.

After consideration of the public comments received, for FY 2013, we are finalizing our proposal to make a change to the MCE edits to include the creation of a new length of stay edit for procedure code 96.72 when reported on a claim with a length of stay less than 4 days. Detailed instructions will be issued in a future Change Request (CR) prior to the implementation date.

b. Sleeve Gastrectomy Procedure for Morbid Obesity

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51539 through 51541), we discussed the issue of sleeve gastrectomy procedures for morbid obesity under the section of the rule titled "MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)" as well as under the section for "Medicare Code Editor (MCE) Changes." We refer the reader to these sections for additional details and background information.

Effective October 1, 2011, procedure code 43.82 (Laparoscopic vertical (sleeve) gastrectomy) was created and designated as a noncoverage procedure in the Medicare Code Editor. A Decision Memo related to Bariatric Surgery for the Treatment of Morbid Obesity was issued effective June 27, 2012, which describes a change in coverage to Medicare beneficiaries for this procedure. Information related to this decision memo can be located at the following CMS Web page: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=258&fromdb=true.

As this noncovered procedure edit for procedure code 43.82 is no longer valid, we are removing it from the MCE for FY 2013. Instructions in the form of a Change Request will be issued prior to October 1, 2012. In addition, updates to the Medicare National Coverage Determinations Manual, Section 100.1, Nationally Noncovered Indications for Bariatric Surgery for Treatment of Morbid Obesity, will be revised to reflect this change in coverage.

6. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS-DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS-DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS-DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of MS-DRG reclassification and recalibrations, for FY 2013, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS-DRGs. For example, in MDC 11, the surgical class "kidney transplant" consists of a single MS-DRG (MS-DRG 652) and the class "major bladder procedures" consists of three MS-DRGs (MS-DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS-DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS-DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS-DRGs 001 and 002 and surgical class B includes MS-DRGs 003, 004, and 005. Assume also that the average

costs of MS-DRG 001 are higher than that of MS-DRG 003, but the average costs of MS-DRGs 004 and 005 are higher than the average costs of MS-DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS-DRG in the class by frequency (that is, by the number of cases in the MS-DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of "other O.R. procedures" as discussed below.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS-DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the "other O.R. procedures" surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS-DRG or MS-DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The "other O.R. procedures" class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients in the MDC with

these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

In the FY 2013 IPPS/LTCH PPS proposed rule, we proposed limited changes to the MS-DRG classifications for FY 2013, as discussed in sections II.G.1. and 4. of this preamble. In our review of these proposed changes, we did not identify any needed changes to the surgical hierarchy. Therefore, in the proposed rule (77 FR 27906), we did not propose any changes to the surgical hierarchy for Pre-MDCs and MDCs for FY 2013.

Comment: Several commenters stated that our proposal to make no changes to the surgical hierarchy seems reasonable, given the data and information provided.

Response: Based on these public comments and our review of the proposal to make no revisions to the surgical hierarchy using the March 2012 update of the FY 2011 MedPAR file and the revised GROUPER software, we found that the proposal to make no revisions is still supported by the data. Therefore, in this final rule, we are making no changes to the surgical hierarchy for FY 2013.

7. Complications or Comorbidity (CC) Exclusions List

a. Background

Under the IPPS MS-DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. We refer readers to section II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS-DRGs we adopted for FY 2008 (72 FR 47121 through 47152).

b. CC Exclusions List for FY 2013

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) to preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. As we indicated above, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be

considered a substantial complication or comorbidity. In previous years, we have made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another.
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions

and to remove diagnoses from the master list that have been shown not to meet the definition of a CC.[13]

(1) No Revisions Based on Changes to the ICD-9-CM Diagnosis Codes for FY 2013

For FY 2013, we did not propose to make any revisions to the CC Exclusions List. There were no changes made to the ICD-9-CM coding system, effective October 1, 2012, due to the partial code freeze. (We refer readers to section II.G.9. of the preamble of this final rule for a discussion of the ICD-9-CM coding system.)

(2) Suggested Changes to the MS-DRG Severity Levels for Diagnosis Codes for FY 2013

(A) Protein-Calorie Malnutrition

We received a request that we consider changing the severity levels for the following protein-calorie malnutrition diagnosis codes:

- 263.0 (Malnutrition of moderate degree)
- 263.1 (Malnutrition of mild degree)
- 263.9 (Unspecified protein-calorie malnutrition)

---

[13] See the FY 1989 final rule (53 FR 38485, September 30, 1988), for the revision made for the discharges occurring in FY 1989; the FY 1990 final rule (54 FR 36552, September 1, 1989), for the FY 1990 revision; the FY 1991 final rule (55 FR 36126, September 4, 1990), for the FY 1991 revision; the FY 1992 final rule (56 FR 43209, August 30, 1991) for the FY 1992 revision; the FY 1993 final rule (57 FR 39753, September 1, 1992), for the FY 1993 revision; the FY 1994 final rule (58 FR 46278, September 1, 1993), for the FY 1994 revisions; the FY 1995 final rule (59 FR 45334, September 1, 1994), for the FY 1995 revisions; the FY 1996 final rule (60 FR 45782, September 1, 1995), for the FY 1996 revisions; the FY 1997 final rule (61 FR 46171, August 30, 1996), for the FY 1997 revisions; the FY 1998 final rule (62 FR 45966, August 29, 1997) for the FY 1998 revisions; the FY 1999 final rule (63 FR 40954, July 31, 1998), for the FY 1999 revisions; the FY 2001 final rule (65 FR 47064, August 1, 2000), for the FY 2001 revisions; the FY 2002 final rule (66 FR 39851, August 1, 2001), for the FY 2002 revisions; the FY 2003 final rule (67 FR 49998, August 1, 2002), for the FY 2003 revisions; the FY 2004 final rule (68 FR 45364, August 1, 2003), for the FY 2004 revisions; the FY 2005 final rule (69 FR 49848, August 11, 2004), for the FY 2005 revisions; the FY 2006 final rule (70 FR 47640, August 12, 2005), for the FY 2006 revisions; the FY 2007 final rule (71 FR 47870) for the FY 2007 revisions; the FY 2008 final rule (72 FR 47130) for the FY 2008 revisions, the FY 2009 final rule (73 FR 48510), the FY 2010 final rule (74 FR 43799); the FY 2011 final rule (75 FR 50114); and the FY 2012 final rule (76 FR 51542). In the FY 2000 final rule (64 FR 41490, July 30, 1999, we did not modify the CC Exclusions List because we did not make any changes to the ICD-9-CM codes for FY 2000.

It was suggested that we change the severity level for diagnosis codes 263.0 and 263.1 from a non-CC to a CC, while changing the severity level for diagnosis code 263.9 from a CC to a non-CC. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). We indicated that we considered this comment outside of the scope of the proposed rule, as we did not propose any severity level changes to these codes for FY 2012, and did not address it in the final rule. However, we addressed this issue in the FY 2013 proposed rule (77 FR 27907 through 27908) and are finalizing our policy in this final rule.

For the proposed rule, we analyzed the claims data in the FY 2011 MedPAR file for diagnosis codes 263.0, 263.1, and 263.9. We used the same approach we used in initially creating the MS-DRGs and classifying secondary diagnosis codes as non-CCs, CCs, or MCCs. A detailed discussion of the process and criteria we used in this process is described in the FY 2008 IPPS final rule with comment period (72 FR 47158 through 47161). We refer the readers to this discussion for complete information on our approach to developing the non-CC, CC, and MCC lists. Each diagnosis for which Medicare data were available was evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average cost for each subset of cases was compared to the expected cost for cases in that subset. The following format was used to evaluate each diagnosis:

Code	Diagnosis	Cnt1	C1	Cnt2	C2	Cnt3	C3

Count (Cnt) is the number of patients in each subset. C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average cost across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is an MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is an MCC. A value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a non-CC. A value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. For additional details on this analysis, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47158 through 47161).

The following chart shows the analysis for each of the protein-calorie malnutrition diagnosis codes:

Code	Diagnosis Description	CC Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
263.0	Malnutrition of moderate degree	Non-CC	6,040	2.14	21,383	2.61	21,635	3.20
263.1	Malnutrition of mild degree	Non-CC	4,139	2.22	11,598	2.50	8,921	3.13
263.9	Unspecified protein-calorie malnutrition	CC	2,737	2.16	165,825	2.54	178,044	3.34

We ran the following data as described in the FY 2008 IPPS final rule with comment period (72 FR 47158 through 47161). The C1 value reflects a patient with no

other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is an MCC.

The chart above shows that the C1 findings ranged from a low of 2.14 to a high of 2.22. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 findings suggest that these codes are more like a CC than a non-CC. The C2 findings ranged from 2.50 to 2.61. A value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. The C2 findings of 2.50 for diagnosis code 263.1 and 2.54 for diagnosis code 263.9 suggest these codes are more similar to a CC than a non-CC, while the finding of 2.61 for diagnosis code 263.0 is borderline more similar to an MCC than a CC or non-CC when there is at least one other secondary diagnosis code that is a CC but none that is an MCC.

CC conditions typically have a C1 value over 1.75, a C2 value under 2.5, and a C3 value under 3.2. MCC conditions typically have a C1 value over 2.4, a C2 value over 2.8, and a C3 value over 3.3. We concluded that diagnosis code 263.0 is more similar to a CC than an MCC.

Therefore, the C1 and C2 findings support changing diagnosis codes 263.0 and 263.1 from a non-CC to a CC and maintaining code 263.9 as a CC. Our clinical advisors

reviewed this issue and are in support of these findings that these conditions are more appropriately classified as CCs. Based on the data and clinical analysis, we proposed for FY 2013 to change diagnosis codes 263.0 and 263.1 from a non-CC to a CC. We did not propose any change to the severity level for diagnosis code 263.9. We invited public comment on our proposals.

Comment: Several commenters supported our proposal to change the severity level for codes 263.0 and 263.1 from a non-CC to a CC and to maintain the severity level of code 263.9 as a CC. Several commenters stated that the proposal seems reasonable, given the data and information provided. Some commenters expressed appreciation for CMS' recognition of the increased costs of care associated with these conditions and support efforts to more accurately reflect its impact.

Response: We appreciate the support of the commenters.

After consideration of the public comments we received, we are finalizing our proposal to change diagnosis codes 263.0 and 263.1 from a non-CC to a CC and to maintain the severity level of a CC for diagnosis code 263.9 for FY 2013.

(B) Antineoplastic Chemotherapy Induced Anemia

We received a request from a commenter that the severity level for diagnosis code 285.3 (Antineoplastic chemotherapy induced anemia) be changed from a non-CC to a CC. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). In that rule, we indicated that we considered this comment outside of the scope of the proposed rule because we did not propose any severity level

changes to diagnosis code 285.3 for FY 2012; therefore, we did not address the issue in the final rule. However, we addressed this issue in the FY 2013 proposed rule and are finalizing our policy in this final rule. For the proposed rule, we examined claims data in the FY 2011 MedPAR file for diagnosis code 285.3 according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis Description	CC level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
285.3	Antineoplastic chemotherapy induced anemia	Non-CC	1,937	1.36	11,858	2.21	6,036	3.11

As discussed above, a value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a non-CC. A value of close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 finding for diagnosis code 285.3 of 1.36 supports the current severity level of a non-CC. The C2 finding of 2.21 for diagnosis code 285.3 suggests that this code is more similar to a CC than a non-CC but not as significant as an MCC when there is at least one other secondary diagnosis code that is a CC. CC conditions typically have a C1 value over 1.75, a C2 value under 2.5, and a C3 value under 3.2.

Therefore, the C1 and C2 findings do not support changing the severity level for diagnosis code 285.3 to a CC. In addition, our clinical advisors reviewed this issue and support the decision not to change the severity level for diagnosis code 285.3 because the anemia is inherent in the treatment of cancer and does not qualify as a CC. As a result of our data analysis as well as the advice of our clinical advisors, we did not propose any change to the severity level for diagnosis code 285.3 for FY 2013. We invited public comment on our proposal.

Comment: Several commenters stated that our proposal to maintain the severity level of a non-CC for code 285.3 seems reasonable, given the data and information provided.

Response: We appreciate the support of the commenters for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to not change the severity level for diagnosis code 285.3 for FY 2013.

(C) Cardiomyopathy and Congestive Heart Failure, Unspecified

We received a comment that recommended changes to the severity levels for the cardiomyopathy and congestive heart failure, unspecified codes. The commenter recommended that cardiomyopathy codes, which are currently classified as CCs, be changed to non-CCs and diagnosis code 428.0 (Congestive heart failure, unspecified) be changed from a non-CC to a CC. According to the commenter, these recommended changes would better represent the resources utilized in caring for this population and reduce the administrative burden in clarifying these diagnoses with providers. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). We indicated that we considered this comment outside of the scope of the proposed rule because we did not propose any severity level changes to these codes for FY 2012; therefore, we did not address it in the final rule. However, we addressed this issue in the FY 2013 proposed rule and are finalizing our policy in this final rule.

The commenter did not provide a list of the cardiomyopathy codes. We identified the following codes for analysis of the claims data in the FY 2011 MedPAR file:

- 425.4 (Other primary cardiomyopathies)
- 425.5 (Alcoholic cardiomyopathy)
- 425.7 (Nutritional and metabolic cardiomyopathy)
- 425.8 (Cardiomyopathy in other diseases classified elsewhere)
- 425.9 (Secondary cardiomyopathy, unspecified)
- 428.0 (Congestive heart failure, unspecified)

We did not include diagnosis codes 425.11 (Hypertrophic obstructive cardiomyopathy) and 425.18 (Other hypertrophic cardiomyopathy) for our analysis because these two codes were created in FY 2012 and the data are not yet available. We examined claims data according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis Description	CC Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
425.4	Other primary cardiomyopathies	CC	39,489	1.47	243,719	2.18	139,689	3.20
425.5	Alcoholic cardiomyopathy	CC	438	1.68	2,643	2.19	1,670	3.26
425.7	Nutritional and metabolic cardiomyopathy	CC	60	1.18	869	2.17	799	3.14
425.8	Cardiomyopathy in other diseases classified elsewhere	CC	940	1.19	5,967	2.15	5,171	3.14
425.9	Secondary cardiomyopathy, unspecified	CC	356	1.56	2,078	2.07	1.372	3.22
428.0	Congestive heart failure, unspecified	Non-CC	304,963	1.40	634,241	2.16	748,649	3.06

The table above shows that the C1 findings for the cardiomyopathy codes ranged from a low of 1.18 to a high of 1.68. A value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a non-CC. A value of close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 findings suggest that the majority of these cardiomyopathy

codes are more similar to a non-CC than a CC. The C2 findings ranged from a low of 2.07 to a high of 2.19. These findings suggest that these cardiomyopathy codes are more similar to a CC.

The C1 finding for diagnosis code 428.0 of 1.40 suggests that the condition is more similar to a non-CC than a CC. The C2 finding for diagnosis code 428.0 of 2.16 suggests that the secondary diagnosis is more similar to a CC than a non-CC.

The data are mixed between the C1 and C2 findings for the cardiomyopathy codes and do not consistently support a change in the severity level. Our clinical advisors reviewed these issues and are not in support of proposing any changes to the severity levels for these codes. Our clinical advisors stated that the diagnosis of cardiomyopathy (diagnosis codes 425.4 through 425.9) is generally severe, with significant impact on the patient requiring additional monitoring resources and cognitive effort, and is appropriately classified as a CC.

The data are mixed between the C1 and C2 findings for the congestive heart failure, unspecified, diagnosis code 428.0. Our clinical advisors reviewed these issues and are not in support of proposing any changes to the severity level of code 428.0. They indicated that diagnosis code 428.0 is very nonspecific and does not identify the severity of the heart failure, and concluded that the current classification for code 428.0 as a non-CC is appropriate. As a result of our data analysis and clinical advisors' review of these issues, we did not propose any changes to the severity level for the cardiomyopathy and congestive heart failure, unspecified codes for FY 2013. We invited public comment on our proposal.

Comment: Several commenters stated that our proposal to make no changes to the severity level for cardiomyopathy and congestive heart failure, unspecified codes seems reasonable, given the data and information provided.

Response: We appreciate the support of the commenters for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current severity level for cardiomyopathy and congestive heart failure, unspecified codes for FY 2013.

(D) Chronic Total Occlusion of Artery of the Extremities

We received a request to change the severity level designation for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities) to a CC. Currently, the diagnosis code is classified as a non-CC. Chronic total occlusion of artery of the extremities forms when plaque accumulates in an artery over an extended period of time, resulting in total cessation of blood flow. We analyzed claims data in the FY 2011 MedPAR file for this diagnosis code according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis Description	CC Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
440.4	Chronic total occlusion of artery of the extremities	Non-CC	8,439	1.38	8,057	2.70	5,366	3.23

The C1 finding of 1.38 for diagnosis code 440.4 supports the current designation of this diagnosis code as a non-CC. However, the C2 findings of 2.70 suggests that this code is similar to a CC or perhaps an MCC, as this value is near to 3.0, which suggests

that this condition is similar to an MCC. However, we would expect a higher C1 value such as 2.4 for this condition to qualify as an MCC.

The C1 and C2 findings support changing diagnosis code 440.4 from a non-CC to a CC. Our clinical advisors reviewed this issue and are in support of changing the severity level because this condition behaves as a CC. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to change the severity level for diagnosis code 440.4 from a non-CC to a CC for FY 2013. We invited public comment on our proposal.

Comment: Several commenters supported our proposed change to the severity level from a non-CC to a CC for code 440.4. Several commenters stated that the proposal seems reasonable, given the data and information provided.

One commenter stated that crossing a stenotic occlusive lesion typically requires manipulation of the guidewire with a single catheter that remains in the vessel lumen. In contrast, crossing a chronic total occlusion typically requires multiple wires and catheters whereby the wire leaves the vessel lumen, dissects through the subintimal plane around the occlusive lesion, and then must be manipulated back into the true outflow lumen. According to the commenter, the additional time, intensity of work, and resources necessary to perform an endovascular revascularization of a chronic total occlusion justify the proposed increase in severity level.

Response: We appreciate the support of the commenters for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to change the severity level for diagnosis code 440.4 from a non-CC to a CC for FY 2013.

(E) Acute Kidney Failure with Other Specific Pathological Lesion in Kidney

We received a request to consider changing the severity level for diagnosis code 584.8 (Acute kidney failure with other specified pathological lesion in kidney). This diagnosis code's severity level is currently classified as an MCC. We examined claims data for this code in the FY 2011 MedPAR file according to the approach described above. The following table illustrates those findings.

Code	Diagnosis Description	Severity Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
584.8	Acute kidney failure with other specified pathological lesion in kidney	MCC	12	0.98	13	1.89	1,350	3.17

As discussed above, a C1 value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a diagnosis code that has been classified as a non-CC. A value close to 2.0 in the C1 field suggests that the condition is more similar to a CC severity level than a non-CC severity level, but not as significant in resource usage as an MCC severity level. In this case, the C1 value finding for diagnosis code 584.8 of 0.98 suggests that this diagnosis code is more similar to a non-CC than an MCC. A C2 value close to 3.0 suggests that the condition is more similar to an MCC than a CC or a non-CC. A C2 value close to 2.0 suggests that the condition is more similar to a CC than a non-CC. The C2 value finding for diagnosis code 584.8 of 1.89

supports classifying the severity level of this diagnosis code as a CC. Therefore, the C1 and C2 value findings support changing the severity level of diagnosis code 584.8 from an MCC to a lower severity level, that is, a CC. Our clinical advisors reviewed this issue and stated that this condition behaves as a CC. Therefore, they supported changing the severity level of this diagnosis code to a CC. Based on the clinical analysis and consistent with supporting claims data, we believe that the severity level of diagnosis code 584.8 should be changed from an MCC to a CC. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to change the severity level of diagnosis code 584.8 from an MCC to a CC for FY 2013. We invited public comment on our proposal.

Comment: Commenters stated CMS' proposed change to the severity level of diagnosis code 584.8 from an MCC to a CC was reasonable, given the data and information provided.

Response: We appreciate the support of the commenters for our proposal.

Comment: One commenter opposed the proposal to change the severity level of diagnosis code 584.8 from an MCC to a CC. The commenter stated that this downgrade penalizes hospitals willing to take on sicker patients because additional care is required to treat patients with this condition. The commenter stated that this change would also hurt hospitals whose clinical documentation staff, in conjunction with providers, perform the additional work of identifying the underlying cause of the kidney failure.

Response: Information from our claims data does not support the commenter's statement that these are sicker patients who should be classified at the MCC severity

level. As discussed above, our claims data suggests that code 584.8 is more appropriately classified as a CC. The C1 finding of 0.98 suggests that this code is more like a non-CC than an MCC. The C2 finding of 1.89 supports classifying this code as either a non-CC or CC. Therefore, the C1 and C2 findings support changing code 584.8 from an MCC to a lower severity level. Our clinical advisors reviewed this issue and support changing the severity level of this code to a CC. Our clinical analysis and consistent claims data support changing code 584.8 from an MCC to CC.

We disagree with the commenter's statement that this severity level change would hurt hospitals whose clinical documentation staff, in conjunction with providers, perform the additional work of identifying the underlying cause of the kidney failure. CMS supports improved documentation practices by providers, which leads to better patient care. Providers should consistently work on improved clinical documentation for all patients, not just those who have a secondary diagnosis on the MCC list. We do not agree that changing the severity level of procedure code 584.8 hurts hospitals who attempt to improve the clinical document in their medical records.

After consideration of the public comments we received, we are finalizing our proposal to change the severity level of diagnosis code 584.8 from an MCC to a CC.

(F) Pressure Ulcer, Unstageable

We received a request to consider changing the severity level for diagnosis code 707.25 (Pressure ulcer, unstageable) from its current classification as a non-CC to an MCC. This issue was referred to as an out-of-scope public comment in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), but was not addressed in that rule.

For the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27910), we analyzed claims data for diagnosis code 707.25 from the FY 2011 MedPAR file according to the process and approach described above. The following table illustrates our findings:

Code	Diagnosis Description	CC Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
707.25	Pressure ulcer, unstageable	Non-CC	1,839	1.87	7,161	2.46	13,285	3.08

As discussed above, a C1 value close to 2.0 suggests the condition is more similar to a CC than a non-CC severity level but not as significant in resource usage as an MCC. The C1 value finding of 1.87 for diagnosis code 707.25, which is near but not that close to a 2.0, suggests that this code is more similar to a CC than an MCC. A C2 value of close to 3.0 suggests the condition is more similar to an MCC than a CC or non-CC. The C2 value finding for diagnosis code 707.25 is 2.46, which is not close to 3.0 and, therefore, the data do not support classifying this as an MCC. The C1 and C2 findings are more supportive of a classification as a CC than an MCC. There is another problem with this request to change diagnosis code 707.25 from a non-CC to an MCC. Currently, only stages III and IV pressure ulcers are MCCs. This unstageable code captures a pressure ulcer whose stage has not been determined. It would be inappropriate to assume that a pressure ulcer reported with diagnosis code 707.25 might be a stage III or IV pressure ulcer. Our claims data C1 and C2 findings do not support the fact that this code acts as an MCC. As mentioned earlier, the claims data are more supportive of a classification as a CC than an MCC. We asked our clinical advisors to review this issue. Our clinical advisors agree that the data findings and their own clinical evaluation support not changing the severity level of this diagnosis code to a CC or an MCC. Our clinical advisors recommend that unstageable pressure ulcers should continue to be

classified as a non-CC because the stage is not clearly designated as a stage III or IV. Unstageable codes do not delineate what the stage of the ulcer might be. As a result of our data analysis as well as the advice of our clinical advisors, we believe that unstageable pressure ulcers should continue to be classified as a non-CC. Therefore, we proposed that diagnosis code 707.25 remain a non-CC for FY 2013.

We invited public comment on our proposal not to change the severity level for diagnosis code 707.25 for FY 2013.

Comment: Several commenters supported our proposal not to change the severity level for diagnosis code 707.25. The commenters stated the proposal seems reasonable, given the data and information provided.

Response: We appreciate the support of the commenters.

Comment: One commenter questioned whether a "not examined ulcer" would be classified the same as unstageable. The commenter stated that an ulcer should not be classified as unstageable simply because it was not examined.

Response: If a pressure ulcer is documented in the medical record and the stage is unspecified, code 707.20 (Pressure ulcer, unspecified stage) would be assigned.

Comment: Some commenters did not support our proposal. The commenters pointed out that the National Pressure Ulcer Advisory Panel defines unstageable pressure ulcers as at least a stage III pressure ulcer and suggested that the resource expenditures associated with treating this condition would meet the definition of an MCC. Another commenter recommended that the severity level for code 707.25 be changed to a CC.

Response: Based on the data and our analysis presented above, we concluded that diagnosis code 707.25 did not warrant a change to the severity level. Our clinical advisors recommend that unstageable pressure ulcers should continue to be classified as a non-CC because the stage is not clearly designated as a stage III or IV. Without knowing the stage of the ulcer, an assumption should not be made.

After consideration of the public comments we received, we are finalizing our proposal to not change the severity level for code 707.25 for FY 2013.

For FY 2013, we proposed changes to Table 6G (Additions to the CC Exclusion List). As we discussed earlier, we are finalizing our proposed changes to the severity level for diagnosis codes 263.0, 263.1, and 440.4 from a non-CC to a CC. There are no proposed and finalized changes to Table 6H (Deletions to the CC Exclusion List). These tables, which contain codes that are effective for discharges occurring on or after October 1, 2012, are not being published in the Addendum to this final rule because of the length of the two tables. Instead, we are making them available through the Internet on the CMS Web site at: http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. Each of these principal diagnosis for which there is a CC exclusion is shown in Tables 6G and 6H with an asterisk, and the conditions that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis.

A complete updated MCC, CC, and Non-CC Exclusions List is available through the Internet on the CMS Web site at: http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. Beginning with discharges on or

after October 1, 2011, the indented diagnoses were not recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

To assist readers in identifying the changes to the MCC and CC lists that occur as a result of our review of severity levels for several ICD-9-CM diagnosis codes, we are providing the following summaries of those MCC and CC changes for FY 2013. There are no new, revised, or deleted diagnosis codes for FY 2013. Therefore, there are no Tables 6A, 6C, and 6E published for FY 2013.

SUMMARY OF ADDITIONS TO THE MS-DRG MCC LIST--TABLE 6I.1

There are no additions to the MS-DRG MCC List**.**

SUMMARY OF DELETIONS FROM THE MS-DRG MCC LIST--TABLE 6I.2

Code	Description
584.8	Acute kidney failure with other specified pathological lesion in kidney

SUMMARY OF ADDITIONS TO THE MS-DRG CC LIST--TABLE 6J.1

Code	Description
263.0	Malnutrition of moderate degree
263.1	Malnutrition of mild degree
440.4	Chronic total occlusion of artery of the extremities
584.8	Acute kidney failure with other specified pathological lesion in kidney

SUMMARY OF DELETIONS FROM THE MS-DRG CC LIST--TABLE 6J.2

There are no deletions from the MS-DRG CC list.

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the

GROUPER program. The current MS-DRG Definitions Manual, Version 29.0, is available on a CD for $225.00. Version 30.0 of this manual, which will include the final FY 2013 MS-DRG changes, will be available on a CD for $225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949-0303, or by obtaining an order form at the Web site: http://www.3MHIS.com. Please specify the revision or revisions requested.

8. Review of Procedure Codes in MS DRGs 981 through 983; 984 through 986; and 987 through 989

Each year, we review cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS-DRGs that we adopted for FY 2008, CMS DRG 468 was split three ways and became MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS-DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS-DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

MS-DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly CMS DRGs 468, 476, and 477, respectively) are reserved for those cases in which none

of the O.R. procedures performed are related to the principal diagnosis. These MS-DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. MS-DRGs 984 through 986 (previously CMS DRG 476) are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0, Incision of prostate
- 60.12, Open biopsy of prostate
- 60.15, Biopsy of periprostatic tissue
- 60.18, Other diagnostic procedures on prostate and periprostatic tissue
- 60.21, Transurethral prostatectomy
- 60.29, Other transurethral prostatectomy
- 60.61, Local excision of lesion of prostate
- 60.69, Prostatectomy, not elsewhere classified
- 60.81, Incision of periprostatic tissue
- 60.82, Excision of periprostatic tissue
- 60.93, Repair of prostate
- 60.94, Control of (postoperative) hemorrhage of prostate
- 60.95, Transurethral balloon dilation of the prostatic urethra
- 60.96, Transurethral destruction of prostate tissue by microwave thermotherapy
- 60.97, Other transurethral destruction of prostate tissue by other thermotherapy
- 60.99, Other operations on prostate

All remaining O.R. procedures are assigned to MS-DRGs 981 through 983 and 987 through 989, with MS-DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.[14]

Our review of MedPAR claims data showed that there were no cases that merited movement or should logically be assigned to any of the other MDCs. Therefore, for FY 2013, we did not propose to change the procedures assigned among these MS-DRGs.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are not making any changes to the procedures assigned to MS-DRGs 981 through 983, MS-DRGs 984 through 986, and MS-DRGs 987 through 989 for FY 2013.

a. Moving Procedure Codes from MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into MDCs

We annually conduct a review of procedures producing assignment to MS-DRGs 981 through 983 (Extensive O.R. procedure unrelated to principal diagnosis with MCC,

[14]The original list of the ICD-9-CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the FY 1989 final rule (53 FR 38591). As part of the FY 1991 final rule (55 FR 36135), the FY 1992 final rule (56 FR 43212), the FY 1993 final rule (57 FR 23625), the FY 1994 final rule (58 FR 46279), the FY 1995 final rule (59 FR 45336), the FY 1996 final rule (60 FR 45783), the FY 1997 final rule (61 FR 46173), and the FY 1998 final rule (62 FR 45981), we moved several other procedures from DRG 468 to DRG 477, and some procedures from DRG 477 to DRG 468. No procedures were moved in FY 1999, as noted in the final rule (63 FR 40962); in FY 2000 (64 FR 41496); in FY 2001 (65 FR 47064); or in FY 2002 (66 FR 39852). In the FY 2003 final rule (67 FR 49999) we did not move any procedures from DRG 477. However, we did move procedure codes from DRG 468 and placed them in more clinically coherent DRGs. In the FY 2004 final rule (68 FR 45365), we moved several procedures from DRG 468 to DRGs 476 and 477 because the procedures are nonextensive. In the FY 2005 final rule (69 FR 48950), we moved one procedure from DRG 468 to 477. In addition, we added several existing procedures to DRGs 476 and 477. In the FY 2006 (70 FR 47317), we moved one procedure from DRG 468 and assigned it to DRG 477. In FY 2007, we moved one procedure from DRG 468 and assigned it to DRGs 479, 553, and 554. In FYs 2008, 2009, FY 2010, FY 2011 and FY 2012, no procedures were moved, as noted in the FY 2008 final rule with comment period (72 FR 46241), the FY 2009 final rule (73 FR 48513), the FY 2010 final rule (74 FR 43796); the FY 2011 final rule (75 FR 50122); and the FY 2012 final rule (76 FR 51549).

with CC, and without CC/MCC, respectively) or MS-DRGs 987 through 989 (Nonextensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS-DRGs into one of the surgical MS-DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS-DRGs for the MDC in which the diagnosis falls. As noted above, there were no cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2013, we did not propose to remove any procedures from MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into one of the surgical MS-DRGs for the MDC into which the principal diagnosis is assigned.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are not making any changes to the procedures assigned to MS-DRGs 981 through 983 or MS-DRGs 987 through 989 for FY 2013.

b. Reassignment of Procedures among MS-DRGs 981 through 983, 984 through 986, and 987 through 989

We also annually review the list of ICD-9-CM procedures that, when in combination with their principal diagnosis code, result in assignment to MS-DRGs 981

through 983, 984 through 986 (Prostatic O.R. procedure unrelated to principal diagnosis with MCC, with CC, or without CC/MCC, respectively), and 987 through 989, to ascertain whether any of those procedures should be reassigned from one of these three MS-DRGs to another of the three MS-DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS-DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS-DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

There were no cases representing shifts in treatment practice or reporting practice that would make the resulting MS-DRG assignment illogical, or that merited movement so that cases should logically be assigned to any of the other MDCs. Therefore, for FY 2013, we did not propose to move any procedure codes among these MS-DRGs.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are not moving any procedures assigned to MS-DRGs 981 through 983, MS-DRGs 984 through 986, and MS-DRGs 987 through 989 for FY 2013.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs as described above in sections II.G.1. through 4. of this preamble, we did not propose to add any diagnosis or procedure codes to MDCs for FY 2013. We did not receive any public comments on our proposal. Therefore, as we proposed, we are not adding any diagnosis or procedure codes to MDCs for FY 2013.

9. Changes to the ICD-9-CM Coding System, Including Discussion of the Replacement of the ICD-9-CM Coding System with the ICD-10-CM and ICD-10-PCS Systems in FY 2014

a. ICD-9-CM Coding System

The ICD-9-CM is a coding system currently used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD-9-CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD-9-CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD-9-CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The Official Version of the ICD-9-CM contains the list of valid diagnosis and procedure codes. (The Official Version of the ICD-9-CM is available from the Government Printing Office on CD-ROM for $29.00 by calling (202) 512-1800.) Complete information on ordering the CD-ROM is also available at: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/05CDROM.asp#TopOfPage. The Official Version of the ICD-9-CM is no longer available in printed manual form

from the Federal Government; it is only available on CD-ROM. Users who need a paper version are referred to one of the many products available from publishing houses.

The NCHS has lead responsibility for the ICD-9-CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD-9-CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2013 at a public meeting held on September 14, 2011 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 18, 2011.

The Committee held its 2012 meeting on March 5, 2012. New codes for which there was consensus of public support and for which complete tabular and indexing

changes were made by May 2012 are included in the October 1, 2012 update to ICD-9-CM. Code revisions that were discussed at the March 5, 2012 Committee meeting but that could not be finalized in time to include them in the tables listed in section VI. of the Addendum to the proposed rule are included in Table 6B which is listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site, and are marked with an asterisk (*).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27912), we stated that, for FY 2013, there were no changes to the ICD-9-CM coding system due to the partial code freeze or for new technology. However, at the March 5, 2012 meeting there was a request for a code for a new technology. As discussed below, only codes for new technologies or new diagnoses are being considered during the partial code freeze. After discussions at the meeting and public comment received after the meeting, it was decided that there will be one new procedure code effective October 1, 2012: new code 00.95 (Injection or infusion of glucarpidase).

Therefore, there are no new, revised, or deleted diagnosis codes and no revised or deleted procedure codes that are usually announced in Tables 6A (New Diagnosis Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles), and 6F (Revised Procedure Codes). The new procedure code is listed in Table 6B (New Procedure Codes) for this final rule, which is available via the Internet on the CMS Web site.

Copies of the minutes of the procedure codes discussions at the Committee's September 14, 2011 meeting and March 5, 2012 meeting can be obtained from the CMS

Web site at:

http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp. The minutes of the diagnosis codes discussions at the September 14, 2011 meeting and March 5, 2012 meeting are found at: http://www.cdc.gov/nchs/icd.htm. These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD-9-CM Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by E-mail to: dfp4@cdc.gov.

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson, ICD-9-CM Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4-08-06, 7500 Security Boulevard, Baltimore, MD 21244-1850. Comments may be sent by E-mail to: patricia.brooks2@cms.hhs.gov.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Pub. L. 108-173 included a requirement for updating ICD-9-CM codes twice a year instead of a single update on October 1 of each year. This

requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the "Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) . . . until the fiscal year that begins after such date." This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD-9-CM Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the ICD-9-CM Coordination and Maintenance Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and

research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. The public decides whether or not to attend the meeting based on the topics listed on the agenda. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all changes to ICD-9-CM, both tabular and index, is published on the CMS and NCHS Web sites in May of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4-5, 2005 ICD-9-CM Coordination and Maintenance Committee minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Pub. L. 108-173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these

determinations. Topics considered during the Fall ICD-9-CM Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April l, 2012 implementation of an ICD-9-CM code at the September 14, 2011 Committee meeting. Therefore, there were no new ICD-9-CM codes implemented on April 1, 2012.

Current addendum and code title information is published on the CMS Web site at: http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage. Information on ICD-9-CM diagnosis codes, along with the Official ICD-9-CM Coding Guidelines, can be found on the Web site at: http://www.cdc.gov/nchs/icd9.htm. Information on new, revised, and deleted ICD-9-CM codes is also provided to the AHA for publication in the Coding Clinic for ICD-9-CM. AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD-9-CM coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

These same means of disseminating information on new, revised, and deleted ICD-9-CM codes will be used to notify providers, publishers, software vendors, contractors, and others of any changes to the ICD-9-CM codes that are implemented in April. The code titles are adopted as part of the ICD-9-CM Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We will continue to publish the October code updates in this manner within the IPPS proposed and final rules. For codes that are implemented in April, we will assign the new procedure code to the same MS-DRG in which its predecessor code was assigned so there will be no MS-DRG impact as far as MS-DRG assignment. Any midyear coding updates will be available through the Web sites indicated above and through the Coding Clinic for ICD-9-CM. Publishers and software vendors currently obtain code changes through these sources in order to update their code books and software systems. We will strive to have the April 1 updates available through these Web sites 5 months prior to implementation (that is, early November of the previous year), as is the case for the October 1 updates.

b. Code Freeze

The International Classification of Diseases, 10th Revision (ICD-10) coding system applicable to hospital inpatient services is to be implemented on October 1, 2013, as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS final rule (74 FR 3328 through 3362,

January 16, 2009). However, the Secretary of Health and Human Services issued a proposed rule that would delay, from October 1, 2013, to October 1, 2014, the compliance date for the International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD-10). The proposed rule, CMS-0040-P, went on display at the Office of the Federal Register on April 9, 2012, and was published in the **Federal Register** on April 17, 2012 (77 FR 22950) and is available for viewing at: http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR.

The ICD-10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding, as well as the Official ICD-10-CM and ICM-10-PCS Guidelines for Coding and Reporting. In the January 16, 2009 ICD-10-CM and ICD-10-PCS final rule (74 FR 3328 through 3362), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD-9-CM and ICD-10-CM and ICD-10-PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease l year prior to the implementation of ICD-10. The commenters stated that this freeze of code updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and purchases.

HHS responded to comments in the ICD-10 final rule that the ICD-9-CM Coordination and Maintenance Committee has jurisdiction over any action impacting the

ICD-9-CM and ICD-10 code sets. Therefore, HHS indicated that the issue of consideration of a moratorium on updates to the ICD-9-CM, ICD-10-CM, and ICD-10-PCS code sets in anticipation of the adoption of ICD-10-CM and ICD-10-PCS would be addressed through the Committee at a future public meeting.

The code freeze was discussed at multiple meetings of the ICD-9-CM Coordination and Maintenance Committee and public comment was actively solicited. The Committee evaluated all comments from participants attending the Committee meetings as well as written comments that were received. There was an announcement at the September 15-16, 2010 and September 14, 2011 ICD-9-CM Coordination and Maintenance Committee meetings that a partial freeze of both ICD-9-CM and ICD-10 codes will be implemented as follows:

- The last regular annual update to both ICD-9-CM and ICD-10 code sets was made on October 1, 2011.
- On October 1, 2012, there will be only limited code updates to both ICD-9-CM and ICD-10 code sets to capture new technology and new diseases.
- On October 1, 2013, there were to be only limited code updates to ICD-10 code sets to capture new technology and diagnoses as required by section 503(a) of Pub. L. 108-173. There were to be no updates to ICD-9-CM on October 1, 2013, as the system would no longer be a HIPAA standard and, therefore, no longer be used for reporting. With the proposed ICD-10 implementation delay, there will be only limited code updates to both ICD-9-CM and ICD-10 to capture new technology and new diagnoses on October 1, 2013.

- On October 1, 2014, regular updates to ICD-10 were to begin. As stated earlier, HHS has issued a proposed rule that would delay the compliance date of ICD-10 from October 1, 2013, to October 1, 2014. If this delay is implemented as proposed, there would be only limited ICD-10 code updates for new technologies and new diseases on October 1, 2014. There would be no updates to ICD-9-CM on October 1, 2014, as the system would no longer be a HIPAA standard and, therefore, no longer be used for reporting. Full ICD-10 updates would begin on October 1, 2015, one year after the implementation of ICD-10.

The ICD-9-CM Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public will be encouraged to comment on whether or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD-10 on or after October 1, 2014, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD-9-CM Coordination and Maintenance Committee Web site at: http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03.asp#TopOfPage. A summary of the September 14, 2011 Committee meeting, along with both written and audio transcripts of this meeting, are posted on the "Download" section of this Web page.

Comment: Several commenters expressed concern about the delay in the implementation of ICD-10. Some commenters supported a delay, while others opposed any delay.

Response: Proposals on ICD-10 implementation are being addressed through a separate rulemaking as we have indicated above. These comments will be addressed as part of that separate rulemaking.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims

CMS is currently processing all 25 diagnosis codes and 25 procedure codes submitted on electronic hospital inpatient claims. Prior to January 1, 2011, hospitals could submit up to 25 diagnoses and 25 procedures; however, CMS' system limitations allowed for the processing of only the first 9 diagnosis codes and 6 procedure codes. We discussed this change in processing claims in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25843), in a correction notice issued in the **Federal Register** on June 14, 2011 (76 FR 24633), and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51553). As discussed in these prior rules, CMS undertook an expansion of our internal system capability so that we are able to process up to 25 diagnoses and 25 procedures on hospital inpatient claims as part of the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update. We recognize the value of the additional information provided by this coded data for multiple uses such as for payment, quality measures, outcome analysis,

and other important uses. We will continue to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format.

d. ICD-10 MS-DRGs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received comments on the creation of the ICD-10 version of the MS-DRGs, which will be implemented at the same time as ICD-10 (75 FR 50127 and 50128). As we stated earlier, the Secretary of Health and Human Services has issued a proposed rule that would delay the compliance date of ICD-10 from October 1, 2013 to October 1, 2014. While we did not propose an ICD-10 version of the MS-DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting our current MS-DRGs from ICD-9-CM codes to ICD-10 codes and sharing this information through the ICD-9-CM Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to go about their own conversion projects. We posted ICD-10 MS-DRGs based on Version 26.0 (FY 2009) of the MS-DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for others to follow. All of this information can be found on the CMS Web site at: http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp. We have continued to keep the public updated on our maintenance efforts for ICD-10-CM and ICD-10-PCS coding systems as well as the General Equivalence Mappings that assist in conversion through the ICD-9-CM Coordination and Maintenance Committee.

Information on these committee meetings can be found at: http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html.

During FY 2011, we developed and posted Version 28.0 of the ICD-10 MS-DRGs based on the FY 2011 MS-DRGs (Version 28.0) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD-10 MS-DRGs Version 28.0 also included the CC Exclusion List and the ICD-10 version of the hospital-acquired conditions (HACs), which was not posted with Version 26.0. We also discussed this update at the September 15-16, 2010 and the March 9-10, 2011 meetings of the ICD-9-CM Coordination and Maintenance Committee. The minutes of these two meetings are posted on the CMS Web site at: http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html.

We reviewed comments on the ICD-10 MS-DRGs Version 28.0 and made updates as a result of these comments. We called the updated version the ICD-10 MS-DRGs Version 28 R1. We posted a Definitions Manual of ICD-10 MS-DRGs Version 28 R1 on our ICD-10 MS-DRG Conversion Project Web site at: http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp. To make the review of Version 28 R1 updates easier for the public, we also made available pilot software on a CD ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD-10 MS-DRG Web page. We stated that we believed that, by providing the ICD-10 MS-DRG Version 28 R1 Pilot Software (distributed on CD ROM), the public would be able to more easily review and provide feedback on updates to the ICD-10 MS-DRGs.

We discussed the updated ICD-10 MS-DRGs Version 28 R1 at the September 14, 2011 ICD-9-CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD-10 MS-DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD-10 MS-DRGs Version 29.0, based on the FY 2012 MS-DRGs (Version 29.0) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD-10 MS-DRGs Version 29.0 on our ICD-10 MS-DRGs Web site. We also prepared a document that describes changes made from Version 28.0 to Version 29.0 to facilitate a review. The ICD-10 MS-DRGs Version 29.0 was discussed at the ICD-9-CM Coordination and Maintenance Committee meeting on March 5, 2012. Information was provided on the types of updates made. Once again the public was encouraged to review and comment on the most recent update to the ICD-10 MS-DRGs.

We provided information on a study conducted on the impact on converting MS-DRGs to ICD-10. Information on this study is summarized in a paper entitled "Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments." This paper is posted on the CMS ICD-10 MS-DRG conversion Web site at: http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp. The paper describes CMS' approach to the conversion of the MS-DRGs from ICD-9-CM codes to ICD-10 codes. The study was undertaken using the ICD-9-CM MS-DRGs Version 27.0 (FY 2010) and converted to the ICD-10 MS-DRGs Version 27.0. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across

hospitals. The paper was distributed and discussed at the September 15, 2010 ICD-9-CM Coordination and Maintenance Committee. The impact of the conversion from ICD-9-CM to ICD-10 on Medicare MS-DRG hospital payments was estimated using 2009 Medicare data. The study found a hospital payment increase of 0.05 percent using the ICD-10 MS-DRGs Version 27.0. For detailed information on this study, we refer readers to the complete report which is posted on the CMS Web site at: http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp.

CMS provided an overview of this hospital payment impact study at the March 5, 2012 ICD-9-CM Coordination and Maintenance Committee meeting. This presentation followed presentations on the creation of ICD-10 MS-DRGs Version 29.0. A summary report of this meeting can be found on the CMS Web site at: http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html. At this March 2012 meeting, CMS announced that it would produce an update on this impact study based on an updated version of the ICD-10 MS-DRGs. This update will provide additional information to the public as CMS is evaluating refinements made to the ICD-10 MS-DRGs based on public comments.

We will continue to work with the public to explain how we are approaching the conversion of MS-DRGs to ICD-10 and will post drafts of updates as they are developed for public review. The final version of the ICD-10 MS-DRGs will be implemented at the same time as ICD-10 and will be subject to notice and comment rulemaking. In the meantime, we will provide extensive and detailed information on this activity through the ICD-9-CM Coordination and Maintenance Committee.

10. Public Comments on Issues Not Addressed in the Proposed Rule

We received a number of public comments regarding MS-DRG issues that were outside of the scope of the proposals included in the FY 2013 IPPS/LTCH PPS proposed rule. We have summarized these public comments below. However, because these public comments were outside of the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.G. of this preamble, we encourage individuals with comments about MS-DRG classifications to submit these comments no later than December of each year so they can be considered for possible inclusion in the annual proposed rule and, if included, may be subjected to public review and comment. We will consider these comments for possible proposals in future rulemaking as part of our annual review process.

Some commenters requested that CMS create a new MS-DRG for total ankle replacement procedures. One commenter requested that CMS eliminate the severity levels for heart and liver transplants and implement one MS-DRG for heart transplants and one MS-DRG for liver transplants.

One commenter requested that CMS conduct an analysis of diagnosis code V45.88 (Status post administration of tPA (rt-PA) in a different facility within the last 24 hours prior to admission to current facility) to determine whether new data warrant any change in the MS-DRG structure for these cases.

One commenter recommended that bronchial valve procedures reported with ICD-9-CM procedure codes 33.71 (Endoscopic insertion or replacement of bronchial valve(s), single lobe) and 33.73 (Endoscopic insertion or replacement of bronchial

valve(s), multiple lobes), that are assigned to medical MS-DRGs 190 and 192 (Chronic Obstructive Pulmonary Disease with MCC, with CC, or without MCC/CC, respectively) be assigned instead to surgical MS-DRGs 163 and 165 (Major Chest Procedures with MCC, with CC, or without MCC/CC, respectively).

H. Recalibration of MS-DRG Weights

1. Data Sources for Developing the Weights

In developing the FY 2013 system of weights, we used two data sources: claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2011 MedPAR data used in this final rule include discharges occurring on October 1, 2010, through September 30, 2011, based on bills received by CMS through March 31, 2012, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2011 MedPAR file used in calculating the relative weights includes data for approximately 10,804,695 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR "GHO Paid" indicator field on the claim record is equal to "1" or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR "Indirect Medical Education (IME)" payment field, indicating that the claim was an "IME only" claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the

March 31, 2012 update of the FY 2011 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called "claim type." Claim type "60" indicates that the claim was an inpatient claim paid as fee-for-service. Claim types "61," "62," "63," and "64" relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2013 also excludes claims with claim type values not equal to "60." The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year (that is, for the calculation of the FY 2013 MS-DRG relative weights, we use data from the FY 2010 HCRIS, which are data from cost reports that began on or after October 1, 2009 and before October 1, 2010). However, during the development of this final rule, as was the case with the proposed rule, we have found that those cost reports in the FY 2010 HCRIS dataset with fiscal year begin dates that are on or after May 1, 2010, and before October 1, 2010, are not accessible. This is because cost reports with fiscal year begin dates of May 1, 2010, through September 30, 2010, were filed on the new cost report Form 2552-10, and cost reports filed on Form 2552-10 are not currently accessible in the HCRIS. However, because data from cost reports filed on Form 2552-10 are not currently available, to ensure that the FY 2013 MS-DRG relative weights are calculated with a dataset that is as comprehensive and accurate as possible, as we proposed, we are calculating the final FY 2013 MS-DRG relative weights with data from FY 2010 cost

reports for providers with fiscal year begin dates of on or after October 1, 2009 and before May 1, 2010, and backfilling with data from FY 2009 cost reports for those providers that have fiscal year begin dates on or after May 1, 2010 through September 30, 2010. We used cost report data from the March 31, 2012 update of the HCRIS for FY 2009 and FY 2010 in calculating the FY 2013 cost-based relative weights.

2. Methodology for Calculation of the Relative Weights

The methodology we used to calculate the FY 2013 MS-DRG cost-based relative weights based on claims data in the FY 2011 MedPAR file and data from the FY 2009 and FY 2010 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2013 MS-DRG classifications discussed in sections II.B. and G. of the preamble of this final rule.

- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS-DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2010 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)

- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each

transplant bill that showed acquisition charges before computing the average cost for each MS-DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $10.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, special equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood charges, and anesthesia charges were also deleted.

- At least 96.2 percent of the providers in the MedPAR file had charges for 10 of the 15 cost centers. Claims for providers that did not have charges greater than zero for at least 10 of the 15 cost centers were deleted.

- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS-DRG.

- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to "Y" for "Yes" for all claims that otherwise have an "N" (No) or a "U" (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the

particular condition is present on admission (that is, a "Y" indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS-DRG). If the particular condition is *not* present on admission (that is, an "N" indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS-DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Thus, if the higher charges of these HAC claims are grouped into lower severity MS-DRGs prior to the relative weight-setting process, the relative weights of these particular MS-DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS-DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to "Y" only for relative weight-setting purposes for all claims that otherwise have an "N" or a "U" in the POA field. This resetting "forced" the more costly HAC claims into the higher severity

MS-DRGs as appropriate, and the relative weights calculated for each MS-DRG more closely reflect the true costs of those cases.

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 15 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS-DRG for each of the 15 cost groups so that each MS-DRG had 15 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2009 and FY 2010 cost report data.

The 15 cost centers that we used in the relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 15 national cost center CCRs.

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_25	C_1_C6_25	D4_HOS_C2_25	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges	012X, 013X and 016X-019X								
	Ward Charges	015X								
Intensive Days	Intensive Care Charges	020X		Intensive Care Unit	C_1_C5_26	C_1_C6_26	D4_HOS_C2_26	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_27	C_1_C6_27	D4_HOS_C2_27	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Burn Intensive Care Unit	C_1_C5_28	C_1_C6_28	D4_HOS_C2_28	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
				Surgical Intensive Care Unit	C_1_C5_29	C_1_C6_29	D4_HOS_C2_29	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
				Other Special Care Unit	C_1_C5_30	C_1_C6_30	D4_HOS_C2_30	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_48	C_1_C6_48	D4_HOS_C2_48	C_1_C5_64	C_1_C6_64	D3_HOS_C2_64

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_48			C_1_C7_64	
				Drugs Charged To Patient	C_1_C5_56	C_1_C6_56	D4_HOS_C2_56	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73
						C_1_C7_56			C_1_C7_73	
Supplies and Equipment	Medical/Surgical Supply Charges	0270, 0271, 0272, 0273, 0274, 0277, and 0621, 0622, 0623		Medical Supplies Charged to Patients	C_1_C5_55	C_1_C6_55	D4_HOS_C2_55	C_1_C5_71	C_1_C6_71	D3_HOS_C2_71
						C_1_C7_55			C_1_C7_71	
		0275, 0276, 0278, 0624		Implantable Devices Charged to Patients	C_1_C5_55.30	C_1_C6_55.30	D4_HOS_C2_55.30	C_1_C5_72	C_1_C6_72	D3_HOS_C2_72
						C_1_C7_55.30			C_1_C7_72	
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299		DME-Rented	C_1_C5_66	C_1_C6_66	D4_HOS_C2_66	C_1_C5_96	C_1_C6_96	D3_HOS_C2_96

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_66			C_1_C7_96	
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_67	C_1_C6_67	D4_HOS_C2_67	C_1_C5_77	C_1_C6_97	D3_HOS_C2_97
						C_1_C7_67			C_1_C7_97	
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_50	C_1_C6_50	D4_HOS_C2_50	C_1_C5_66	C_1_C6_66	D3_HOS_C2_66
						C_1_C7_50			C_1_C7_66	
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_51	C_1_C6_51	D4_HOS_C2_51	C_1_C5_67	C_1_C6_67	D3_HOS_C2_67
						C_1_C7_51			C_1_C7_67	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_52	C_1_C6_52	D4_HOS_C2_52	C_1_C5_68	C_1_C6_68	D3_HOS_C2_68

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_52			C_1_C7_68	
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_49	C_1_C6_49	D4_HOS_C2_49	C_1_C5_65	C_1_C6_65	D3_HOS_C2_65
						C_1_C7_49			C_1_C7_65	
Operating Room	Operating Room Charges	036X		Operating Room	C_1_C5_37	C_1_C6_37	D4_HOS_C2_37	C_1_C5_50	C_1_C6_50	D3_HOS_C2_50
For all DRGs but Labor & Delivery						C_1_C7_37			C_1_C7_50	
		071X		Recovery Room	C_1_C5_38	C_1_C6_38	D4_HOS_C2_38	C_1_C5_51	C_1_C6_51	D3_HOS_C2_51
						C_1_C7_38			C_1_C7_51	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Labor & Delivery	Operating Room Charges	072X		Delivery Room and Labor Room	C_1_C5_39	C_1_C6_39	D4_HOS_C2_39	C_1_C5_52	C_1_C6_52	D3_HOS_C2_52
ONLY FOR THE 6 Labor & Delivery DRGs						C_1_C7_39			C_1_C7_52	
370, 371, 372, 373, 374, 375				Obstetrics Clinic	C_1_C5_63	C_1_C6_63	D4_HOS_C2_63	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
						C_1_C7_63			C_1_C7_93	
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_40	C_1_C6_40	D4_HOS_C2_40	C_1_C5_53	C_1_C6_53	D3_HOS_C2_53
						C_1_C7_40			C_1_C7_53	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_53	C_1_C6_53	D4_HOS_C2_53	C_1_C5_69	C_1_C6_69	D3_HOS_C2_69
						C_1_C7_53			C_1_C7_69	
		0481		Cardiac Catheterization				C_1_C5_59	C_1_C6_59	D3_HOS_C2_59
									C_1_C7_59	
Laboratory	Laboratory Charges	030X, 031X, and 075X		Laboratory	C_1_C5_44	C_1_C6_44	D4_HOS_C2_44	C_1_C5_60	C_1_C6_60	D3_HOS_C2_60
						C_1_C7_44			C_1_C7_60	
				PBP Clinic Laboratory Services	C_1_C5_45	C_1_C6_45	D4_HOS_C2_45	C_1_C5_61	C_1_C6_61	D3_HOS_C2_61
						C_1_C7_45			C_1_C7_61	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
		074X, 086X		Electro-encephalography	C_1_C5_54	C_1_C6_54	D4_HOS_C2_54	C_1_C5_70	C_1_C6_70	D3_HOS_C2_70
						C_1_C7_54			C_1_C7_70	
Radiology	Radiology Charges	040X		Radiology - Diagnostic	C_1_C5_41	C_1_C6_41	D4_HOS_C2_41	C_1_C5_54	C_1_C6_54	D3_HOS_C2_54
						C_1_C7_41			C_1_C7_54	
		0333, 0339, 0342		Radiology - Therapeutic	C_1_C5_42	C_1_C6_42	D4_HOS_C2_42	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344		Radioisotope	C_1_C5_43	C_1_C6_43	D4_HOS_C2_43	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56
						C_1_C7_43			C_1_C7_56	
		035X		Computed Tomography (CT) Scan				C_1_C5_57	C_1_C6_57	D3_HOS_C2_57

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
									C_1_C7_57	
	MRI Charges	061X		Magnetic Resonance Imaging (MRI)				C_1_C5_58	C_1_C6_58	D3_HOS_C2_58
									C_1_C7_58	
Emergency Room	Emergency Room Charges	045x		Emergency	C_1_C5_61	C_1_C6_61	D4_HOS_C2_61	C_1_C5_91	C_1_C6_91	D3_HOS_C2_91
						C_1_C7_61			C_1_C7_91	
Blood and Blood Products	Blood Charges	038x		Whole Blood & Packed Red Blood Cells	C_1_C5_46	C_1_C6_46	D4_HOS_C2_46	C_1_C5_62	C_1_C6_62	D3_HOS_C2_62
						C_1_C7_46			C_1_C7_62	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_47	C_1_C6_47	D4_HOS_C2_47	C_1_C5_63	C_1_C6_63	D3_HOS_C2_63
						C_1_C7_47			C_1_C7_63	
Other Services	Other Service Charge	0002-0099, 022X, 023X, 024X,052X,053X								
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X								
				ASC (Non Distinct Part)	C_1_C5_58	C_1_C6_58	D4_HOS_C2_58	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
						C_1_C7_58			C_1_C7_75	
	Outpatient Service Charges	049X and 050X		Other Ancillary	C_1_C5_59	C_1_C6_59	D4_HOS_C2_59	C_1_C5_76	C_1_C6_76	D3_HOS_C2_76
	Lithotripsy Charge	079X				C_1_C7_59			C_1_C7_76	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Clinic Visit Charges	051X		Clinic	C_1_C5_60	C_1_C6_60	D4_HOS_C2_60	C_1_C5_90	C_1_C6_90	D3_HOS_C2_90
						C_1_C7_60			C_1_C7_90	
	Ambulance Charges	054X		Ambulance	C_1_C5_65	C_1_C6_65	D4_HOS_C2_65	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
						C_1_C7_65			C_1_C7_95	
				Observation beds	C_1_C5_62	C_1_C6_62	D4_HOS_C2_62	C_1_C5_92	C_1_C6_92	D3_HOS_C2_92
						C_1_C7_62			C_1_C7_92	
					C_1_C5_6201	C_1_C6_6201	D4_HOS_C2_6201	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
						C_1_C7_6201			C_1_C7_92.01	
	ESRD Revenue Setting Charges	080X and 082X-088X (but not 086X)								

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	(excluding Labor & Delivery DRGs)									
				Rural Health Clinic	C_1_C5_6350	C_1_C6_6350	D4_HOS_C2_6350	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88
	Professional Fees Charges	096X, 097X, and 098X				C_1_C7_6350			C_1_C7_88	
				FQHC	C_1_C5_6360	C_1_C6_6360	D4_HOS_C2_6360	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
						C_1_C7_6360			C_1_C7_89	
				Home Program Dialysis	C_1_C5_64	C_1_C6_64	D4_HOS_C2_64	C_1_C5_94	C_1_C6_94	D3_HOS_C2_94
						C_1_C7_64			C_1_C7_94	
				Other Reimbursable	C_1_C5_68	C_1_C6_68	D4_HOS_C2_68	C_1_C5_98	C_1_C6_98	D3_HOS_C2_98
						C_1_C7_68			C_1_C7_68	

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2009 and FY 2010 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D-4 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D-4. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS-DRG in each of the 15 cost centers by the corresponding national average CCR, we summed the 15 "costs" across

each MS-DRG to produce a total standardized cost for the MS-DRG. The average standardized cost for each MS-DRG was then computed as the total standardized cost for the MS-DRG divided by the transfer-adjusted case count for the MS-DRG. The average cost for each MS-DRG was then divided by the national average standardized cost per case to determine the relative weight.

The FY 2013 cost-based relative weights were then normalized by an adjustment factor of 1.5916044904 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 15 national average CCRs for FY 2013 are as follows:

Group	CCR
Routine Days	0.514
Intensive Days	0.442
Drugs	0.199
Supplies & Equipment	0.335
Therapy Services	0.370
Laboratory	0.143
Operating Room	0.238
Cardiology	0.145
Radiology	0.136
Emergency Room	0.226
Blood and Blood Products	0.389
Other Services	0.397
Labor & Delivery	0.450
Inhalation Therapy	0.189
Anesthesia	0.109

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS-DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27930), we proposed to use that same case threshold in recalibrating the MS-DRG weights for FY 2013. Using data from the FY 2011 MedPAR file, there were 8 MS-DRGs that contain fewer than 10 cases. Under the MS-DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients aged 0 to 17 years. With the exception of newborns, we previously separated some DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these DRGs are identical. The DRGs for patients aged 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric DRGs could lead to significant year-to-year instability in their relative weights. Although we have always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have received frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS-DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS-DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS-DRGs for newborns. All of the low-volume MS-DRGs listed below are for newborns. In FY 2013, because we do not have sufficient MedPAR data to set accurate and stable cost weights for these

low-volume MS-DRGs, we proposed to compute weights for the low-volume MS-DRGs by adjusting their FY 2012 weights by the percentage change in the average weight of the cases in other MS-DRGs. The crosswalk table is shown below:

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
768	Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
789	Neonates, Died or Transferred to Another Acute Care Facility	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

We did not receive any public comments on this section. In this final rule, we are adopting the national average CCRs as proposed without modification, with the MS-DRG weights recalibrated based on these CCRs.

4. Bundled Payments for Care Improvement (BPCI) Initiative

a. Background

Section 3021 of the Affordable Care Act, codified at section 1115A of the Act, authorizes CMS to test innovative payment and service delivery models with the goal of reducing Medicare program expenditures while preserving or enhancing the quality of care furnished to individuals. Because initiatives established under this authority could result in IPPS hospitals receiving a payment different than what they otherwise would receive under the IPPS, we believe it is important to identify how these initiatives are addressed in the context of MS-DRG recalibration and ratesetting, budget neutrality, and the impact analysis in the Addendum of this final rule, as we did in the proposed rule.

Under the Bundled Payments for Care Improvement (BPCI) initiative, CMS would link payments for multiple services that patients receive during an episode of care. CMS is working in partnership with providers to develop and test models of bundling payments through the BPCI initiative. On August 23, 2011, CMS invited providers to apply to help develop and test four different models of bundling payments. For additional information, we refer readers to the CMS Web site at: http://www.innovations.cms.gov/initiatives/Bundled-Payments/index.html. We are providing below a brief overview of payments under each model. However, the BPCI initiative Request for Application and related information on the CMS Web site at

http://www.innovations.cms.gov/initiatives/Bundled-Payments/index.html/ provide more details of this initiative.

As described below and also in the Addendum to the proposed rule and this final rule, we generally proposed to include, and for this final rule are including, data from hospitals participating in the BPCI initiative and to treat these hospitals without regard to their participation in the BPCI initiative for the purposes of IPPS ratesetting.

We did not receive any public comments about our proposals. Therefore, as discussed in greater detail below, we are finalizing the treatment of hospitals participating in the BPCI initiative as proposed. For hospitals participating in Models 1, 2, and 4, we are finalizing treating these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative).

Model 1

In Model 1, the episode of care is defined as the inpatient hospital services for the acute care hospital stay only. Applicants for this model were asked to propose discount percentages for various periods of the 3-year program, which would be applied to the IPPS operating MS-DRG payment for each participating hospital's MS-DRGs over the lifetime of the initiative. That is, for hospitals participating in Model 1, Medicare would continue to pay participating acute care hospitals under the IPPS. However, these payments to participating acute care hospitals would be at a reduced payment amount that reflects the applicable discount percentage for cases in all MS-DRGs for the specific

period of the program. We note that an adjustment would be made such that payments for IME, DSH, and outliers would be calculated based on the nondiscounted MS-DRG operating IPPS payment amount and then paid, if applicable, in addition to the discounted MS-DRG operating IPPS payment. The minimum discount percentage that awardees are expected to offer would be phased in over time, with the discount percentage updated as frequently as every 6 months.

Model 2

In Model 2, the episode of care is defined as the inpatient acute care hospital stay for specific clinical conditions and a specified period of time following discharge (with a minimum episode length of at least 30 days following hospital discharge). The payment bundle for Model 2 would encompass all Medicare Part A payments for designated MS-DRGs, Part B professional services paid under the Medicare Physician Fee Schedule (MPFS) during the hospital stay, and related professional services furnished after discharge during the episode, "related readmissions" (as defined under the BPCI initiative), care by a postacute care provider such as an HHA, IRF, SNF, LTCH, and other related services furnished during the episode (that is, all Medicare Part A and Part B with the exception of hospice care). Applicants, which may be a Medicare supplier or provider, groups of such entities, or other organizations that bring together providers and suppliers to test the model, were asked to propose specific MS-DRG(s) for the clinical condition(s) to be tested in Model 2. Furthermore, the applicants were asked to propose the target price on an MS-DRG basis for the episode that includes a single rate of discount off of the expected Medicare payment (including hospital, postacute care,

Medicare Part B professional services, and other services, as applicable) for all Model 2 beneficiaries discharged from the inpatient hospital stay with the specified MS-DRG(s). We note that, when proposing the target price, applicants were instructed to include IPPS outlier payments in their calculation; however, IPPS IME and DSH payments should be excluded from the target price. In Model 2, payments would be made at the usual fee-for-service payment rates to the participating providers through the regular claims processing system, after which the aggregate Medicare payment for the episode would be reconciled against the target price. If aggregate Medicare expenditures are less than the target price, the awardee would be paid the difference as a reconciliation payment. Conversely, if aggregate Medicare expenditures exceed the target price, CMS would recoup that amount from the awardee.

Model 3

In Model 3, the episode of care begins at initiation of postacute services at one of four postacute care providers (HHAs, IRFs, SNFs, and LTCHs) within 30 days after discharge from any acute care hospital for specific clinical conditions. As with the other three models, applicants may be one or more Medicare providers or supplier or other organization(s) bringing those entities together to test the model. Applicants were asked to propose an episode length that would extend to at least 30 days following initiation of care at an HHA, IRF, SNF, or LTCH. The payment bundle for Model 3 would encompass care by a postacute care provider, and other related services furnished during the episode, including Medicare Part B professional services paid under the MPFS, and inpatient hospital readmissions (as defined under the BPCI initiative). In contrast to

Model 2, the payment bundle for Model 3 does not include services provided in the initial acute care hospital stay. We note that, while the episode is initiated at one of the four postacute care providers rather than at an acute care hospital, applicants were asked to specify the clinical conditions(s) to be tested in Model 3 by proposing relevant MS-DRG(s). Therefore, applicable to all Model 3 beneficiaries discharged from any inpatient acute care hospital stay with the specified MS-DRG(s), applicants were to propose a target price on an MS-DRG basis for the episode that includes a single rate of discount off of the expected Medicare payment, which includes care by a postacute care provider, related Medicare Part B professional services paid under the MPFS, inpatient hospital readmissions, and other related services furnished during the episode. In Model 3, payments would be made at the usual fee-for-service payment rates to the participating providers through the regular claims processing process, after which the aggregate Medicare payment for the episode would be reconciled against the target price. Like Model 2, if aggregate Medicare expenditures are less than the target price, the awardee would be paid the difference as a reconciliation payment. Conversely, if aggregate Medicare expenditures exceed the target price, CMS would recoup that amount from the awardee. We note that Model 3 does address payment for related hospital readmissions.

Model 4

In Model 4, the episode of care is defined as the acute care hospital stay and includes all "related readmissions" (as defined under the BPCI initiative). The payment bundle for Model 4 would encompass Medicare inpatient hospital services, Medicare Part B professional services paid under the MPFS furnished during the initial

hospitalization, as well as hospital services and Medicare Part B professional services during any related readmissions. Applicants were asked to propose specific MS-DRG(s) for the clinical condition(s) to be tested in Model 4. Applicants for this model were asked to propose a target price for the episode that includes a single rate of discount off of expected Medicare payment (including both Medicare Part A hospital services and Part B professional services) for all beneficiaries discharged from the inpatient hospital stay with the specified MS-DRG(s).

In contrast to Models 2 and 3, where usual Medicare fee-for-service payments are made to all providers and reconciliation of Medicare spending against the target price for the episode is conducted retrospectively, under Model 4, hospitals would receive a prospectively established bundled payment for specified MS-DRGs. This payment would include both the MS-DRG payment for the hospital and a fixed payment amount for the Medicare Part B professional services anticipated to be furnished during the episode. That is, separate payment for providers' professional services furnished during the inpatient hospital stay would not be made. Participating Model 4 hospitals receiving payment would take responsibility for distributing payment to providers that would otherwise be paid separately. We note that IPPS IME and DSH payments to Model 4 hospitals would be calculated based on the nondiscounted base MS-DRG operating IPPS payment that would have been made in the absence of the model. Other applicable payment adjustors would also be calculated based on the base MS-DRG operating IPPS payment amount that would otherwise have applied to the case, as opposed to the prospectively established amount paid through this initiative, which would be higher as it

includes payment for Part B services as well as the base MS-DRG payment. Under Model 4, no separate IPPS outlier payments would be made.

b. Treatment of Data from Hospitals Participating in the BPCI Initiative

As discussed above, acute care hospitals had the opportunity to apply and participate in the BPCI payment models described above. As we discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27932), for Model 1 and Model 2, participating acute care hospitals would continue to receive an IPPS payment under section 1886(d) of the Act (subject to a predetermined discount for hospitals participating in Model 1). For Model 2, participating hospitals may also receive a reconciliation payment under the BPCI initiative (based on their predetermined target price). Under Model 3, services provided in the initial acute care hospital stay are not included; however, the model does address payment for possible hospital readmissions. Under Model 1, hospitals participate for all MS-DRGs, while, under Model 2, hospitals participate for only pre-selected MS-DRGs. We believe it is appropriate to include all applicable data from these subsection(d) hospitals in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act (in addition to, with respect to Model 2 hospitals, any reconciliation payment the hospital may receive under the BPCI initiative). Moreover, even if these hospitals were not receiving IPPS payments under section 1886(d) of the Act (and were participating in Models 1 and 2), the Secretary has the authority to make appropriate adjustments for payment amounts under section 1886(d)(5)(I)(i) of the Act to include all applicable data from these subsection(d) hospitals in our IPPS ratesetting

calculations. We believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS, short-term, acute care hospitals within the IPPS ratesetting calculations because excluding these hospitals would diminish the number of providers used to determine the IPPS rates, which could cause fluctuations in the IPPS rates and could produce instability to the IPPS rates. Therefore, because we believe it is appropriate to include all claims from hospitals participating within Models 1 and 2 within the IPPS ratesetting calculations, using the Secretary's authority under section 1886(d)(5)(I)(i) of the Act, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27932), we proposed to include all applicable data from "subsection (d)" hospitals participating in Models 1 and 2 under the BPCI initiative in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS-DRG weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis). In essence, we proposed to continue to treat these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these two bundled payment models (that is, we would treat these hospitals as if they are not participating in Model 1 or Model 2 under the BPCI initiative). We did not receive any public comments on our proposal. Therefore, we are finalizing treating these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these two bundled payment models (that is, we would treat these hospitals as if they are not participating in Model 1 or Model 2 under the BPCI initiative), as we proposed.

In contrast to BPCI Models 1 and 2 (wherein participating IPPS hospitals would receive an IPPS payment under section 1886(d) of the Act, and, in the case of Model 2, may also receive a reconciliation payment under the BPCI initiative), IPPS hospitals participating in Model 4 would receive a predetermined bundled payment for Medicare Part A and Part B services for a pre-specified MS-DRG "episode" (and any "related readmissions" as defined under the BPCI initiative). These bundled payments are for certain pre-specified MS- DRG(s) episodes (not all cases) and would be made in accordance with the terms of the model, as authorized by section 1115A of the Act (these IPPS hospitals would also receive "regular" IPPS payments under section 1886(d) of the Act for those MS-DRGs not included in the bundling model). Similar to Models 1 and 2, we believe it is appropriate to keep all applicable data from these "subsection (d)" hospitals in our IPPS payment modeling and ratesetting calculations because the majority of Medicare payments these hospitals would receive would be IPPS payments under section 1886(d) of the Act (that is, payments for cases in MS-DRGs that are not included in the bundled payment model). Moreover, although these hospitals are not receiving payments under 1886(d) of the Act for the cases included in the prospective bundled payment under Model 4, the Secretary has the authority to make appropriate adjustments for payment amounts at section 1886(d)(5)(I)(i) of the Act to include all applicable data from these subsection(d) hospitals in our IPPS ratesetting calculations. We believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS, short-term, acute care hospitals and their claims within the IPPS ratesetting calculations because excluding these hospitals would diminish the number of

providers used to determine the IPPS rates, which could cause fluctuations in the IPPS rates and could produce instability to the IPPS rates. Therefore, because we believe it is appropriate to include all claims from hospitals participating within Models 1 and 2 within the IPPS ratesetting calculations and use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include those hospitals and claims, we also believe it is appropriate to include all applicable data from subsection (d) hospitals participating in Model 4 in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS-DRG weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) and proposed to do so in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27932 through 27933). In essence, we proposed to continue to treat these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within this bundled payment model (that is, we would treat these hospitals as if they are not participating in Model 4 under the BPCI initiative). We did not receive any public comments on our proposal. Therefore, we are finalizing treating these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these two bundled payment models (that is, we would treat these hospitals as if they are not participating in Model 4 under the BPCI initiative), as we proposed.

We note that Model 3 only addresses payments for related readmissions and postacute care services (rather than IPPS payments). Therefore, we believed it was not

necessary to propose to address the treatment of any data for participating hospitals in Model 3. We continue to believe it is not necessary to address the treatment of any data for participating hospitals in Model 3. We did not receive any public comments on our decision not to propose to address the treatment of any data for participating hospitals in Model 3.

Because we did not receive any public comments, we are finalizing the treatment of hospitals participating in the BPCI initiative as proposed. For hospitals participating in Models 1, 2, and 4, we are finalizing treating these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative).

I. Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as "new technologies") under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate." We note that beginning with discharges occurring in FY 2008, CMS transitioned from CMS-DRGs to MS-DRGs.

The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. The regulations at 42 CFR 412.88 also implement these provisions and describe the additional payment for the new medical service or technology. Below, we highlight some of the major statutory and regulatory provisions relevant to the new

technology add-on payment criteria, as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in 42 CFR 412.87(b)(2), a specific medical service or technology will be considered "new" for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS-DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. In the FY 2006 IPPS final rule (70 FR 47351) and FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 and 43814), we explained our policy regarding substantial similarity in detail.

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS-DRG prospective payment rate otherwise applicable to the discharge involving the new medical services or technologies must be assessed for adequacy. Under the cost criterion, to assess the adequacy of payment for a new technology paid under the applicable MS-DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. Table 10 that was released with the FY 2012 IPPS/LTCH PPS final rule contains the final thresholds that we used to evaluate

applications for new technology add-on payments for FY 2013 in this final rule. We refer readers to the Web site http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FR2012/list.asp#TopOfPage for a complete viewing of Table 10 from the FY 2012 IPPS/LTCH PPS final rule.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR Parts 160 and 164 applies to claims information that providers submit with applications for new technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents "an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. We refer readers to the September 7, 2001 final rule for a complete discussion of this criterion (66 FR 46902).

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the

cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment for new medical services and technologies is limited to the full MS-DRG payment plus 50 percent of the estimated costs of the new technology.

Section 503(d)(2) of Pub. L. 108-173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Pub. L. 108-173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also amended § 412.87(c) to specify that all

applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Pub. L. 108-173. The Council is co-chaired by the Director of the Center of Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local claims-payment contractors (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the

promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an "Innovator's Guide" to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in August 2008 and is available on the CMS Web site at: http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf.

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any potential applicants, such as product developers or manufacturers of new medical technologies, to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage and/or payment decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at CTI@cms.hhs.gov.

We note that applicants for add-on payments for new medical services or technologies for FY 2014 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any

clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2014, the Web site also will post the tracking forms completed by each applicant.

2. Public Input before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 108-173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to--

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;

- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;

- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and

- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2013 prior to publication of the FY 2013 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 18, 2011 (76 FR 71571 through 71572), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 14, 2012. In the announcement notice for the meeting, we stated that the opinions and alternatives provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2013 new medical service and technology add-on payment applications before the publication of the FY 2013 proposed rule.

Approximately 70 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. Four of the five FY 2013 applicants presented information on its technology, including a discussion of data reflecting the substantial clinical improvement aspect of the technology. We considered each applicant's presentation made at the town hall meeting, as well as written

comments submitted on the applications that were received by the due date of March 6, 2012, in our evaluation of the new technology add-on payment applications for FY 2013 in the proposed rule.

In response to the published notice and the new technology town hall meeting, commenters submitted and presented public comments that were unrelated to the substantial clinical improvement criterion in regard to the new technology applications for FY 2013. We also received public comments on the proposed rule relating to topics such as marginal cost factors for new technology add-on payments, and the use of external data in determining the cost threshold and mapping new technologies to the appropriate MS-DRG. Because we did not request public comments nor propose to make any changes to any of the issues above, we are not summarizing these public comments nor responding to them in this final rule.

3. FY 2013 Status of Technology Approved for FY 2012 Add-On Payments: Auto Laser Interstitial Thermal Therapy (AutoLITT™) System

Monteris Medical submitted an application for new technology add-on payments for FY 2011 for the AutoLITT™. AutoLITT™ is a minimally invasive, MRI-guided laser tipped catheter designed to destroy malignant brain tumors with interstitial thermal energy causing immediate coagulation and necrosis of diseased tissue. The technology can be identified by ICD-9-CM procedure codes 17.61 (Laser interstitial thermal therapy [LITT] of lesion or tissue of brain under guidance), and 17.62 (Laser interstitial thermal therapy [LITT] of lesion or tissue of head and neck under guidance), which became effective on October 1, 2009.

The AutoLITT™ received a 510K FDA clearance in May 2009. The AutoLITT™ is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers. The AutoLITT™ may be used in patients with glioblastoma multiforme brain tumors. The applicant stated in its application and through supplemental information that, due to required updates, the technology was actually introduced to the market in December 2009. The applicant explained that it was necessary to reduce the thermal damage lines from three to one and complete International Electrotechnical Commission/Underwriter Laboratory testing, which led to the introduction of the technology to the market in December 2009, although the technology was approved by FDA in May 2009. The applicant also stated through supplementary information to its application that the first sale of the product took place on March 19, 2010. However, because the product was already available for use in December 2009, it appears that the newness date would begin in December 2009. In the FY 2011 IPPS/LTCH PPS proposed rule, we welcomed public comments on this issue.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the AutoLITT™ and consideration of the public comments we received in response to the FY 2011 IPPS/RY 2011 LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the AutoLITT™ for new technology add-on payments for FY 2011. Consistent with the applicant's clinical trial, the add-on payment is intended only for use of the device in cases of glioblastoma multiforme. Therefore, we

limited the new technology add-on payment to cases involving the AutoLITT™ in MS-DRGs 025 (Craniotomy and Endovascular Intracranial Procedures with MCC), 026 (Craniotomy and Endovascular Intracranial Procedures with CC), and 027 (Craniotomy and Endovascular Intracranial Procedures without CC or MCC). Cases involving the AutoLITT™ that are eligible for the new technology add-on payment are identified by assignment to MS-DRGs 025, 026, and 027 with a procedure code of 17.61 (Laser interstitial thermotherapy of lesion or tissue of brain under guidance) in combination with a principal diagnosis code that begins with a prefix of 191 (Malignant neoplasm of brain). We note that using the procedure and diagnosis codes above and restricting the add-on payment to cases that map to MS-DRGs 025, 026, and 027 is consistent with information provided by the applicant, which demonstrated that cases of the AutoLITT™ would only map to MS-DRGs 025, 026, and 027. Procedure code 17.62 (Laser interstitial thermotherapy of lesion or tissue of head and neck under guidance) does not map to MS-DRGs 025, 026, or 027 under the GROUPER software and, therefore, is ineligible for new technology add-on payment.

The average cost of the AutoLITT™ is reported as $10,600 per case. Under § 412.88(a)(2) of the regulations, new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS-DRG payment for the case. As a result, the maximum add-on payment for a case involving the AutoLITT™ is $5,300.

The new technology add-on payment regulations provide that “a medical service or technology may be considered new within 2 or 3 years after the point at which data

begin to become available reflecting the ICD-9-CM code assigned to the new service or technology" (42 CFR 412.87(b)(2)). Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362). In the proposed rule, with regard to the newness criterion for the AutoLITT™, we stated that we consider the beginning of the newness period for the device to commence from the market release date of December 2009. Therefore, for FY 2013, as of December 2012, the AutoLITT™ will have been on the market for 3 years, and would therefore no longer be considered "new" as of December 2012 nor be considered eligible for new technology add-on payments in FY 2013. However, we received information from the applicant that the market release date of the AutoLITT™ occurred after April 2010 (which occurs in the latter half of the fiscal year) and, therefore, it appears that the AutoLITT™ would still be considered "new" for FY 2013 and would still be eligible for new technology add-on payments in FY 2013. We note that we received this information in close proximity to the publication of the proposed rule and anticipated receiving further information on the delayed market release date from the applicant and welcomed public comment as well.

Comment: The applicant submitted a public comment to demonstrate that the AutoLITT™ was first available on May 11, 2010, which would make the AutoLITT™

eligible for new technology add-on payments in FY 2013 (because the 3-year anniversary date of AutoLITT™ would take place in the latter half of the fiscal year). The manufacturer explained that some of the sterile disposable products were not released from quarantine until May 11, 2010, which prevented the AutoLITT™ from being used prior to May 11, 2010. Therefore, the manufacturer asserted that the first time the AutoLITT™ was available on the market was May 11, 2010.

Response: We appreciate the manufacturer providing this information and we agree that the AutoLITT™ is considered new as of May 11, 2010, instead of December 2009. As stated above, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362). Because the 3-year anniversary date of the AutoLITT™ entry on the market occurs in the latter half of the fiscal year, we still consider the AutoLITT™ to be new for FY 2013. Therefore, we are continuing to make new technology add-on payments for the AutoLITT™ in FY 2013. We discuss the coding and payment policies for the AutoLITT™ earlier in this section.

Comment: Several public commenters recommended extending new technology add-on payments for the AutoLITT™ in FY 2013.

Response: As stated above, we still consider the AutoLITT™ to be new for FY 2013, and will continue to make new technology add-on payments for the AutoLITT™ in FY 2013.

4. FY 2013 Applications for New Technology Add-On Payments

We received six applications for new technology add-on payments for FY 2013. However, two applicants withdrew their applications prior to the publication of the proposed rule.

a. Glucarpidase (Trade Brand Voraxaze®)

BTG International, Inc. (BTG) submitted an application for new technology add-on payments for Glucarpidase (trade brand Voraxaze®) for FY 2013. In the proposed rule, we summarized this application, and stated that Glucarpidase is used in the treatment of patients who have been diagnosed with toxic methotrexate (MTX) concentrations as a result of renal impairment. The administration of Glucarpidase causes a rapid and sustained reduction of toxic MTX concentrations.

Methotrexate (MTX) is a widely used anticancer agent. The administration of high-dose methotrexate (HDMTX) is an important component of the treatment provided to patients who have been diagnosed with various types of cancer. According to the applicant, HDMTX, in particular, is specifically used in the treatment of patients who have been diagnosed with osteosarcoma, acute lymphoblastic leukemia, non-Hodgkin's lymphoma, or primary CNS lymphoma. The applicant further stated that the administration of HDMTX can cause renal dysfunction. Renal dysfunction impairs the elimination of MTX, which in turn causes the levels of MTX to rise to the point of life-threatening toxicity.

The applicant maintains that there are not any currently FDA-approved pharmaceutical treatment options available to rapidly decrease MTX levels in patients

who have been diagnosed with toxic MTX concentrations as a result of renal impairment. The applicant asserts that extracorporeal treatment options that are routinely employed to rapidly treat this condition, such as hemodialysis, hemodiafiltration, high-flux hemodialysis, charcoal hemoperfusion or hemofiltration, peritoneal dialysis, exchange transfusion, or plasma exchange, are invasive, may add excess morbidity to the treatment regimen, and have proven to have limited effects.[15] High flux hemodialysis is the most effective method of extracorporeal MTX removal, but this method requires 5 to 6 days of daily treatment (4 to 6 hours per session).[16] The risks associated with repeated hemodialysis procedures such as anemia, infection, and increased mortality, especially in neutropenic or thrombocytopenic patients, are significant and cause rebounds in MTX levels. The applicant maintains that other treatment options, such as the administration of leucovorin, hydration, and urinary alkalinization, also are commonly used to reduce harmful levels of MTX. However, these treatment options do not reduce toxic MTX concentrations in all patient populations.[17]

Voraxaze® was approved by the FDA on January 17, 2012. Beginning in 1993, certain patients could obtain expanded access for treatment use to Voraxaze® as an investigational drug. Since 2007, the applicant has been authorized to recover the costs of making Voraxaze® available through its expanded access program. We describe expanded access for treatment use of investigational drugs and authorization to recover certain costs of investigational drugs in more detail below. Voraxaze® was available on

[15] Widemann et al., [Cancer, 2004, and Vilay et al.,], Pharmacotherapy, Vol 30, January, 2010).
[16] Wall et al., American Journal of Kidney Diseases, Vol. 28, No. 6, 1996.
[17] Pinedo et al, Cancer Research, 36, 4418-4424 December, 1976.

the market in the United States as a commercial product to the larger population as of April 30, 2012.

With regard to newness, in the proposed rule we expressed concern that Voraxaze® may no longer be considered "new." Specifically, section 1886(d)(5)(K)(ii)(II) of the Act requires that we provide for the collection of cost data for a new medical service or technology for a period of at least 2 years and no more than 3 years "beginning on the date on which an inpatient hospital code is issued with respect to the service or technology". In addition, the regulations at § 412.87(b)(2) state that "A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion of this section." As we have indicated in the past, we generally believe that the newness period begins on the date that FDA approval is granted. The FDA approval date is typically the date when new technologies are available on the market and as a result begin to be reflected within the MS-DRGs cost data.

As noted above, Voraxaze® was approved by the FDA in January 2012. However, starting in 1993, certain patients were able to obtain access to Voraxaze® as an investigational drug through an expanded access program, and the applicant has been

authorized to recover certain costs of making Voraxaze® available through its expanded access program since 2007. We discuss below in more detail whether the cost of Voraxaze® is already reflected within the MS-DRG relative weights.

To determine the date of newness for Voraxaze®, as we stated in the proposed rule, we believe it is appropriate to compare investigational drugs provided under the expanded access program to devices eligible for the Humanitarian Use Device (HUD) Program because these programs contain similarities for the purpose of evaluating the newness criterion.

In prior final rules, we have evaluated and approved technologies with a Humanitarian Device Exemption (HDE) approval. In the FY 2010 IPPS/LTCH PPS final rule, we approved new technology add-on payments for the Spiration® IBV®, which received a HDE approval from the FDA on October 24, 2008, and had its first Institutional Review Board (IRB) approval on March 12, 2009 (74 FR 43754, 43819). Therefore, technologies with an HDE approval may be eligible for new technology add-on payments. In other words, we have concluded that HDE approval constitutes an FDA approval in the context of the newness criterion and would begin the newness period, subject to market availability.

There are separate processes and standards for providing expanded access to investigational drugs for treatment use and for the HUD Program. The term "expanded access" refers to the use of investigational drugs, or approved drugs where availability is limited by a risk evaluation or mitigation strategy, when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. When the requirements in

(FDA's regulations at) 21 CFR Part 312, Subpart I are met, a patient or group of patients with a serious or immediately life-threatening disease or condition, and no comparable or satisfactory alternative therapy, may obtain expanded access to an investigational drug. When patients obtain expanded access to an unapproved investigational drug, the safety and effectiveness of the drug have not been fully established, and the drug does not have formal FDA approval under a New Drug Application (NDA) or Biologics Licensing Application (BLA) for commercial marketing. Manufacturers may continue conducting clinical trials in parallel to the expanded access program in order to pursue formal market approval from the FDA under an NDA or BLA for commercial marketing. The FDA's Office of Orphan Products Development administers the Humanitarian Use Device (HUD) Program. A HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. To obtain approval for a HUD, a HDE application is submitted to FDA. A HDE application is similar in both form and content to a Premarket Approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. A HDE application must, however, contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. An approved HDE authorizes marketing of the HUD, however, an HDE approval requires that the device only be used in facilities that have established a local IRB to supervise clinical testing of devices, and that an IRB approve the use of the device

to treat or diagnose the specific disease. Although HUDs can be marketed, they are subject to a general prohibition on profit; that is, they may not, except in narrow circumstances, be sold for an amount that exceeds the cost of research and development, fabrication and distribution.

Expanded access to investigational drugs and the HUD Program have similarities and differences that are relevant to the newness criterion as we stated in the proposed rule. Both have limits on who is eligible to receive a drug or use a device. In addition, to satisfy the requirements for expanded access in FDA's regulations, and for a HDE to meet the standard for approval, a sponsor is not required to demonstrate effectiveness of the product at the same level as for approval of a PMA, NDA, or BLA. Expanded access to investigational drugs and the HUD Program differ in many ways, including that the HUD Program is for devices, and the expanded access programs provide access to drugs. In addition, under the HUD Program, the device is granted FDA approval for limited use. However, while FDA authorizes expanded access to an investigational drug, FDA does not approve the investigational drug when it authorizes expanded access.

This second difference is key to our interpretation of our policy to recognize a HDE approval as an FDA approval. We believe that the availability of a drug through the expanded access program would not constitute FDA approval in the context of the newness criterion because unapproved, investigational drugs made available to certain patients through the expanded access program do not receive FDA approval prior to enrollment in the program and cannot be marketed. In other words, we believe that for the purposes of evaluating whether a new technology meets the newness criterion, it may

be appropriate not to consider the date when Voraxaze® became available to certain patients through the applicant's expanded access program as the date of market availability.

We note that cost recovery for investigational drugs is of concern with regard to the newness criterion. Although a sponsor (for example, a drug manufacturer) may not commercially distribute an investigational drug, in certain circumstances, a sponsor of a clinical trial or an expanded access program may receive authorization from FDA to charge for certain costs associated with making an investigational drug available. The applicant has been authorized to recover certain costs by making Voraxaze® available since 2007. As we stated earlier, once CMS has recalibrated the DRGs based on available data to reflect the costs of an otherwise new technology, that technology will no longer be considered "new"' for the purposes of the new technology add-on payments. It is possible that a hospital may have submitted a claim to Medicare for the cost of Voraxaze® provided through the applicant's expanded access program. Therefore, it is also possible that the costs associated with this technology may already be reflected in some limited fashion in the data used to determine the MS-DRG relative weights. While these are possibilities, we have not in the past been confronted with a situation where an applicant has indicated that hospitals have sought cost recovery for their technology when the technology was available through the expanded access program. We also have not been confronted with a situation where an applicant has indicated that cost recovery was sought for technologies (that were not available via an expanded access program) during clinical trials. We note that our data do not distinguish charges for drugs by FDA

approval status, and, therefore, we do not exclude from the relative weight calculation costs (as derived from charges) associated with investigational drugs if they are included by hospitals on a claim. Therefore, cost data for non-FDA approved technologies (that is, still involved in clinical trials) may be present in the relative weights on a very limited basis prior to FDA approval, regardless of whether a technology received new technology add-on payments.

We invited public comment regarding the issue of whether a drug is considered "new" for the purposes of new technology add-on payments starting with its availability in the expanded access program, and how that may differ from devices being considered "new" starting from the date the device received FDA approval under a HDE (subject to market availability or availability to Medicare beneficiaries) and specifically requested comment on these considerations in the context of Voraxaze®. We also invited public comment on whether the costs of Voraxaze®, or more generally, any unapproved investigational drug for which cost recovery is authorized are already included in data used to determine relative weights, and how that influences the start of a newness period, if at all. In addition, we invited public comment regarding the market availability of Voraxaze® between its FDA approval date of January 17, 2012, and the market availability date according to the applicant of April 2012 and the reasons for the delay in availability.

Comment: Several public commenters responded with opinions regarding whether Voraxaze® should be considered new for the purposes of new technology add-on payments. One commenter stated that Voraxaze® was available on a "very limited basis"

since 1993, and recommended that it be considered "new" for the purpose of new technology add-on payments. The commenter also stated that because the manufacturer was only covering its costs under the expanded access program, existing charge data do not adequately reflect the "true price" of the technology. The commenter further noted that the frequency with which the technology is used is low, and that the associated relative weights are "likely artificially low."

The applicant submitted information through the submittal of a public comment documenting that Voraxaze® was approved by the FDA in January 2012 and that marketing of Voraxaze did not begin until April 2012. The applicant added that the FDA's Office of Prescription Drug Promotion (OPDP) considers a product new from the point of initial marketing and promotion, stating that, "OPDP generally considers that 'new' is an accurate description of the marketing phase for six months from the time a product is initially marketed and this should be distinguished from the time a product is cleared by FDA for marketing." The applicant concluded that the FDA recognizes a time delay between approval and commercial availability as standard in the pharmaceutical industry.

In addition, the applicant provided supplemental information that demonstrated that Voraxaze was not available on the market until April 30, 2012. This documentation included specific information regarding training, manufacturing/packaging and trade/distribution activities that needed to take place prior to April 30, 2012. Once these activities were completed, the applicant stated that it discontinued the treatment of

IND/cost recovery program for Voraxaze® on April 29, 2012, and that market availability of Voraxaze® began on April 30, 2012.

The applicant also noted that one of the reasons it did not initiate commercialization activities prior to the FDA approval date of January 30, 2012 was because the company was awaiting final FDA labeling approval (that is, prescribing information) for Voraxaze®, which was delivered to BTG on the day of approval, which was January 17, 2012. The applicant believed it would not have been prudent for BTG to initiate commercialization activities before receiving the final labeling approval because it would have required expensive and time-consuming rework.

One commenter stated that Voraxaze® meets the newness criteria. The commenter explained that the FDA approval date is reasonable to use for determination of newness. The commenter stated that prior to FDA approval, Voraxaze® was only available through a laborious expanded access process that many oncology centers did not have in place. Thus, it was truly only available at many centers for the first time as of April 30, 2012.

Another commenter stated that it believed that Voraxaze® does not meet the newness criterion but did not provide additional information.

Response: Generally, our policy is to begin the newness period on the date of FDA approval/clearance or, if later, the date of market availability for the technology. Availability under the expanded access program neither represents the date of FDA approval (in this case, January 2012) nor the date of market availability (April 30, 2012).

Therefore, we consider Voraxaze® to be "new" as of April 30, 2012, its date of market availability.

We note, as discussed in section II.G.7. of the preamble to this final rule, we are creating a new ICD-9-CM procedure code 00.95 (Injection or infusion of glucarpidase) to identify this new technology. This new code is effective October 1, 2012.

With respect to the cost criterion, as we described in the proposed rule, the applicant researched the 2009 Standard Analytic Inpatient File (SAF) for cases with a principal or secondary diagnosis of osteosarcoma (ICD-9-CM code series 170.xx), acute lymphoblastic leukemia (ICD-9-CM code series 204.0x), non-Hodgkin's lymphoma (ICD-9-CM code series 200.xx and 202.xx), or primary CNS lymphoma (ICD-9-CM code series 200.5x) with a corresponding ICD-9-CM procedure code for chemotherapy (99.25) that may be eligible for Voraxaze®, based on the product's approved indications. The applicant's search yielded potentially eligible cases within 249 MS-DRGs, of which 56 MS-DRGs captured 12 or more cases.

Using this universe of cases (249 MS-DRGs), the applicant added the additional costs of Voraxaze® to the case-weighted average standardized charge per case. Although the applicant submitted data related to the estimated cost of Voraxaze®, the applicant noted that the cost of the technology was proprietary information. According to the applicant, it did not convert the costs to charges for this analysis because of the technology's high cost. The applicant maintains that an average adult receiving treatment for one of the diagnoses above would require a minimum of four vials of Voraxaze®.

The applicant used the following multiple analysis of different subsets of MS-DRGs to compare the average case-weighted standardized charge per case to the average case-weighted threshold to determine that Voraxaze® met the cost criteria:

- The applicant found 12,324 eligible cases within 249 MS-DRGs, and determined a case-weighted average standardized charge per case of $87,582 (which includes the cost of Voraxaze®) and a case-weighted threshold of $39,216. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.

- The applicant excluded those MS-DRGs that had fewer than 11 cases, which resulted in 12,134 eligible cases within 56 MS-DRGs. The applicant determined a case-weighted average standardized charge per case of $84,039 (which includes the cost of Voraxaze®) and a case-weighted threshold of $37,195. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.

- The applicant analyzed the 20 MS-DRGs that contained the highest number of cases and, based on the 11,534 cases they stated they found, determined a case-weighted average standardized charge per case of $80,400 (which includes the cost of Voraxaze®) and a case-weighted threshold of $34,990. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.

We invited public comment on whether or not Voraxaze® meets the cost criterion. Specifically, we welcomed public comment on the methodologies used in the applicant's

analysis, including (1) the methods used to identify the eligible cases used in the cost analysis of this technology, especially if there are cases that should be excluded from the analysis because of clinical reasons, and if there are other ways to identify cases for which this technology may be appropriate, and (2) the appropriateness of not converting the costs to charges for the purposes of this analysis and what would be an accurate and appropriate CCR for this technology.

Comment: The applicant submitted a public comment stating that it believed that Voraxaze® meets the cost criterion because the commercial costs of Voraxaze® are not reflected in the MS-DRG relative weights. The applicant added that Voraxaze® was available via expanded access since 2007 and hospitals were not allowed to submit for reimbursement of Voraxaze® because it was an investigational drug. Even if hospitals attempted to submit for reimbursement, the applicant noted that the Voraxaze® cost recovery price is substantially lower than its commercial price of $22,500 (effective April 30, 2012) and any existing data prior to April 30, 2012 used to determine MS-DRG relative weights would not capture such a price difference and would largely underestimate the cost of Voraxaze®. Other commenters stated that Voraxaze® clearly meets the cost criterion. The commenters explained that they believed the situations where Voraxaze® is indicated for use were rare, and in those situations they believed that the cost of care for the affected patient rises substantially.

Response: We appreciate the commenters' input. We agree that Voraxaze® meets the cost criterion.

With regard to substantial clinical improvement, the applicant maintains that Voraxaze® is a clinical improvement compared to current treatment options because it is less time intensive, allows certain patient populations to avoid risks associated with current treatment options, and has characteristics that allows it to reduce MTX concentrations more effectively. As noted above, the applicant maintains that current treatment options for renal impairment as a result of toxic MTX concentrations are limited to extracorporeal methods that are time-intensive and could subject patients in certain populations to harm from the associated risks. The applicant states that the administration of Voraxaze® to patients who have been diagnosed with HDMTX-induced renal dysfunction metabolizes circulating MTX to the inactive metabolite DAMPA. The applicant asserts that this characteristic action of the technology represents a substantial clinical improvement over current treatment options available to patients who have toxic MTX concentrations in a more effective, and rapid way, and provides protection to eligible patient populations against potential harm associated with current treatment options.

In addition, the applicant provided the results from a study of 23 patients diagnosed with MTX-induced renal dysfunction treated with Voraxaze®. During this study, the applicant reported that the administration of Voraxaze® lowered toxic MTX concentrations in patients within 15 minutes after the administration by more than 98 percent. Because the administration of Voraxaze® could metabolize both leucovorin and its active metabolite, 5-mTHF, these patients were also administered Leucovorin, a drug used to enhance the treatment for patients with high levels of MTX. The applicant noted

that the combination of Voraxaze® and Leucovorin rescue was well tolerated by the 23 patients studied, and MTX-related toxicities were reduced from severe to mild to moderate. The range of age of these 23 patients was 19 to 94 years old with 18 of the 23 patients being 50 years or older[18]. The applicant asserted that the types of health conditions treated with HDMTX, such as acute lymphoblastic leukemia, osteosarcoma, central nervous system (CNS) lymphoma, and leptomeningeal cancer, tend to occur within the Medicare population and cites research that states "HD-MTX-induced renal failure with persistence of toxic blood MTX levels is a rare but life threatening complication that occurs more frequently in adults, particularly those with advanced age and CNS lymphoma." [19] When these malignancies arise which require treatment with HDMTX, HDMTX–induced renal failure with persistent toxic MTX levels is a complication that occurs more frequently in adults. The applicant asserted that the administration of Voraxaze® has been shown to be well-tolerated by older adult patients, while achieving similar reduction rates in younger patient populations who have been diagnosed with toxic MTX concentrations and treated with Voraxaze®.[20] The applicant also provided additional published peer-reviewed articles[21,22,23,24,25,26] relevant to their

---

[18] Green and Chamberlan, Cancer Chemotherapy and Pharmacology Volume 63, November 4, 2009.
[19]Schwartz, Borner et al., The Oncologist, December 2007.
[20]Schwartz, Borner et al,. The Oncologist, December 2007.
[21] Levy CC, Goldman P. The enzymatic hydrolysis of methotrexate and folic acid. J Biol Chem. 1967; 242:2993-2998.
[22] Minton NP, Atkinson T, Sherwood RF. Molecular cloning of the Pseudomonas carboxypeptidase G2 gene and its expression in Escherichia coli and Pseudomonas putida. J Bacteriol. 1983; 156: 1222-1227.
[23] Widemann BC, Balis FM, Kim A, et al. Glucarpidase, leucovorin and thymidine for high-dose methotrexate induced renal dysfunction. Clinical and pharmacologic factors affecting outcome. J Clin Oncology 2010; 28:1-8.
[24] Patterson DM, Lee SM. Glucarpidase following high-dose methotrexate: update on development. Expert Opin Biol Ther. 2010;10(1):105-111.
[25] Phillips M, Smith W, Balan G, et al. Pharmacokinetics of glucarpidase in subjects with normal and impaired renal function. J Clin Pharmacol 2008; 48:279-284.

application to support their assertion that they meet the substantial clinical improvement criteria.

We invited public comment on whether or not Voraxaze® meets the criterion of representing a substantial clinical improvement for Medicare beneficiaries.

Comment: The applicant submitted public comments that stated, "Voraxaze® meets the substantial clinical benefit criterion because the FDA accepted, reviewed, and approved the biologic licenses application (BLA) for Voraxaze® on an accelerated timeline. The FDA initiates an expedited review when a high unmet need exists and when an applicant has a product that may qualify as a substantial clinical improvement."

Several other public comments also stated that Voraxaze® meets the substantial clinical improvement criteria. One of the commenters, a pediatric oncologist, asserted that prior to Glucarpidase, there were no reliably effective interventions for patients suffering from high dose MTX induced renal dysfunction, a life threatening medical emergency. The commenter further noted that numerous interventions historically employed were generally invasive (that is, charcoal hemoperfusion), had variable but limited impact, and were not readily available at most treatment centers. The commenter concluded that Glucarpidase is a highly effective pharmacologic rescue that can be readily delivered to patients at high risk of or experiencing a life threatening complication of cancer therapy, that there is no other comparable pharmacologic intervention available, and that Glucarpidase is superior to less reliable, invasive measures. Another commenter stated that when Voraxaze® is used in a timely fashion, it can improve severe

---

[26] Bleyer WA. Methotrexate: clinical pharmacology, current status and therapeutic guidelines. Cancer Treat Rev. 1977;4:87–101.

MTX-induced toxicity, prevent the need for dialysis and other invasive procedures, and can be lifesaving. The commenter believed that Voraxaze® is a unique medication, which can treat a rare and life-threatening complication of methotrexate therapy which has no alternative mediation. The commenter believed that alternative supportive care to Voraxaze®, including hospitalization and dialysis, is exceptionally expensive.

Another commenter who also supported new technology add-on payments for the Voraxaze® believed that Voraxaze® is a drug that can provide life-saving reversal of toxic levels of methotrexate. The commenter further stated that patients with toxic levels of methotrexate are hospitalized and receive the drug during an inpatient admission. However, due to its high cost, the commenter explained that many hospitals are reluctant to stock Voraxaze® in the pharmacy or use it at all due to the lack of reimbursement available when used as an inpatient medication. The commenter continued by stating that the alternative is to provide Leucovorin rescue and vigorous hydration, which often is effective and significantly cheaper. However, the commenter noted that this approach results in prolonged hospital stays, which have their own costs (to the system at large) and expose the patient to potential iatrogenic complications. If a new technology add-on payment is available, the commenter believed that Voraxaze® would become the standard of care for methotrexate toxicity and enable a more rapid discharge of the patient from the inpatient setting. Another commenter stated that it believed "certain new biologic agents that prevent toxicity but have high drug acquisition costs are underused because of financial disincentives," and cited this technology as an example. The commenter noted

that this technology "can reduce the need for dialysis, reduce morbidity and decrease the length of hospital stay," and cited this background as an oncologist for support.

Response: After reviewing the totality of the evidence and the public comments we received, we agree that Voraxaze® represents a substantial clinical improvement for Medicare beneficiaries. It appears that Voraxaze® is less time intensive and allows select patient populations to avoid risks associated with current treatment options. Also, Voraxaze® is able to treat patients who have toxic MTX concentrations in a more effective and rapid way than existing treatment options in certain situations, and provides protection to eligible patient populations against potential harm associated with current treatment options. Specifically, the applicant provided the results from a study of 23 patients diagnosed with MTX-induced renal dysfunction treated with Voraxaze®. Based on the clinical trial data, the administration of Voraxaze® lowered toxic MTX concentrations in patients within 15 minutes after the administration by more than 98 percent. Therefore, we believe that Voraxaze® represents a substantial clinical improvement for Medicare beneficiaries. However, we remain interested in seeing clinical endpoints that show that reduction in methotrexate levels leads to improved renal function.

Voraxaze® has met all three criteria for new technology add-on payments and is eligible for new technology add-on payments in FY 2013. Cases of Voraxaze® will be identified with ICD-9-CM procedure code 00.95 (Injection or infusion of glucarpidase). The cost of Voraxaze® is $22,500 per vial. The applicant stated that an average of four vials is used per Medicare beneficiary. Therefore, the average cost per case for

Voraxaze® is $90,000 ($22,500 x 4). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technologh or 50 percent of the costs in excess of the MS-DRG payment for the case. As a result, the maximum new technology add-on payment for Voraxaze® is $45,000 per case.

b. DIFICID™ (Fidaxomicin) Tablets

Optimer Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2013 for the use of DIFICID™ (Fidaxomicin) tablets. In the proposed rule, we summarized this application and stated that the applicant asserts that Fidaxomicin is a major clinical advancement in the options available to treat *Clostridium difficile*-associated diarrhea (CDAD).

Clostridium difficile (*C. Diff.*) is a bacterium that can cause infection with symptoms that range from diarrhea to life-threatening inflammation of the colon, and is also commonly referred to as CDAD. The symptoms associated with CDAD can be treated by stopping administration of an antibiotic because often antibiotics can alter the native intestinal microflora and thus trigger CDAD. For mild cases of CDAD, this step may be sufficient to relieve the associated symptoms. However, many patients who have been diagnosed with more severe cases of CDAD require further treatment. Further treatment options include prescribing antibiotics such as Metronidazole or Vancomycin, prescribing probiotics administered in conjunction with antibiotics, and performing surgery using a fecal transplant to restore healthy intestinal bacteria by placing donor stool in the colon. According to the applicant, about one-fourth of the patients diagnosed with CDAD experience a recurrence of these associated symptoms.

As indicated on the labeling submitted to the FDA, the applicant noted that Fidaxomicin is taken twice a day as a daily dosage (200 mg tablet twice daily = 400 mg per day) as an oral antibiotic. The applicant asserts that Fidaxomicin provides potent bactericidal activity against *C. Diff.,* and moderate bactericidal activity against certain other gram-positive organisms, such as enterococcus and staphylococcus. Unlike other antibiotics used to treat CDAD, the applicant noted that the effects of Fidaxomicin preserve bacteroides organisms in the fecal flora. These are markers of normal anaerobic microflora. The applicant asserts that this helps prevent pathogen introduction or persistence, which potentially inhibits the re-emergence of *C. Diff.*, and reduces the likelihood of overgrowths as a result of vancomycin-resistant Enterococcus (VRE). Because of this narrow spectrum of activity, the applicant asserts that Fidaxomicin does not alter this native intestinal microflora.[27]

With regard to the newness criterion, Fidaxomicin was approved by the FDA on May 27, 2011, for the treatment of CDAD in adult patients, 18 years of age and older. Fidaxomicin was commercially available on the market within 7 weeks after the FDA's approval was granted. Currently, there are not any ICD-9-CM diagnosis or procedure codes that exist to uniquely identify the use of Fidaxomicin, or any oral drug, as a procedure. Optimer submitted a request to the ICD-9-CM Coordination and Maintenance Committee for a new ICD-9-CM procedure code, which was discussed at the committee's meeting on March 5, 2012. For further information regarding the code

---

[27] Koo, Garey et al. Future novel therapeutic agents for Clostridium difficile infection. Expert Opin Investig Drugs.,2010;19(7):825-836.
Tannock, Munro et al., A new macrocyclic antibiotic, fidaxomicin (OPT-80), causes less alteration to the bowel microbiota of Clostridium difficile-infected patients than does vancomycin. Microbiology. 2010 Nov;156(Pt 11):3354-9.

proposal, we refer readers to the CMS Web site at: http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.

In the proposed rule, we stated that we believe that under our current new technology add-on payment policy, eligibility for consideration for new technology add-on payments is limited to new technologies associated with procedures described by ICD-9-CM codes. In the FY 2002 IPPS final rule, we established the framework for our current policy (66 FR 46907 through 46915). The discussion of technologies in that rule focuses on those technologies identifiable by ICD-9-CM codes. We also discuss in response to comments the feasibility and appropriateness of HCPCS codes and V-codes. Similar to ICD-9-CM codes, HCPCS codes are also a procedure-based system and identify procedures. We noted in that rule that V-codes would not be appropriate to use for identification of new technology because they are not a substitute for procedure coding. Volume 3 of ICD-9-CM contains codes that describe inpatient procedures (65 FR 50325). In other words, we have not considered drugs that are only taken orally to be eligible for consideration for new technology add-on payments, because there is no procedure associated with these drugs and, therefore, no ICD-9-CM code(s).

As we stated in the proposed rule, this interpretation is also consistent with other Medicare payment policies. For example, when drugs taken orally are given as part of an outpatient encounter, they would likely be considered self-administered drugs under the Hospital Outpatient Prospective Payment System (OPPS). If a Medicare beneficiary who has outpatient status were to be provided a self-administered drug by a hospital or

wholly-owned or wholly-operated entity of that hospital and that beneficiary were subsequently admitted to that hospital for a related reason within three days, the hospital may not include these self-administered drugs on the inpatient bill (under the 3-day payment window policy), because self-administered drugs are not covered under the OPPS. However, they would be required to include nondiagnostic services related to admission and all other diagnostic services on the inpatient bill (under the 3-day payment window).

We invited public comment on our interpretation of our policy regarding drugs that are only self-administered for consideration for new technology add-on payments. Further, we invited public comment on whether or not Fidaxomicin meets the newness criterion.

Comment: A number of public commenters, including the applicant, stated that the technology meets the newness criterion. Specifically, commenters discussed: (1) the ICD-9-CM coding for this technology, (2) the statutory authority for the policy in relation to the coding of oral therapies, (3) CMS' current policy and practices regarding coding, (4) CMS' practices with regard to establishing new codes to implement payment policies, (5) the use of V-codes in the ICD-9-CM system for oral drugs, and (6) the non-ICD-9-CM options for coding this technology for the new technology add-on payments. We summarize each issue, in turn, in the following comments and responses below.

Response: We appreciate the commenters' supporting rationale for how this technology meets the newness criterion under the new technology add-on payment policy. We respond to each of the six points, in turn, below. We note that, as a result of

our analysis of the public comments we received, in our responses below, we, in this final rule, revised our policy to allow the use of National Drug Codes (NDCs) to identify oral medications that have no inpatient procedure for the purposes of new technology add-on payments. This change will be effective for payments for discharges occurring on or after October 1, 2012. We note that this does not preclude CMS from using additional ICD-9-CM procedure or diagnosis codes to identify cases for this new technology in conjunction with NDCs. In particular, for this technology, we established a methodology to identify cases for new technology add-on payments by using the NDC for the drug (52015-0080-01) and ICD-9-CM diagnosis code 008.45, Intestinal infection due to Clostridium difficile. Furthermore, we establish that the beginning of the newness period for this technology is its FDA approval date of May 27, 2011.

Comment: The applicant submitted a public comment asserting that it believed that an ICD-9-CM procedure code would be the "best option" and noted that this should be limited to the "sole purpose of tracking use of the product" for new technology add-on payments. The applicant indicated that it did not believe this created a precedent for inpatient procedure coding.

Response: With regard to use of an ICD-9-CM procedure code for this technology, subsequent to and as recommended by CMS at the March 12, 2012 ICD-9-CM Coordination and Maintenance (C&M) Committee meeting, no new ICD-9-CM procedure code for the administration of this technology was created. Public comments received during and subsequent to the public meetings opposed the establishment and addition of codes for self-administered drugs. The commenters stated

that this type of service has never been included in ICD-9-CM procedure codes. Other commenters believed that such an addition to the ICD-9-CM system would be setting a major new precedent. Hospitals currently code and report procedures and more invasive services such as surgeries, infusion of drugs, and specialized procedures such as cardiac catheterizations. Hospitals do not code nor report self- administered drugs. While we appreciate the commenters' belief that a new ICD-9-CM procedure code should be created and that this code could be limited to new technological procedures and would thus not create a precedent for inpatient procedure codes, we disagree for the reasons stated above and described in more detail below. While the ICD-9-CM procedure coding system has been used to create codes for categories of service not previously coded for the purpose of new technology add-on payments, these new codes have been limited to inpatient procedures associated with their respective technologies. The commenters cited, as an example, the creation of procedure code 00.11, Infusion of drotrecogin alfa (activated) [Xigris], as an example of where CMS has "created unique new ICD-9-CM codes in categories of service that did not previously exist." We note that infusions of drugs have been part of the ICD-9-CM inpatient procedure coding system since it was created in 1979. Infusion of drugs requires specialized health care personnel to administer the infusion procedure. Patients taking self-administered drugs do not require the use of hospital or health care personnel to perform a procedure. Since the inception of the ICD-9-CM coding system, drugs given to a patient through use of an infusion have been considered procedures described by ICD-9-CM codes. The identification of a patient taking a self-administered drug has never been described by ICD-9-CM codes

because it was not deemed to be a hospital procedure. This technology is an orally administered drug and, as noted by the applicant in its public comment, "must be administered orally to effectively treat CDAD". Orally-administered drugs require no inpatient procedure to administer. Therefore, we believe it would be inappropriate to establish an ICD-9-CM procedure code for their administration, even for the purpose of new technology add-on payments.

Comment: One commenter asserted that the statutory authority exists for new technology add-on payments for oral therapies with no inpatient procedure (that is, infusion). The commenter reiterated our statement in the proposed rule that, "we believe that under our current new technology add-on payment policy, eligibility…is limited to new technologies associated with procedure codes described by ICD-9-CM codes" (77 FR 27939). Similarly, another commenter stated that, "CMS asked whether DIFICID™ could qualify under the statute and regulations for new technology because it is an oral therapy." Both commenters stated that the proposed rule "does not assert that there is any corresponding statutory or regulatory bar to granting a [new technology add-on payment] to an oral therapy, and indeed there is none." Another commenter stated that, while self-administered drugs are not covered by Part B, they are covered by Part A. Another commenter stated that, "the fact that DIFICID™ must be administered orally to effectively treat [clostridium dificile associated disease] should not preclude it from being considered under the [new technology add-on] policy." Commenters pointed out that the statute "require[s] that the agency 'shall' establish a mechanism to recognize costs of new medical services or technologies…which 'shall' provide for additional payment when

such services are used." Another commenter further stated that it believed that "the Congressional intent was explicit" and stated that the statute "allow[s] 'any code such as ICD-9-CM and its subsequent revision' (emphasis added [in the public comment])." Another commenter stated that, "the FY2002 [final rule on the new technology add-on payment] exemplifies CMS' authority and flexibility to use codes broadly for [the new technology add-on payment], if needed." Another commenter recognized that the statute explicitly points out the use of ICD-9-CM codes, but reminded the agency that they believed that "the regulation permits administrative flexibility." Additionally, the commenter described the application form, and noted that, "this policy document includes 5 specific questions not necessarily reflected directly in statute or regulation." Of the five items pointed out by the commenter, four refer to FDA approval, and one to ICD-9-CM procedure coding.

Response: With regard to the question of whether or not statutory authority exists to allow new technology add-on payments for oral medications without inpatient procedures (that is, infusion), we note that, as the commenters pointed out, in the proposed rule, we did not assert that such statutory authority did not exist. We believe that under our current new technology add-on payment policy, eligibility for new technology add-on payments is limited to new technologies associated with procedure codes described by ICD-9-CM codes (77 FR 27939). We believe that the statute could be interpreted in a manner that does not preclude new technology add-on payments for oral medications that have no inpatient procedure (that is, infusion) insofar as such an oral medication meets the other aspects of the newness criterion in addition to meeting the

cost and substantial clinical improvement criteria. We interpret our current policy as limiting new technology add-on payments to technologies associated with inpatient procedures, as described in the FY 2002 final rule on CMS' new technology add-on payment policy (66 FR 46915). We note that this technology is the first application we have received for a technology that is an oral medication where no inpatient procedure is associated. In light of public comments we received, we are revising our policy to allow for the use of an alternative code set to identify oral medications where no inpatient procedure is associated for the purposes of new technology add-on payments. We are establishing the use of NDCs as the alternative code set for this purpose and describe our rationale for this particular code set in response to comments below. This change will be effective for payments for discharges occurring on or after October 1, 2012. We note that this does not preclude CMS from using additional ICD-9-CM procedure or diagnosis codes to identify cases for this new technology in conjunction with this alternative code set. We also agree with the comment that these oral medications for which no inpatient procedure is associated may be considered self-administered drugs under Part B and are not payable under the outpatient prospective payment system (OPPS). We remind hospitals that, although hospitals are required to bundle related therapeutic services within the 3 days prior to and on the day of inpatient admission on the inpatient claim, hospitals may not include services that are not payable under the OPPS within the 3 days prior to and on the day of inpatient admission as part of the inpatient claim (42 CFR 412.2(c)(5)).

Comment: Commenters reviewed our current policy and practice with regard to identification of new technologies for new technology add-on payments. They reiterated statements from the FY 2002 final rule on CMS' new technology add-on payment policy, while one commenter pointed out that, "CMS considered several coding options to track new procedures and technologies…and discussed use of ICD-9-CM V-codes, HCPCS Level II codes, and G codes to classify new technologies." Another commenter stated that CMS has in the past created ICD-9-CM codes for new technology add-on payments, and cited as an example the creation of procedure code 00.11, Infusion of drotrecogin alfa (activated) [Xigris], as an example of where CMS has "created unique new ICD-9 codes in categories of service that did not previously exist."

Response: With regard to our current policy and practice on the use of code sets to identify new technologies for new technology add-on payments, we appreciate the commenters' input. As we stated in response to other public comments, we interpret our current policy as limiting new technology add-on payments to technologies associated with inpatient procedures, as described in the FY 2002 final rule on the new technology add-on payment policy. We note that this technology is the first application we have received for a technology that is an oral medication with no inpatient procedure. Also, as we stated in response to other comments, we point out that the example the commenters cite, procedure code 00.11, Infusion of drotrecogin alfa (activated) [Xigris], is for an infusion and that infusion can be an inpatient procedure.

Comment: Commenters reviewed our practice with regard to establishing new codes to implement Medicare policies. Specifically, they mentioned the creation of a

claim modifier to reflect the use of surgical devices that CMS created to "implement claims processing of a new policy" and also the creation of policy claim codes MX (wrong surgery on patient), MY(wrong surgery on body part), and MZ (surgery on wrong patient) to identify claims to implement a national coverage decision regarding certain never events. They asserted that CMS is able to establish new codes to implement policies.

Response: With regard to the examples of CMS' practices of establishing new codes to implement Medicare policies, we appreciate the commenters' responses. We agree that from time to time CMS will implement, as needed, new codes and processes to implement Medicare policies, including payment and coverage policies. The examples provided by the commenters do not specifically address the new technology add-on payment policy instead they address other Medicare payment policies and national coverage decisions.

Comment: One commenter pointed out that V-codes currently exist for oral drugs. Specifically, the commenter cited code V58.66 for long term (current) use of aspirin and code V58.68 for long-term (current) use of bisphosphonates. The commenter also pointed out that three codes in subcategory V07.5 for the use of agents affecting estrogen receptors and estrogen levels have inclusion notes for multiple medications, some of which are oral.

Response: With regard to the existence of V-codes for oral drugs, we agree with the commenters that V-codes exist that capture the long term use of certain drugs, including those that may be orally administered. V-codes are used to capture additional

information about factors influencing health status and contact with health services. The codes for long-term (current) drug use were created to assist in following patients who use certain drugs over a long period of time. The codes do not necessarily indicate that a patient received the specific drug during the current health care encounter. The patient may be taking the drug based on a prescription received during a prior health care encounter and did not receive it during the current encounter.

However, we have not adopted the use of V-codes for use in the new technology add-on payment policy. Currently, the new technology add-on payment policy is based on the use of ICD-9-CM procedure codes, which indicate that a procedure or service is provided during the hospital stay. The long-term (current) drug use V-codes described do not provide this information. As indicated earlier, the V-codes indicate the patient has been on certain drugs on a long-term basis, and do not necessarily indicate that the patient received the drug during the current health care encounter. We continue to believe that V-codes are not appropriate for new technology add-on payments because we do not believe the nature of these codes appropriately identifies new technologies; they indicate that some circumstance or problem is present which influences the person's health status, but is not in itself a current illness or injury. Common V-codes are status codes, history codes, aftercare codes, and follow-up codes. In addition, V-codes do not identify items related to current resource use for an inpatient stay. For the most part, V-codes do not impact the DRG, and they are not taken into consideration when forming DRG assignment and, thus, are not used in setting relative weights for the IPPS. However, we note that we continue to explore the usefulness of these and other alternatives, such as

those available in ICD-10, for coding and identifying technologies for the purposes of new technology add-on payments.

Comment: One commenter described non-ICD-9-CM alternatives for coding this technology for the purposes of the new technology add-on payment policy. One option described by the commenter was the use of a value code and condition code to identify this technology. The commenter pointed out that a value code, value code 77, currently exists to identify when a new technology add-on payment is being claimed. The commenter noted that value codes are used with condition codes, and suggested that an option could be for CMS to submit a request to the National Uniform Billing Committee (NUBC) for a "unique Condition Code to describe DIFICID™ administration." A second option described by the commenters was to use a national drug code (NDC) on the claim to identify the technology for the purposes of new technology add-on payments. The commenter described two ways to implement such an option, one where the NDC would be used in isolation (as product information in Box 80 of the UB-04 claims form) and one where it would be used in combination with ICD-9 diagnosis code 008.45, Intestinal infection due to Clostridium difficile (where the NDC would be reported on the UB-04 in Box 43 and the diagnosis code reported on the UB-04 in Box 65). The commenter pointed out that using the NDC in isolation may require hospitals to "make changes to their billing systems" and that using the NDC in combination with a diagnosis code may require hospitals to "make substantial reprogramming to their systems." Because of the possibility that hospitals may need to make changes, the commenter stated

that they believed that other options would be preferable and that an ICD-9-CM code is the "best option."

Response: With regard to the non-ICD-9-CM options for identifying this technology and new technologies for new technology add-on payments, we appreciate the commenters' suggestions. The commenters first discussed a value code or condition code option for identifying new technologies. We agree that currently value code 77 is used to identify claims for new technology add-on payments. Commenters suggested that CMS could request a condition code from the NUBC to be used in conjunction with this value code to identify this new technology. While we appreciate the commenters' suggestion, we believe that this unnecessarily subjects eligibility for new technology add-on payments to a non-CMS claims identifier field. Furthermore, we note that even on an expedited basis, it is not likely that the NUBC process would necessarily result in the timely creation of a condition code to identify this technology. Therefore, we disagree with the commenters that this is a feasible option for coding and identifying technologies for the purposes of new technology add-on payments. Commenters then discussed two ways to use the NDC to identify this technology. We agree that NDCs can be used to identify drugs and that, in the instance where no inpatient procedures are associated with a drug, the NDC could be used to identify an oral drug for new technology add-on payments. While commenters stated that they believed this may require hospitals to change their "billing practices" or "make substantial reprogramming to their systems," we believe that these changes, insofar as they might be needed, would not represent a large burden for hospitals. We note that currently the NDC code is used on outpatient

claims for the ESRD-PPS to identify oral equivalent ESRD drugs. We further note that the hospital would be required to report the NDC code for the purposes of new technology add-on payments so that it could receive a new technology add-on payment which, by definition, is an increase relative to the payment they would have received in the absence of such an add-on payment. Specifically, the commenter discussed using the NDC in Box 43 in conjunction with the diagnosis code 008.45 (Intestinal infection due to Clostridium difficile) or using the NDC as product information in Box 80. We agree with the applicant and the other commenters that it is important to identify cases for new technology add-on payments using the diagnosis code 008.45. Because the NDC can specifically identify this technology, and other technologies that are oral drugs where no inpatient procedure is associated, we believe it can be used to identify these technologies for purposes of new technology add-on payments. We continue to believe our current policy to recognize new technologies associated with inpatient procedures through ICD-9-CM coding is appropriate and, in response to public comments we received, are expanding our policy prospectively for discharges occurring on or after October 1, 2012, to recognize oral medications where no inpatient procedure can be associated through the coding of NDCs. In the case of this application, we agree with the commenter that the NDC code of 52015-0080-01 can be used in conjunction with diagnosis code 008.45 to identify the use of this technology, and establish that the use of both codes will identify this technology for the purposes of new technology add-on payments. We discuss our broader policy change to allow NDCs as an alternative code set to identify oral drugs where no inpatient procedure is associated in response to other comments.

With regard to the cost criterion, Optimer researched the FY 2010 MedPAR file for cases that would be eligible for treatment with Fidaxomicin to determine if it would qualify for the cost criterion for new technology add-on payments. Based on its analysis, the applicant identified cases in which a patient had been diagnosed with CDAD by searching the MedPAR file for claims that included ICD-9-CM diagnosis code 008.45 (Intestinal infection due to *Clostridium difficile*) as a principal diagnosis or secondary diagnosis. Optimer provided three examples of how the results of the analyses of different MS-DRGs demonstrate that it meets the cost criterion.

Under the first analysis, the applicant researched the FY 2010 MedPAR file for cases that included ICD-9-CM diagnosis code 008.45 as a principal or secondary diagnosis across all MS-DRGs. The applicant found 162,310 cases within 536 MS-DRGs, and determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $50,136. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical Consumer Price Index (CPI), the applicant determined a case weighted standardized charge per case that equals $53,394. The applicant then added the charges related to the technology to the inflated charges. Finally, the applicant determined a final case-weighted average standardized charge per case of $58,994, which exceeds the case-weighted threshold of $43,673. Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount in this first analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

Under the second analysis, the applicant researched the FY 2010 MedPAR file for cases that included ICD-9-CM diagnosis code 008.45 only as a principal diagnosis, which mapped to MS-DRGs 371 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC), 372 (Major Gastrointestinal Disorders and Peritoneal Infections with CC), and 373 (Major Gastrointestinal Disorders and Peritoneal Infections without CC/MCC). The applicant found 55,410 cases, and determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $28,007. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical CPI, the applicant determined a case-weighted standardized charge per case that equals $29,828. The applicant then added the charges related to the drug to the inflated charges. The applicant then determined a final case-weighted average standardized charge per case of $35,428, which exceeds the case-weighted threshold of $34,730. Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount in this second analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

Under the third analysis, the applicant again researched the FY 2010 MedPAR file for cases that included ICD-9-CM diagnosis code 008.45 as a principal or secondary diagnosis across all MS-DRGs. The applicant then narrowed the results of the analysis to include only the top 37 MS-DRGs (in volume of cases), which accounted for 75 percent of all cases. The applicant's methodology resulted in 121,748 cases, and the applicant determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $45,523. Using a factor of 6.5 percent to inflate the charges

to 2012 rates based on the Medical CPI, the applicant determined a case-weighted standardized charge per case that equals $48,482. The applicant then added the charges related to the drug to the inflated charges. The applicant then determined a final case-weighted average standardized charge per case of $54,082, which exceeds the case-weighted threshold of $42,452. Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount in this third analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

In the three analyses discussed above, the applicant submitted data related to the estimated cost and charge of the drug (using a charge markup). However, the applicant has not released the cost of the technology, asserting that it is proprietary information. The applicant converted the cost of the technology to a charge using a charge markup (a factor of 6.5 percent based on the Medical CPI) that represented a 10-day dosage.

In the proposed rule, we expressed concern that these analyses do not take into account situations in which patients would be prescribed Fidaxomicin later in the duration of their inpatient stay, and may finish the course of Fidaxomicin sometime after being discharged from the hospital. In addition, as discussed above, if Fidaxomicin is prescribed and self-administered during the 3-day period prior to admission to an IPPS hospital for a related encounter, we do not believe that this service is payable under the OPPS, and we do not believe that charges associated with it can be included on the inpatient claim submitted to Medicare because of the 3-day payment window policy. Therefore, in the proposed rule, we noted that it may not be appropriate to include in the

applicant's calculations the full charges related to Fidaxomicin and the corresponding proprietary charges for the 10-day dose. In addition, in the proposed rule, we stated that we believed that it is necessary for the applicant to adjust its estimates to remove from the MedPAR file's claims for the charges that describe other types of treatment options such as Vancomycin, since use of these treatments would preclude use of Fidaxomicin. Furthermore, to identify the cases that may be eligible for the technology's use, the applicant researched and analyzed claims that included ICD-9-CM diagnosis code 008.45 as the principal diagnosis or as the principal or secondary diagnosis. We are concerned that this baseline for eligible cases may not represent the appropriate universe of cases, such as if all MS-DRGs were considered or if a subset of MS-DRGs were considered.

We invited public comment on whether or not Fidaxomicin meets the cost criterion. In addition, we invited public comment on the methodologies used by the applicant in its analyses, in particular the assumptions made about the dosage in developing the cost analysis. We were also interested in comments about the applicant's selection of claims with an ICD-9-CM diagnosis code 008.45 as the principal diagnosis or secondary diagnosis, and whether those cases accurately represented the Medicare population that may benefit from the technology's use.

Comment: The applicant submitted public comments responding to our concerns from the proposed rule. Our first concern was that these analyses did not take into account situations in which patients would be prescribed Fidaxomicin later in the duration of their inpatient stay and may finish the course of Fidaxomicin sometime after being discharged from the hospital. The applicant responded by providing a sample of

claims of patients that received DIFICID™ during their inpatient stay to determine the amount of days that DIFICID™ is used within the inpatient setting. The applicant collected 116 inpatient stays across 26 unique MS-DRGs for patients who received DIFICID™ during their stay of which, 71 of the claims were Medicare fee-for-services (FFS) cases which mapped to 22 unique MS-DRGs. Regarding these data (from all 116 cases) the applicant noted the following: the average length of stay for all DIFICID™ (Fidaxomicin) cases is 13.9 days; on average, patients started DIFICID™ (Fidaxomicin) on day 6.7 of their stay; and on average, patients received DIFICID™ for 6.2 days of their stay. Using the subset of 71 Medicare claims also demonstrated that patients received DIFICID™ on average of 6.2 days of their stay.

Using the 116 cases from the sample, the applicant computed a case-weighted average standardized charge per case of $92,684, which exceeds the case-weighted threshold of $45,388. The applicant also conducted a similar analysis using the Medicare subset of 71 Medicare cases. The applicant computed a case-weighted average standardized charge per case of $100,146, which exceeds the case-weighted threshold of $44,980. Because the case-weighted average standardized charge per case for both scenarios exceeds the case-weighted threshold amount (in both scenarios), the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

Our second concern was with regard to the 3-day payment window. If Fidaxomicin is prescribed and self-administered during the 3-day period prior to admission to an IPPS hospital for a related encounter, as we noted in the proposed rule, we do not believe that this service is payable under the OPPS, and we do not believe that

charges associated with it can be included on the inpatient claim submitted to Medicare because of the 3-day payment window policy. Therefore, it may not be appropriate to include in the applicant's calculations the full charges related to Fidaxomicin and the corresponding proprietary charges for the 10-day dose. The applicant noted that all cases from the sample data show that treatment was initiated well after admission to the inpatient setting. Even for those patients who presented at admission with a clostridium difficile infection (CDI) diagnosis, DIFICID™ (Fidaxomicin) began an average of 4.6 days after the patient was admitted. The applicant believed that these data address CMS' concern over the potential for outpatient administration of DIFICID™ (Fidaxomicin) prior to inpatient admission. The applicant asserted that to date, utilization patterns of DIFICID™ (Fidaxomicin) show that the drug is used primarily in the inpatient setting and that outpatient use prior to admission is very limited.

Our third concern was that the applicant's analyses may not represent the appropriate universe of cases, such as if all MS-DRGs were considered or if a subset of MS-DRGs were considered. The applicant reiterated that it submitted three different types of MedPAR analysis, one of which captured all cases where C. Difficile infection (CDI) occurred. The applicant added that the first MedPAR analysis contained no restrictions on its search for cases of CDI and as such should represent the complete universe of patients who may be eligible for DIFICID™. The applicant further stated that its data sample of 116 inpatient claims contains the actual MS-DRGs and standardized charges of patients who received DIFICID™ which meets the cost criteria.

The applicant noted that the sample data (of 116 claims) does not represent the full universe of eligible DIFICID™ (Fidaxomicin) patients for the following reasons: First, because DIFICID™ was new, the applicant asserted that hospitals may not have been aware of the full benefit of the drug. Second, the applicant asserted that hospitals may have believed they were not adequately compensated for the cost of DIFICID™ within the existing MS-DRG payment and, therefore, may not have considered DIFICID™ for treatment except in cases where the patient's costs were significantly higher than average and additional outlier payments were anticipated. The applicant concluded that it believed that its original analysis of the FY 2010 MedPAR data with all patients diagnosed with CDI during their inpatient stay represents the full universe of potential DIFICID™ cases, and is the most appropriate case scenario for purposes of calculating DIFICID™'s (Fidaxomicin's) qualifications for the new technology add-on payment cost criterion.

We were also concerned that it is necessary for the applicant to adjust its estimates to remove from the MedPAR file's claims the charges that describe other types of treatment options such as Vancomycin because use of these treatments would preclude use of Fidaxomicin. The applicant replied in its comment that it performed a cost criterion estimate with DIFICID™ removed from the inflation-adjusted weighted average standardized charge. The applicant explored additional data analyses to separate Vancomycin charges from the total MedPAR charges. However, the applicant asserted that no approach was viable due to (1) lack of distinct coding to identify inpatient cases in which Vancomycin was administered, (2) lack of data on Vancomycin dosing per case,

and (3) lack of data on the appropriate hospital mark-up applied to Vancomycin costs. Therefore, the applicant stated that it believed, in the absence of data to estimate Vancomycin charges included in the MedPAR CDI cases, one methodology to approximate this was by, removing the inflated adjusted charges for DIFICID™ from the case-weighted average standardized charge per case of the first scenario. The applicant also noted that, although it determined an average use of DIFICID™ for 6.2 days within the inpatient setting based on the sample of 116 claims, it recommended that CMS consider 6.5 days of inpatient administration of DIFICID™. The applicant justified this increase based on its belief that hospitals and physicians will use it more. In particular, the applicant believed that the increased adoption of DIFICID™ would lead to earlier prescription of DIFICID™ by physicians for primary CDAD treatment in the inpatient setting as opposed to a secondary treatment. Using this methodology (of removing inflated adjusted charges for DIFICID™ and assuming utilization of DIFICID™ for 6.5 days within the inpatient setting), the applicant revised its calculation for the first analysis (which included all cases of C. Diff) and determined a case-weighted average standardized charge per case of $55,214, which exceeds the case-weighted threshold of $43,673. Because the case-weighted average standardized charge per case exceeds the case-weighted threshold amount, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

Response: We appreciate the applicant's response to our concerns and believe that the sample of claims the applicant submitted substantiates the average use of DIFICID™ within the inpatient setting. We agree with the applicant that the appropriate

universe of cases is the first MedPAR analysis which contained no restrictions on its search for cases of CDI and as such should represent the complete universe of patients who may be eligible for DIFICID™. However, at this time we believe it is appropriate to use an estimate of 6.2 days of inpatient administration of DIFICID™ from the sample of claims rather than the 6.5 days that the applicant recommended. The estimate of 6.2 days is based on actual data while the extra 0.3 days (for a total of 6.5 days) is based on projected assumptions by the applicant. Therefore, we are revising the applicant's analysis described above of the first MedPAR analysis by substituting 6.2 days instead of 6.5 days for the administration of DIFICID™ within the inpatient setting. We also appreciate the applicant's discussion of the difficulties associated in the removing of charges associated with Vancomycin, which represents one potential treatment option this technology could replace. We do not disagree with the applicant's suggestion to remove inflated adjusted charges for DIFICID™ as an alternative. Using this methodology (of removing inflated adjusted charges for DIFICID™ and assuming utilization of DIFICID™ for 6.2 days within the inpatient setting), we determined a case weighted average standardized charge per case of $55,130, which still exceeds the case-weighted threshold of $43,673. Because the case-weighted average standardized charge per case exceeds the case-weighted threshold amount, we believe the applicant has met the cost criterion.

With regard to the substantial clinical improvement criterion, in the proposed rule, we stated that the applicant maintained that Fidaxomicin represents a substantial clinical improvement to the treatment options currently available. According to the applicant,

Fidaxomicin represents the first major clinical advancement in the treatment options available to address CDAD in more than 25 years, and it is one of only two agents indicated by the FDA to treat this condition. The applicant noted that reports from its clinical trials show that a higher proportion of patients achieve positive clinical response to treatment with Fidaxomicin as opposed to treatment with Vancomycin. The applicant reported that these patients did not experience recurrences of associated symptoms for at least 25 days after the end of treatment. The applicant asserted that Fidaxomicin has longer acting antimicrobial activity and inhibits spore formation in *C. difficile* in vitro. The applicant stated that *C. difficile* cells produce spores when exposed to air; therefore, transmission of infection occurs even when the cells themselves are killed.

The applicant reported on two randomized, double-blinded trials.[28,29] A non-inferiority design was utilized to demonstrate the efficacy of administering Fidaxomicin (200 mg twice daily for 10 days) compared to administering Vancomycin (125 mg four times daily for 10 days) to adult patients diagnosed with CDAD. The demographic profile and baseline CDAD characteristics of the subjects enrolled in both trials were similar. These patients had a median age of 64 years, were mainly white (90 percent), female (58 percent), and inpatients (63 percent).

---

[28] Pivotal trial 101.1.C.003:
Thomas J. Louie, M.D., Mark A. Miller, M.D., Kathleen M. Mullane, D.O., Karl Weiss, M.D., Arnold Lentnek, M.D., Yoav Golan, M.D., Sherwood Gorbach, M.D., Pamela Sears, Ph.D., and Youe-Kong Shue, Ph.D. for the OPT-80-003 Clinical Study Group. *Fidaxomicin versus Vancomycin for Clostridium difficile Infection*. N Engl J Med 2011; 364:422-431February 3, 2011.
Attached reference: 12_LouieNEJM2011.pdf

[29] Crook D, Weiss K, Comely O, Miller M, Esposito R, Gorbach 8. Randomized Clinical Trial (RCT) in *Clostridium difficile* Infection (CDI) Confirms Equivalent Cure Rate and Lower Recurrence Rate of Fidaxomicin (FDX) versus Vancomycin (VCN). 20th European Congress of Clinical Microbiology and Infectious Diseases; April 10-13, 2010; Vienna, Austria.

The applicant reported that the primary efficacy endpoint (for both trials) was the clinical response rate at the end of therapy, based upon improvement in diarrhea or other symptoms such that, in the investigator's judgment, further CDAD treatment was not needed. An additional efficacy endpoint was a sustained clinical response 25 days after the end of treatment. Sustained response was only evaluated for patients who were clinical successes at the end of treatment. Sustained response was defined as clinical response at the end of treatment, and survival without proven or suspected reoccurrence of a diagnosis of CDAD beyond 25 days after the end of treatment. The results for clinical response at the end of treatment in both trials, which the applicant submitted in the table below, indicate that the effects of administering Fidaxomicin is noninferior to the effects of administering Vancomycin based on the 95 percent confidence interval (CI) lower limit being greater than the non-inferiority margin of -10 percent.

The applicant stated that the results for sustained clinical response at the end of the follow-up period, also shown in the table below, indicate that the effects of administering Fidaxomicin is superior to the effects of administering Vancomycin on this endpoint. Because clinical success at the end of treatment and mortality rates were similar across treatment arms (approximately 6 percent in each group), the applicant determined that the differences in sustained clinical response were due to lower rates of proven or suspected reoccurrence of diagnoses of CDAD in patients during the follow-up period. In addition, the applicant asserts that the effects of administering Fidaxomicin has minimal impact on normal gut flora due to its limited specificity, and could be

associated with a lower risk of acquisition of VRE if used as a treatment option instead of administering Vancomycin.

Clinical Response Rates at End-of-Therapy and Sustained Response at 25 days Post-Therapy

	Clinical Response at End of Treatment			Sustained Response at Follow-Up		
	FIDAXOMICIN % (N)	Vancomycin % (N)	Difference (95% CI)	FIDAXOMICIN % (N)	Vancomycin % (N)	Difference (95% CI)'
Trial 1	88% (N=289)	86% (N=307)	2.6% (-2.9%, 8.0%)	70% (N=289)	57% (N=307)	12.7% (4.4%,. 20.9%)
Trial 2	88% (N=253)	87% (N=256)	1.0% (-4.8%, 6.8%)	72% (N=253)	57% (N=256)	14.6% (5.8%, 23.3%)

Based on the analysis described above, the applicant asserts Fidaxomicin meets the substantial clinical improvement criterion as a treatment option with the potential to decrease hospitalizations and physician office visits, as well as to improve the quality of life for patients who have been diagnosed with CDAD.

We expressed concern in the proposed rule that this technology may not offer a substantial clinical improvement compared to other effective treatment alternatives already available in the treatment of patients who have been diagnosed with CDAD. In addition, although the applicant maintains that there is no evidence of significant clinical resistance developing with the use of this drug, in the proposed rule, we expressed concern about the long-term possibility that patients may develop resistance to this drug since the applicant provided no data to substantiate its claim. We invited public comment on whether or not Fidaxomicin meets the substantial clinical improvement criterion based on the analysis and results presented by the applicant.

Comment: Regarding our concern that the technology may not offer a substantial clinical improvement, the applicant noted that "DIFICID™ is the only agent proven to

provide a superior sustained clinical response versus Vancomycin – meaning a higher proportion of patients achieve clinical response and remain free of potentially devastating recurrences through 25 days after the end of treatment…Recurrence are a unique challenge in the management of CDAD in large part due to the ability of C. difficile to form spores." The applicant also noted that its technology prevents sporulation while other existing medications do not. In addition, the applicant discussed oral administration as being "advantageous in treating CDAD".

Regarding our concern about the long-term possibility that patients may develop resistance to this drug, the applicant responded with several pieces of information. First, the applicant cited advice from "antimicrobial stewardship programs, such as those recommended by the CDC 'Get Smart' program (http://www.cdc.gov/getsmart/) and SHEA/IDSA policy (http://www.idsociety.org/Stewardship Policy/)," which the applicant noted, "advise utilizing the most narrow spectrum agent to treat an infection to help decrease the likelihood of resistant development." The applicant believed Fidaxomicin "uniquely fits in this profile as, unlike broad spectrum antibacterial drugs, it is targeted specifically against C. difficile with minimal impact on other bacteria, including the normal flora found in the gastrointestinal tract." Second, the applicant further stated that, "The potential for resistance to antibacterial agents increases when bacteria are exposed to suboptimal drug concentrations at the site of infection. However, DIFICID™ has minimal absorption from the intestines and fecal concentrations that are > 1000 times that required to kill C. difficile." Third, the applicant also noted that, "In laboratory testing, DIFICID™ exhibited no crossresistance with other classes of antibacterial drugs." and

"The low potential for patients to develop resistance to DIFICID™ was also demonstrated in two pivotal phase 3 clinical trials."Fourth, the applicant noted that, "resistance to treating agents is not an issue with this disease, as it has not been reported with the other two commonly used agents, Metronidazole and Vancomycin." Further, the applicant stated that, "Despite Metronidazole and Vancomycin being utilized to treat C. difficile infection (CDI) and C. difficile-associated diarrhea (CDAD) for over 25 years, resistance has not been reported for either agent." Fifth, the applicant refers to the SHEA/IDSA guidelines noting that these "specifically state that considering the high fecal concentrations achieved with oral Vancomycin, emergence of resistance is likely not a concern." The applicant then concluded that, "Fidaxomicin is similar in this regard given its extremely high fecal concentrations." and that, "This indicates that the potential for resistance is extremely low when treating CDAD."

Response: We appreciate the applicant's response to our concerns from the proposed rule. We considered this information in our decision below on whether DIFICID™ meets the substantial clinical improvement criterion.

Comment: Several public commenters stated that Fidaxomicin meets the substantial clinical improvement criterion. One commenter noted, "In the past year, DIFICID™ clinically has been invaluable in treating some of these more difficult cases. The drug has been well tolerated, and we have seen fewer patients with recurrence after therapy with DIFICID™…DIFICID™ is revolutionary because it offers a significant advancement that we have not seen in previous CDI therapies: targeted therapy and reduced recurrences." Another commenter expressed support for the literature, research,

and data pertaining to the use of DIFICID™ on its patients with C. difficile infections. The commenter added that it has had the opportunity to use DIFICID™ on a few occasions thus far and has had very good outcomes, especially regarding the rapid improvement in symptoms.

Response: We appreciate the commenters' input. After reviewing the totality of the evidence and the public comments we received, we agree with the commenters that DIFICID™ (Fidaxomicin) represents a substantial clinical improvement over existing technologies. We believe that DIFICID™ represents a treatment option with the potential to decrease hospitalizations and physician office visits, and reduce the recurrence of CDAD, as well as to improve the quality of life for patients who have been diagnosed with CDAD.

Therefore, DIFICID™ (Fidaxomicin) has met all three criteria for the new technology add-on payment policy and is eligible for new technology add-on payments in FY 2013. Cases of DIFICID™ (Fidaxomicin) will be identified with ICD-9-CM diagnosis code 008.45 in combination with NDC code 52015-0080-01. Providers must code the NDC on the 837i Health Care Claim Institutional form (in combination with ICD-9-CM diagnosis code 008.45) in order to receive the new technology add-on payment. Further guidance will be issued after this final rule with how to code the NDC code on the 837i form. According to the applicant, the cost of DIFICID™ (Fidaxomicin) is $2,800 for a 10-day dosage. The average cost per day for DIFICID™ is $280 ($2,800/10). As discussed above, cases of DIFICID™ (Fidaxomicin) within the inpatient setting typically incur an average dosage of 6.2 days, which results in an average cost per

case for DIFICID™ of $1,736 ($280 x 6.2). We note, as stated above in our discussion of the cost criteria, we are not using an average dosage of 6.5 days for DIFICID™ because we prefer to rely on statistical data from the sample of 116 claims that received DIFICID™ rather than information based on multiple assumptions. However, the applicant is welcome to submit additional data for FY 2014 that demonstrate changes to the average dosage of 6.2 days (within the inpatient setting). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS-DRG payment for the case. As a result, the maximum new technology add-on payment for FY 2013 for DIFICID™ (Fidaxomicin) is $868.

c. Zilver® PTX® Drug Eluting Stent

Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Stent (Zilver® PTX®) for FY 2013. In the proposed rule, we summarized this application. The Zilver® PTX® is intended for use in the treatment of peripheral artery disease (PAD) of the above–the-knee femoropopliteal arteries (superficial femoral arteries). According to the applicant, the stent is percutaneously inserted into the artery(s), usually by accessing the common femoral artery in the groin. The applicant states that an introducer catheter is inserted over the wire guide and into the target vessel where the lesion will first be treated with an angioplasty balloon to prepare the vessel for stenting. The applicant indicates that the stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel. Paclitaxel is a drug approved for use as an anticancer agent and for use with

coronary stents to reduce the risk of renarrowing of the coronary arteries after stenting procedures.

The applicant maintains that there are currently no FDA approved drug-eluting stents used for superficial femoral arteries. At the time of the proposed rule, the applicant expected to receive FDA approval for the stent in the second quarter of 2012. However, at the time of this final rule, the technology has still not received FDA approval. The technology is currently described by ICD-9-CM procedure code 00.60 (Insertion of drug-eluting stent(s) of the superficial femoral artery). We invited public comment regarding how the Zilver® PTX® meets the newness criterion.

Comment: The applicant stated that it received a letter from the FDA indicating that the FDA's Center for Devices and Radiological Health considers the device to be "approvable." The applicant added that it expects formal FDA approval before September 2012. With FDA approval imminent and expected before the implementation date of October 1, 2012, the applicant requested that the "approvable" letter from the FDA's Center for Devices and Radiological Health be allowed to serve as a proxy for FDA approval.

Response: In accordance with § 412.87(c) of the regulations, we require that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. Because the Zilver® PTX® is not approved by the FDA as of such date, we cannot consider this application for new

technology add-on payments for FY 2013. Therefore, the Zilver® PTX® does not meet the newness criteria.

With regard to the cost criterion, the applicant believes that cases of superficial femoral arteries typically map to MS-DRGs 252 (Other Vascular Procedures with MCC), 253 (Other Vascular Procedures with CC), and 254 (Other Vascular Procedures without CC/MCC). The applicant searched the FY 2009 MedPAR file for cases with a procedure code of 39.90 (Insertion of non-drug-eluting peripheral vessel stents) in combination with a diagnosis code of 440.20 (Atherosclerosis of the extremities, unspecified), 440.21 (Atherosclerosis of the extremities, with intermittent claudication), 440.22 (Atherosclerosis of the extremities with rest pain), 440.23 (Atherosclerosis of the extremities with ulceration), and 440.24 (Atherosclerosis of the extremities with gangrene). The applicant found 7,144 cases (or 24.4 percent of all cases) in MS-DRG 252; 9,146 cases (or 31.2 percent of all cases) in MS-DRG 253; and 13,012 cases (or 44.4 percent of all cases) in MS-DRG 254. The average charge per case was $78,765 for MS-DRG 252, $63,758 for MS-DRG 253, and $47,586 for MS-DRG 254, equating to a case-weighted average charge per case of $60,236.

The case-weighted average charge per case above does not include charges related to the Zilver® PTX®; therefore, it is first necessary to remove the amount of charges related to the nondrug-eluting peripheral vessel stents and replace them with charges related to the Zilver® PTX®. The applicant used two methodologies to remove the charges of the nondrug-eluting peripheral vessel stents and replace them with charges related to the Zilver® PTX®. Although the applicant submitted data related to the

estimated cost of the nondrug-eluting peripheral vessel stents and the Zilver® PTX®, the applicant noted that the cost of these devices was proprietary information.

Under the first methodology, the applicant determined the amount of stents per case based on the following ICD-9-CM codes on each claim: 00.45 (Insertion of one vascular stent), 00.46 (Insertion of two vascular stents), 00.47 (Insertion of three vascular stents) and 00.48 (Insertion of four or more vascular stents). If a claim had a code of 00.48, the applicant assumed a maximum of four stents per case. The applicant multiplied the amount of stents used per case by the average market price for nondrug-eluting peripheral vessel stents and then converted the cost of the stents used per case to a charge by dividing the results by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case and then standardized the charges per case. Because the applicant used FY 2009 MedPAR data, it was necessary to inflate the charges from FY 2009 to FY 2012. Using data from the U.S. Department of Labor Bureau of Labor Statistics Consumer Price Index, the applicant inflated the average standardized charge per case with an inflation factor of 6 percent. To determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD-9-CM codes above, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study[30]. The applicant believed that it is appropriate to use data from the clinical study (to determine the average amount of stents used per case) rather than

[30] Dake, M.D., Ansel, G.M., Jaff, M.R., Ohki, T., Saxon, R.R., Smouse, H.B., Zeller, T., Roubin, G.S., Burket, M.W., Khatib, Y., Snyder, S.A., Ragheb, A.O., White, J.K., Machan, L.S.(2011), Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month zilver PTX randomized study results. Circulation Cardiovascular Interventions, published online September 27, 2011, 495-504.

the actual data from the claims because the length of a nondrug-eluting peripheral vessel stent typically ranges from 80mm to 120 mm, while the length of the Zilver® PTX® is 80 mm (which could cause a variance in the actual amount of stents used per case when using the Zilver® PTX®). Similar to above, the applicant multiplied the average of 1.9 stents used per case by the future market price for the Zilver® PTX® and then converted the cost of the stents used per claim to a charge by dividing the results by the national average CCR of 0.329 for supplies and equipment. The applicant then added the amount of charges related to the Zilver® PTX® to the inflated average standardized charge per case and determined a final case-weighted average standardized charge per case of $60,014. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 252, 253, and 254 was $52,293 (all calculations above were performed using unrounded numbers). Because the case-weighted average standardized charge per case for the applicable MS-DRGs exceed the case-weighted threshold amount, the applicant maintains that the Zilver® PTX® meets the cost criterion.

The second methodology was similar to the first methodology described above, but the applicant used hospital-specific CCRs from the FY 2009 IPPS impact file to convert the cost of the nondrug-eluting peripheral vessel stents and the cost of the Zilver® PTX® to charges. In summary, the applicant determined the amount of nondrug-eluting peripheral vessel stents used per case based on the ICD-9-CM codes on each claim (as discussed above). The applicant multiplied the amount of stents used per case by the average market price for nondrug-eluting peripheral vessel stents and then converted the cost of the stents used per case to a charge by dividing by the hospital-specific CCR

(from the FY 2009 IPPS impact file). The applicant removed the appropriate amount of charges per case and then standardized the charges per case. Similar to the step described above, because the applicant used FY 2009 MedPAR data, it was necessary to inflate the charges from FY 2009 to FY 2012. Using data from the Bureau of Labor Statistics Consumer Price Index, the applicant inflated the average standardized charge per case with an inflation factor of 6 percent. To determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD-9-CM codes above, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study (because of the reason stated in the first methodology). The applicant then multiplied the average of 1.9 stents used per case by the future market price for the Zilver® PTX® and then converted the cost of the stents used per claim to a charge by dividing the results by the hospital-specific CCR (from the FY 2009 IPPS impact file). The applicant then added the amount of charges related to the Zilver® PTX® to the inflated average standardized charge per case and determined a final case-weighted average standardized charge per case of $60,339. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 252, 253, and 254 was $52,293 (all calculations above were performed using unrounded numbers). Because the case-weighted average standardized charge per case for the applicable MS-DRGs exceed the case-weighted threshold amount, the applicant maintains that the Zilver® PTX® would meet the cost criterion.

We invited public comment on whether or not the Zilver® PTX® meets the cost criterion. Additionally, we invited public comment on the methodologies used by the

applicant in its analysis, including its assumptions regarding the types of cases in which this technology could potentially be used, the number of stents required for each case, and the CCRs used in the cost calculation.

Comment: We received several public comments regarding whether the Zilver® PTX® meets the cost criterion.

Response: Because the Zilver® PTX® has not yet received FDA approval, and therefore, does not meet the newness criterion, as discussed above, it is not eligible for the IPPS new technology add-on payments for FY 2013. Therefore, we are not summarizing the details of these comments nor responding to them in this final rule.

In an effort to demonstrate that the technology meets the substantial clinical improvement criterion, the applicant shared several findings from the clinical trial data. The applicant stated that current treatment options for patients who have been diagnosed with PAD includes angioplasty, bare metal stenting, bypass graft and endarterectomy. The applicant asserts that the Zilver® PTX® meets the substantial clinical improvement because it decreases the recurrence of symptoms arising from restenotic SFA lesions, the rate of subsequent diagnostic or therapeutic interventions required to address restenotic lesions, and the number of future hospitalizations.

The applicant cited a 480-patient, multicenter, multinational randomized controlled trial that compared the Zilver® PTX® to balloon angioplasty; an additional component of the study allowed a direct comparison of the Zilver® PTX® to a bare (uncoated) metal Zilver® stent. The primary safety endpoint of the randomized controlled study was "Event-Free Survival" (EFS), defined as "freedom from the major

adverse events of death, target lesion revascularization, target limb ischemia requiring surgical intervention or surgical repair of the target vessel, and freedom of worsening systems as described by the Rutherford classification by 2 classes or to class 5 or 6." The primary effectiveness endpoint was primary patency (defined as a less than 50 percent re-narrowing).

The applicant noted that the Zilver® PTX® had an EFS of 90.4 percent compared to balloon angioplasty, which had an EFS of 83.9 percent, demonstrating that the Zilver® PTX® is as safe or safer than balloon angioplasty. In addition, the applicant noted that the Zilver® PTX® demonstrated a 50-percent reduction in restenosis rates compared to angioplasty and a 20-percent reduction compared to bare metal stents. The 12-month patency rate for the Zilver® PTX® was 83.1 percent, which compared favorably to the balloon angioplasty patency rate of 32.8 percent. In the provisional stenting arm of the study, which allowed a direct comparison of the Zilver® PTX® and a bare metal stent, the Zilver® PTX® primary patency exceeded the bare metal stent patency by nearly 20 percent (89.9 percent versus 73.0 percent[1]). The applicant stated that these differences are significant, as they result in a substantial clinical improvement compared to angioplasty and bare metal stenting, with patients being spared a recurrence of their leg pain and the need to be admitted to the hospital for repeat procedures on these treated lesions.

The applicant also cited a prospective, multicenter, multinational, 787-patient single arm study on the Zilver® PTX® that demonstrated similar safety and effectiveness results consistent with those from the pivotal randomized controlled study above. The

applicant cited an EFS for the Zilver® PTX® of 89.0 percent and an 86.2 percent primary patency rate. The applicant stated that these results confirm the safety and effectiveness of the Zilver® PTX®, and compare favorably to current results for angioplasty and bare metal stenting. The applicant added that these results also demonstrate a 67 to 81 percent relative reduction in Target Lesion Revascularization (the need to retreat an already treated lesion that has restenosed, resulting in a recurrence of symptoms) rates compared to recently published results of contemporary bare metal stents.[31]

We invited public comment regarding whether the Zilver® PTX® meets the substantial clinical improvement criterion.

Comment: Several commenters commented on whether the Zilver® PTX® meets the substantial clinical improvement criterion.

Response: Because the Zilver® PTX® has not yet received FDA approval, and therefore, does not meet the newness criterion, as discussed above, it is not eligible for IPPS new technology add-on payments for FY 2013. Therefore, we are not summarizing the details of these public comments or responding to them in this final rule.

d. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft

Cook® Medical submitted an application for new technology add-on payments for the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft (Zenith® F. Graft) for FY 2013. In the proposed rule, we summarized this application. The applicant stated that the current treatment for patients who have had an AAA is an

[31] Dake, M. D., Scheinert, D., Tepe, G., Tessarek, J., Fanelli, F., Bosiers, M., et al. (2011). Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: Twelve-month safety and effectiveness results from the zilver PTX single-arm clinical study. *Journal of Endovascular Therapy, 18*(5), 613-623.

endovascular graft. The applicant explained that the Zenith® F. Graft is an implantable device designed to treat patients who have an AAA and who are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. The applicant noted that, currently, an AAA is treated through an open surgical repair or medical management for those patients not eligible for currently approved AAA endovascular grafts.

The applicant stated that the Zenith® F. Graft is custom-made for each patient. It is a modular system consisting of three components: a two-part main body graft and one iliac leg. The two-part main body of the graft consists of a proximal tubular graft and a distal bifurcated graft body. The proximal body graft contains precisely located holes (fenestrations) and/or cut-outs from the proximal margin (scallops) of the polyester graft material along with a bare proximal stent with barbs to provide fixation. The iliac leg component, which couples with the main bifurcated body, completes the basic fenestrated endograft.

With respect to newness, the applicant stated that FDA approval for the use of the Zenith® F. Graft was granted on April 4, 2012. The technology is described by ICD-9-CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta), which became effective October 1, 2011. While procedure code 39.78 maps to MS-DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without MCC/CC, respectively), the applicant believes that MS-DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) would be a more appropriate assignment for procedure code 39.78. We note that in section

III.G.3.b. of this preamble, we discuss our final policy which reassigns procedure code 39.78 from MS-DRG 252, 253, and 254 to MS-DRGs 237 and 238. We invited public comment regarding whether the Zenith® F. Graft meets the newness criterion for new technology add-on payment.

We did not receive any public comments regarding whether the Zenith® F. Graft meets the newness criterion. However, because the Zenith® F. Graft was approved by the FDA on April 4, 2012, we believe the Zenith® F. Graft meets the newness criterion as of that date.

With regard to the cost criterion, the applicant used clinical trial data and three separate analyses of FY 2010 MedPAR data to demonstrate that the Zenith® F. Graft meets the cost criteria. We note that in the proposed rule the applicant believed that it met the cost criteria since it demonstrated that the case weighted average charge per case exceeded the threshold for MS-DRGs 252-254 since at that time procedure code 39.78 was assigned to MS-DRG 252-254. However, as mentioned above, in this final rule we have reassigned procedure code 39.78 from MS-DRG 252-254 to MS-DRGs 237-238. Therefore, for this final rule, in order for the applicant to meet the cost criteria, it must demonstrate that the case weighted average standardized charge per case exceeds the thresholds for MS-DRGs 237-238.

The applicant submitted clinical trial data[32] which was based on 173 claims (all Medicare patients except one patient). The applicant found that, of the 173 cases, 35 cases (or 20.2 percent of all cases) mapped to MS-DRG 252, 86 cases (or 49.7 percent of

[32] Evaluation of the Safety and Effectiveness of the Zenith(R) Fenestrated AAA Endovascular Graft, Zenith Fenestrated AAA Endovascular Graft Pivotal Study, Clinicaltrials.gov: identifier NCT00875563 and a Physician Sponsored IDE.

all cases) mapped to MS-DRG 253, and 52 cases (or 30.1 percent of all cases) mapped to MS-DRG 254, equating to a case-weighted average charge per case of $87,733.

The applicant noted that the investigational devices (the bare metal renal stents that are used in the procedure and the Zenith® F. Graft) were sold to the trial sites at reduced prices. Therefore, the average charge per case cited above contains reduced charges for the investigational devices rather than commercial charges. As a result, the applicant believes it is necessary to remove the reduced charges for the investigational devices and replace them with commercial charges, in order to determine the cost of the investigational devices for each of the three analyses. Although the applicant submitted data related to the estimated cost of the investigational devices, the applicant noted that the cost of these devices was proprietary information.

To remove the reduced charges for the investigational devices, the applicant searched the clinical trial claims data and removed those charges with a revenue code of 0624 (investigational device exempt). Because the claims data for the clinical trial ranged from 2002 to 2010, it was necessary to inflate the charges. Using data from the U.S. Department of Labor Bureau of Labor Statistics (BLS) Consumer Price Index, the applicant applied an inflation factor to the claim charges ranging from 3 percent to 27 percent, depending on the year of the claim. After inflating the charges, the applicant then added the commercial charges of the investigational devices to the inflated charge per case. To determine the amount of commercial charges related to the investigational devices, the applicant divided the cost of the investigational devices by the hospital-specific CCR from the FY 2012 IPPS Final Rule Impact File. After adding the charges

of the investigational devices to the inflated charges, the applicant then standardized the charges on each claim. As a result, the applicant determined a final case-weighted average standardized charge per case of $122,821. In the proposed rule, the applicant used the FY 2013 Table 10 thresholds for MS-DRGs 252, 253, and 254 and determined a case-weighted threshold of $53,869 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for MS-DRGs 252, 253, and 254 exceeds the case-weighted threshold amount, the applicant maintained that the Zenith® F. Graft met the cost criterion for new technology add-on payments. As noted above, for this final rule the applicant must demonstrate that it meets the cost criteria for MS-DRGs 237 and 238. The thresholds for MS-DRGs 237 and 238 are $101,728 and $69,591, respectively. If the applicant compared the final case-weighted average standardized charge per case of $122,821 (under MS-DRGs 252, 253, and 254) to the highest threshold for MS-DRGs 237 and 238 ($101,728), it would still exceed the threshold in excess of $20,000. Therefore, under this analysis the applicant would meet the cost criterion since the final case-weighted average standardized charge per case would exceed the threshold under MS-DRGs 237 and 238.

We note that, in addition to the analysis above, the applicant conducted a similar cost analysis using drug eluting renal stents instead of bare metal renal stents. The applicant noted that the price of drug eluting renal stents exceeds the price of bare metal renal stents by approximately $2,200 per stent. Therefore, the applicant asserted that if the price of drug eluting renal stents is more expensive than bare metal renal stents and the Zenith® F. Graft meets the cost criteria with bare metal renal stents, the Zenith® F.

Graft also meets the cost criteria when the applicant uses drug eluting renal stents in its analysis.

As mentioned above, the applicant conducted three separate analyses using FY 2010 MedPAR data to identify cases eligible for the Zenith® F. Graft to demonstrate that it meets the cost criterion. Because procedure code 39.78 was effective October 1, 2011, the applicant noted that it was unable to conduct a MedPAR data analysis with claims that contained a procedure code of 39.78. Therefore, in order to identify cases eligible for the Zenith® F. Graft prior to October 1, 2011, the applicant searched the MedPAR file for the following three scenarios. The first analysis searched the FY 2010 MedPAR file for cases with procedure code 39.71 (Endovascular implantation of graft in abdominal aorta) in combination with a diagnosis code of 441.4 (Abdominal aneurysm without mention of rupture). Procedure code 39.71 maps to MS-DRGs 237 and 238. The applicant found 1,679 cases (or 9.1 percent of all cases) in MS-DRG 237 and 16,793 cases (or 90.9 percent of all cases) in MS-DRG 238. The average charge per case was $122,252 for MS-DRG 237 and $76,883 for MS-DRG 238, equating to a case-weighted average charge per case of $81,006.

The applicant noted that these MedPAR claims data included charges for the existing stent graft but did not include charges for the Zenith® F. Graft. Therefore, the applicant stated that it was first necessary to remove the amount of charges related to the existing stent graft and replace them with charges for the Zenith® F. Graft. Although the applicant submitted data related to the estimated cost of the existing stent graft and the

Zenith® F. Graft, the applicant noted that the cost of these devices was proprietary information.

To determine the amount of charges for the existing stent graft, the applicant divided the costs for the existing stent graft by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. Because the applicant used FY 2010 MedPAR data, it was necessary to inflate the charges from FY 2010 to FY 2012. Using data from the BLS' Consumer Price Index, the applicant inflated the case-weighted average standardized charge per case with an inflation factor of 4 percent. The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. The applicant determined a final case-weighted average standardized charge per case of $80,509. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 237 and 238 was $72,512 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount under this first analysis, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payment.

For its second analysis, the applicant searched the FY 2010 MedPAR file for cases with procedure code 38.44 (Resection of vessel with replacement, aorta) in combination with a diagnosis code of 441.4. Similar to the first analysis, the applicant

conducted this analysis using MS-DRGs 237 and 238 because procedure code 38.44 maps to MS-DRGs 237 and 238. The applicant found 1,310 cases (or 37.9 percent of all cases) in MS-DRG 237 and 2,145 cases (or 62.1 percent of all cases) in MS-DRG 238. The average charge per case was $110,708 for MS-DRG 237 and $64,095 for MS-DRG 238, equating to a case-weighted average charge per case of $81,769.

The next steps of the applicant's second analysis were similar to the steps in the first analysis. The applicant noted that the MedPAR claims data included charges for the vascular graft for open procedures but did not include charges for the Zenith® F. Graft. Therefore, the applicant indicated that it was first necessary to remove the amount of charges related to the vascular graft for open procedures and replace them with charges for the Zenith® F. Graft. Although the applicant submitted data related to the estimated cost of the vascular graft for open procedures and the Zenith® F. Graft, the applicant noted that the cost of these devices was proprietary information.

To determine the amount of charges for the vascular graft for open procedures, the applicant divided the costs for the vascular graft for open procedures by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. Similar to the first analysis, the applicant inflated the case-weighted average charge per case with an inflation factor of 4 percent (based on data from the BLS' Consumer Price Index). The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft

to the inflated charges and then standardized the charges. The applicant determined a final case-weighted average standardized charge per case of $118,774. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 237 and 238 was $81,776 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount in this second analysis, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payments. In the proposed rule, we noted that while the applicant removed charges for the vascular graft for open procedures, we were concerned that the applicant did not remove charges for other services such as extra operating room time and other possible charges that would be incurred during an open procedure but would possibly not be incurred during cases when the Zenith® F. Graft is implanted.

Comment: In response to our concerns, the applicant took the following steps to demonstrate that the Zenith® F. Graft meets the cost criterion under the second analysis. The applicant first determined the average hospital length of stay (LOS), ICU time and OR time for open AAA repairs versus fenestrated AAA repairs. The applicant researched several peer reviewed studies that contain data for OR time, LOS and ICU time for open procedures. Based on these studies, the applicant calculated a weighted average for each of these measures. The weighted average was a LOS of 9.53 days, 4.07 ICU days, and 261 minutes of OR time.

The applicant used clinical trial data to determine the average OR time, LOS, and ICU time for AAA fenestrated procedures. Based on Cook's clinical trial data,[33] the applicant determined an average LOS of 3.5 days and ICU time of 0.5 days for AAA fenestrated procedures. To determine the amount of OR minutes, the applicant used literature from eight studies including the Cook clinical trial data and determined a weighted average of 235 OR minutes. The applicant noted that the reported hospital LOS and ICU length of stay for fenestrated procedures from outside the United States is significantly longer than those experienced in the study in the United States. Because the applicant believed that the standard of care related to length of hospital stay and ICU stay from European experience are dissimilar to practices within the United States, it only used data from the Cook clinical trial rather than other clinical trial data (which included data from Europe) to determine the average for ICU days and LOS.

The applicant then calculated the percentage savings or rate of savings for the OR time, LOS and ICU time with the following formula: (open procedure minutes or days – fenestrated minutes or days)/open procedure minutes or days. This resulted in savings of 9.96 percent for OR minutes, 87.71 percent for ICU days, and 63.27 percent for LOS days. The applicant then applied the savings at a claim level by applying the rate of savings to the service charge categories from the MedPAR data (rate of savings * open device service charge category). Savings of 9.96 percent for OR time was applied to Service Category 12 (which contains OR charges for revenue centers 36X, 71X and 72X), savings of 87.71 percent for ICU days was applied to Accommodation Charge

[33] Unpublished results, Evaluation of the Safety and Effectiveness of the Zenith(R) Fenestrated AAA Endovascular Graft, Zenith Fenestrated AAA Endovascular Graft Pivotal Study, Clinicaltrials.gov identifier NCT00875563.

Category 4 (which includes total ICU charges), and savings of 63.27 percent for LOS was applied to Accommodation Charge Category 1 (which includes standard room charges). To determine the case-weighted average standardized charge per case, the applicant deducted the reduced charges (savings) from the case-weighted average charge per case ($81,769), which resulted in a revised case-weighted average charge per case of $66,206. The applicant then inflated the revised case-weighted average charge per case by 4 percent (based on data from the BLS' Consumer Price Index), which resulted in an inflated case weighted average charge per case of $68,854. Next, the applicant determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. The applicant determined a final case-weighted average standardized charge per case of $106,731. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 237 and 238 was $81,776 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount in this revised second analysis, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payments.

Response: We appreciate the applicant's response and submittal of this supplemental analysis, which addresses our concerns from the proposed rule.

The third analysis was a combination of the first and second analyses discussed above. The applicant searched the FY 2010 MedPAR file for cases with a procedure

code of 38.44 or 39.71 in combination with a diagnosis code of 441.4. Similar to the first and second analyses, the applicant conducted this analysis using MS-DRGs 237 and 238 because both procedure codes map to MS-DRGs 237 and 238. The applicant found 2,981 cases (or 13.6 percent of all cases) in MS-DRG 237 and 18,928 cases (or 86.4 percent of all cases) in MS-DRG 238. The applicant removed those cases that had both procedure codes 38.44 and 39.71 on the claim. The average charge per case was $116,826 for MS-DRG 237 and $75,298 for MS-DRG 238, equating to a case-weighted average charge per case of $80,948.

The applicant noted that the MedPAR claims data included charges for the existing stent graft or vascular graft for open procedures but did not include charges for the Zenith® F. Graft. Therefore, the applicant stated that it was first necessary to remove the amount of charges related to the existing stent graft or vascular graft for open procedures and replace them with charges for the Zenith® F. Graft. Similar to the first and second analyses, to determine the amount of charges for the existing stent graft or vascular graft for open procedures, the applicant divided the costs for these devices by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. The applicant inflated the case-weighted average standardized charge per case with an inflation factor of 4 percent (based on data from the BLS' Consumer Price Index). The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft

to the inflated charges and then standardized the charges. As a result, the applicant determined a final case-weighted average standardized charge per case of $86,081. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 237 and 238 was $73,964 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payment.

In the proposed rule, similar to our concerns with the second analysis, we were concerned that for this third analysis the applicant did not remove charges for other services such as extra operating room time and other possible charges that would be incurred during an open procedure, but would possibly not be incurred during cases when the Zenith® F. Graft is implanted.

Comment: The applicant applied the same analysis above and deducted the reduced charges (savings) for OR time, LOS, and ICU days from the case-weighted average charge per case ($80,948), which resulted in a revised case-weighted average charge per case of $39,756. The applicant then inflated the revised case-weighted average charge per case by 4 percent (based on data from the BLS' Consumer Price Index), which resulted in an inflated case-weighted average charge per case of $41,346. The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. The applicant determined a final case-

weighted average standardized charge per case of $82,497. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 237 and 238 was $73,964 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount in this revised second analysis, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payments.

Response: We thank the commenter for submitting this supplemental analysis which addresses our concerns from the proposed rule.

We appreciate the multiple analyses of the FY 2010 MedPAR data provided by the applicant and as stated above we believe the commenter has addressed our concerns from the proposed rule. Therefore, we believe that the Zenith® F. Graft meets the cost criterion for new technology add-on payments.

The applicant maintains that the technology also meets the substantial clinical improvement criterion. The applicant first explained that current treatment for those patients who are not eligible for standard endovascular AAA devices is an open repair. The applicant referenced data from a published series[34] that demonstrated an open repair can lead to a high risk of morbidity and increased mortality. The applicant added that an open procedure requires suprarenal aortic cross-clamping.[35] The applicant also noted that there is a high risk of blood loss during an open procedure and the de-branching of vessels increases the level of surgical risk. The applicant further noted that 30 to 40

[34] Wilderman, M. et al. Fenestrated Grafts or Debranching Procedures for Complex Abdominal Aortic Aneurysms. Perspectives in Vascular Surgery and Endovascular Therapy, March 2009; 21(1): 13-18.
[35] Jongkind V, Yeung K, et al. Juxtarenal aortic aneurysm repair. Journal of Vascular Surgery 2010 Sept; 29(3) 760-767.

percent of patients who have an infrarenal AAA cannot be treated with current commercial devices because of anatomical reasons (for example, insufficient neck length to achieve graft adequate seal).[36] The applicant added that use of standard endografts in patients with neck lengths less than 10 mm can result in a fourfold increase in an endoleak.[37]

The applicant also stated that the intended use of the Zenith® F. Graft differs from standard AAA endovascular grafts in that the fenestrated device provides physicians the ability to treat patients who have infrarenal aortic neck lengths as short as 4 mm, where standard endovascular AAA devices require an infrarenal aortic neck length of at least 10 to 15 mm. Therefore, the applicant believes that the Zenith® F. Graft offers an additional AAA repair option to those patients who have limited surgical treatment options (for example, if short infrarenal neck lengths make the patients at too high a risk to be candidates for open surgical repair).

The applicant also stated, for patients who have AAAs and short infrarenal neck lengths, the Zenith® F. Graft offers a less invasive treatment option than open surgical repair. The applicant referred to several sources of literature to support the following endpoints for fenestrated endovascular aortic repair (EVAR) versus open repair of the juxtarenal AAA relative to open repair of the juxtarenal AAA: reduced peri-operative mortality (2.4 percent (range: 0 to 5.7 percent))[38,39,40,41,42,43,44,45,46] reported for

---

[36] Wilderman, M. et al. Fenestrated Grafts or Debranching Procedures for Complex Abdominal Aortic Aneurysms. Perspectives in Vascular Surgery and Endovascular Therapy, March 2009; 21(1): 13-18.
[37] Amiot, S., et al., Fenestrated endovascular grafting: the French multicentre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 537-44.
[38] Nordon, I.M., et al., Modern treatment of juxtarenal abdominal aortic aneurysms with fenestrated endografting and open repair--a systematic review. Eur J Vasc Endovasc Surg, 2009. 38(1): p. 35-41

fenestrated EVAR repairs versus 2.9 percent (range 0 to 7.4 percent)[47,48] reported for open repair of juxtarenal AAA); reduced morbidity by reducing renal failure requiring permanent dialysis (1.9 percent (pooled average) for fenestrated EVAR repairs versus 3.4 percent reported for open repair of juxtarenal AAA); shorter hospital stay and less operative blood loss to open repair. The applicant maintains that fenestrated EVAR repair results in an average length of stay of 3.5 days, compared to 14.2 days for open repair of juxtarenal AAA, and blood loss of 537 ml, compared to 2586 ml for open repair of juxtarenal AAA.

In the proposed rule, we noted that the information provided by the applicant to evaluate substantial clinical improvement compares this technology to open surgical repair. We expressed concern that the applicant did not present publicly available information comparing the technology to medical management, which the applicant mentions as another method for treating patients anatomically unsuited for currently approved AAA endovascular grafts. In these comparisons, we were also concerned that information regarding the longevity of the Zenith® F. Graft as well as long-term

---

[39] Verhoeven, E.L., et al., Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single-centre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 529-36.
[40] Chisci E, Kristmundsson T, de Donato G, et al. The AAA with a challenging neck: outcome of open versus endovascular repair with standard and fenestrated stent-grafts. J Endovasc Ther 2009;16:137-146.
[41] Amiot, S., et al., Fenestrated endovascular grafting: the French multicentre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 537-44.
[42] Kristmundsson T, Sonesson B, Malina M, et al. Fenestrated endovascular repair for juxtarenal aortic pathology. J Vasc Surg 2009;49:568-574.
[43] Beck AW, Bos WT, Vourliotakis G, et al. Fenestrated and branched endograft repair of juxtarenal aneurysms after previous open aortic reconstruction. J Vasc Surg 2009;49:1387-1394.
[44] Tambyraja, A.L., et al., Fenestrated aortic endografts for juxtarenal aortic aneurysm: medium term outcomes. Eur J Vasc Endovasc Surg, 2011. 42(1): p. 54-8.
[45] Unpublished results, Evaluation of the Safety and Effectiveness of the Zenith(R) Fenestrated AAA Endovascular Graft, Zenith Fenestrated AAA Endovascular Graft Pivotal Study, Clinicaltrials.gov identifier NCT00875563.
[46] Unpublished results, British Society of Endovascular Therapy-sponsored GlobalStar Collaborative Study.
[47] Jongkind V, Yeung K, et al. Juxtarenal aortic aneurysm repair.J. Vasc. Surg. 2010 Sept; 29(3) 760-767.
[48] Landry G, Lau I, Liem T, Mitchell E, Moneta G.. Open abdominal aortic aneurysm repair in the endovascular era: effect of clamp site on outcomes. Arch. Surg., 144 (9) Sep. 2009, 811-6.

complications and secondary interventions or reinterventions has not been presented. In terms of the data presented by the applicant, we were concerned that these clinical study data were nonrandomized, did not differentiate between patients by infrarenal neck length and/or suitability for other endovascular grafts, and were of noninferiority. We invited public comment on whether or not the Zenith® F. Graft meets the substantial clinical improvement criterion.

Comment: The applicant responded to our concerns from the proposed rule by submitting a public comment with supplemental information. With respect to the concern that the applicant did not compare the technology to medical management which the applicant listed as a treatment option (in addition to an open procedure), the applicant cited the FDA indications of the device and noted that while the application referred to medical management it was not intended to suggest that medical management was a reasonable alternative treatment option for AAAs at heightened risk of rupture. Therefore, the applicant assumed that medical management had already been maximized in the patients' treatment regimen and that some type of surgical intervention was necessary to treat the aneurysm and prevent rupture. Additionally, the applicant further explained that in its application, prior to the Zenith® F. Graft, surgery was considered the most appropriate option for patients who have a suitably large aneurysm. However, certain patient factors may prevent surgical intervention including anatomical limitations that prevent the use of current endovascular stents or the patient's attendant comorbidities may alter the risk/benefit equation so that surgery is not a viable option. As a result, the applicant stated that medical management represented the default treatment and at risk of

aneurysm rupture but is still considered inferior to a definitive surgical intervention. The applicant concluded that it is for these patients that the Zenith® F. Graft was developed.

The applicant also cited clinical data that demonstrated little improvement has been achieved in the survival rates of patients who do not undergo a surgical intervention for their aneurysm (because the aneurysm may rupture) in contrast to the published series on fenestrated repair, which has indicated low 30-day mortality rates. Therefore, the applicant believed that surgical intervention with the Zenith® F. Graft is considered a suitable treatment for a patient population (where a surgical intervention was not an option prior to the Zenith® F. Graft) when considering the potential risk and benefit of the procedure.

The applicant also responded to the concern that there is a lack of data on long term complications and secondary interventions or re-interventions. The commenter noted that *Mastracci et al* presented at the 2012 Society of Vascular Surgery annual meeting on the durability of branched and fenestrated endografts reported that 650 patients underwent endovascular aortic repair with branched or fenestrated devices at the Cleveland Clinic. Approximately one-third of these patients underwent a fenestrated AAA repair; the balance were branched thoracoabdominal and thoracic aortic aneurysm repairs. Through 9 years of follow-up (with a mean of 3 years), secondary procedures were performed for 0.6 percent of celiac, 4 percent of SMA, 6 percent of right renal, and 5 percent of left renal arteries. The average time to reintervention was 237 days and the 30 days, 1 year and 5 year freedom from any intervention was 98 percent, 94 percent, and 84 percent, respectively. Death resulted from branch stent complications in only two

patients (related to SMA thrombosis). *Mastracci et al* concluded that branches, following branched or fenestrated aortic repair, appear to be durable, and are rarely the cause of patient death; the absence of long-term data on the branch patency in open repair precludes comparison, yet the lower morbidity and mortality risk coupled with longer-term durability data will further alter the balance of repair options. The applicant noted that this conclusion is consistent with the applicant's conclusion.

Finally, in response to the concern that the studies conducted were non randomized, did not differentiate between patients by infrarenal neck length and/or suitability for other endovascular grafts and were of non inferiority, the commenter responded that a randomized test was not conducted because it was anticipated that the clinical trial conducted for FDA registration would primarily enroll high risk patients in whom open surgical repair would present an unacceptably high risk of operative mortality. The applicant stated that this precluded a randomized study design. With regard to the concern about not considering other endovascular graft options, the applicant explained that the shortest FDA- approved neck length indication of an available standard AAA graft is > 10mm (IFU – Medtronic Endurant Endovascular Graft). The Zenith® F. Graft is designed to treat neck lengths of ≥ 4mm, and there is no other endovascular graft available in the USA indicated to treat such short neck lengths. The applicant also clarified that the study of non-inferiority was for the IDE clinical study performed for FDA approval. One of the study's goals was to show non-inferiority in 6-month treatment success, comparing matched patients treated with a standard Zenith AAA Endovascular Graft (used to treat AAAs anatomically suited for treatment) with

patients treated with a standard endovascular device. The purpose was to demonstrate that the Zenith® F. Graft could offer a treatment option to patients with a juxtarenal AAA that was not worse than the well-established treatment success experienced with a standard AAA endovascular graft when used to treat patients anatomically suited for a standard device (*not* when using a standard AAA graft to treat a short-necked, juxtarenal aneurysm). The applicant concluded that for this device, this intended patient population, and this comparator a non-inferiority design is a valid study design demonstrating non-inferiority to the high standard of success experienced in standard AAA endovascular repair and provides compelling evidence of Zenith® F. Graft's effectiveness.

Response: We appreciate the applicant's response in regard to our concerns presented in the proposed rule. We agree that the Zenith® F. Graft represents a substantial clinical improvement over existing technologies because it offers a treatment option to a patient population that would otherwise require an open procedure or a treatment option to those patients who are ineligible for an open procedure. The Zenith® F. Graft offers a less invasive treatment option compared to an open procedure which results in reduced mortality, reduced morbidity, shorter hospital stays and less operative blood loss.

Comment: Other commenters were concerned that the Zenith® F. Graft may not meet the substantial clinical criterion because of the concerns expressed by CMS in the proposed rule.

Response: As discussed above, the applicant has responded to our concerns and we agree that the Zenith® F. Graft meets the substantial clinical improvement criterion.

Based on the discussion above, the Zenith® F. Graft meets all of the new technology add-on payment policy criteria. Therefore, we are approving the Zenith® F. Graft for new technology add-on payments in FY 2013. Cases involving the Zenith® F. Graft that are eligible for new technology add-on payments will be identified by ICD-9-CM procedure code 39.78. In the application, the applicant provided a breakdown of the costs of the Zenith® F. Graft. The total cost of the Zenith® F. Graft utilizing bare metal (renal) alignment stents was $17,264. Of the $17,264 in costs for the Zenith® F. Graft, $921 are for components that are used in a standard Zenith AAA Endovascular Graft procedure. Because the costs for these components are already reflected within the MS-DRGs (and are no longer "new"), we do not believe it is appropriate to include these costs in our determination of the maximum cost to determine the add-on payment for the Zenith® F. Graft. Therefore, the total maximum cost for the Zenith® F. Graft is $16,343 ($17,264 - $921). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS-DRG payment for the case. As a result, the maximum add-on payment for a case involving the Zenith® F. Graft is $8,171.50.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2013 hospital wage index based on the statistical areas, including OMB's revised definitions of Metropolitan Areas, appears under section III.B. of this preamble.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section of the Act provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2013 is discussed in section II.B. of the Addendum to this final rule.

As discussed below in section III.H. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and

1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2013 is discussed in section II.A.4.b. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are applying beginning October 1, 2012 (the FY 2013 wage index) appears under section III.F. of this preamble.

In response to concerns frequently expressed by providers and other relevant parties that the current wage index system does not effectively reflect the true variation in labor costs for a large cross-section of hospitals, two studies were undertaken by the Department. First, section 3137(b) of the Affordable Care Act required the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 report entitled “Report to Congress: Promoting Greater Efficiency in

Medicare" and to "consult with relevant affected parties." Second, the Secretary commissioned the Institute of Medicine (IOM) to "evaluate hospital and physician geographic payment adjustments, the validity of the adjustment factors, measures and methodologies used in those factors, and sources of data used in those factors." Reports on both of these studies recently have been released. We refer readers to section IX.B. of this preamble for summaries of the studies, their findings, and recommendations on reforming the wage index system.

B. Core-Based Statistical Areas for the Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with the broad discretion under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we define hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by OMB and announced in December 2003 (69 FR 49027). For a discussion of OMB's delineations of CBSAs and our implementation of the CBSA definitions, we refer readers to the preamble of the FY 2005 IPPS final rule (69 FR 49026 through 49032). We also discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582) that, in 2013, OMB plans to announce new area delineations based on new standards adopted in 2010 (75 FR 37246) and the 2010 Census of Population and Housing data. For the FY 2013 wage index, to be effective October 1, 2012 and before the availability of OMB's new area delineations, we proposed to use the same labor market areas that we used for the FY 2012 wage index (76 FR 51581).

We did not receive any public comments on the use of labor market areas for the FY 2013 wage index. Therefore, we are finalizing, for FY 2013, the use of the same labor market areas that we used for the FY 2012 wage index.

C. Worksheet S-3 Wage Data for the FY 2013 Proposed Wage Index

The FY 2013 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2009 (the FY 2012 wage indices were based on data from cost reporting periods beginning during FY 2008).

1. Included Categories of Costs

The FY 2013 wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty)
- Home office costs and hours
- Certain contract labor costs and hours (which includes direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315))
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2012, the wage index for FY 2013 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2013 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index, for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397).

3. Use of Wage Index Data by Providers Other Than Acute Care Hospitals under the IPPS

Data collected for the IPPS wage index are also currently used to calculate wage indices applicable to other providers, such as SNFs, home health agencies (HHAs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indices for non-IPPS providers, other than for LTCHs. Such comments should be made in response to separate proposed rules for those providers.

D. Verification of Worksheet S-3 Wage Data

The wage data for the FY 2013 wage index were obtained from Worksheet S-3, Parts II and III of the Medicare cost report for cost reporting periods beginning on or after October 1, 2008, and before October 1, 2009. For wage index purposes, we refer to cost reports during this period as the "FY 2009 cost report," the "FY 2009 wage data," or the "FY 2009 data." Instructions for completing Worksheet S-3, Parts II and III are in the Provider Reimbursement Manual (PRM), Part II, Sections 3605.2 and 3605.3. The data file used to construct the wage index includes FY 2009 data submitted to us as of June 27, 2012. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries/MACs to revise or verify data elements that result in specific edit failures. For the FY 2013 proposed wage index, we identified and excluded 32 providers with data that were too aberrant to include in the proposed wage index, although we stated that if data elements for some of these providers are corrected, we intended to include some of these providers in the FY 2013 final wage index. We have received corrected data for 8 providers, and therefore, we are including the data for these 8 providers in the FY 2013 final wage index. However, we also have determined that the data for 14 additional providers are too aberrant to include in the FY 2013 final wage index. Thus, in total we are excluding the data of 38 providers from the FY 2013 final wage index.

In constructing the FY 2013 proposed wage index, we included the wage data for facilities that were IPPS hospitals in FY 2009, inclusive of those facilities that have since

terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397). For the proposed rule, we removed 7 hospitals that converted to CAH status between February 15, 2011, the cut-off date for CAH exclusion from the FY 2012 wage index, and February 14, 2012, the cut-off date for CAH exclusion from the FY 2013 wage index. However, after the issuance of the proposed rule, we have learned that one provider which we believed was a CAH actually is an IPPS hospital with valid wage data for FY 2013. Therefore, we have added that provider's wage data for purposes of the FY 2013 final wage index. Accordingly, for this final rule, we removed the data of only 6 (not 7) hospitals that have converted to CAH status between February 15, 2011 and February 14, 2012. After removing hospitals with aberrant data and hospitals that converted to CAH status, the FY 2013 final wage index is calculated based on 3,447 hospitals.

For the FY 2013 final wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner we allotted such hospitals' data in the FY 2012 wage index (76 FR 51591). Table 2 containing the FY 2013 wage index associated with this final

rule (available on the CMS Web site) includes separate wage data for the campuses of four multicampus hospitals.

E. Method for Computing the FY 2013 Unadjusted Wage Index

The method used to compute the FY 2013 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012 final wage index without an occupational mix adjustment (76 FR 51591 through 51593).

As discussed in that final rule, in "Step 5," for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2008, through April 15, 2010, for private industry hospital workers from the BLS' Compensation and Working Conditions. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and as we proposed, we are not making any changes to the usage for FY 2013. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2008	11/15/2008	1.03003
11/14/2008	12/15/2008	1.02786
12/14/2008	01/15/2009	1.02582
01/14/2009	02/15/2009	1.02386
02/14/2009	03/15/2009	1.02199
03/14/2009	04/15/2009	1.02014
04/14/2009	05/15/2009	1.01826
05/14/2009	06/15/2009	1.01635
06/14/2009	07/15/2009	1.01446

After	Before	Adjustment Factor
07/14/2009	08/15/2009	1.01263
08/14/2009	09/15/2009	1.01086
09/14/2009	10/15/2009	1.00910
10/14/2009	11/15/2009	1.00728
11/14/2009	12/15/2009	1.00539
12/14/2009	01/15/2010	1.00352
01/14/2010	02/15/2010	1.00172
02/14/2010	03/15/2010	1.00000
03/14/2010	04/15/2010	0.99830

For example, the midpoint of a cost reporting period beginning January 1, 2009, and ending December 31, 2009, is June 30, 2009. An adjustment factor of 1.01446 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as described above and in the FY 2012 IPPS/LTCH PPS final rule, the FY 2013 national average hourly wage (unadjusted for occupational mix) is $37.4855. The Puerto Rico overall average hourly wage (unadjusted for occupational mix) is $15.8643.

F. Occupational Mix Adjustment to the FY 2013 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients.

The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Development of Data for the FY 2013 Occupational Mix Adjustment Based on the 2010 Occupational Mix Survey

As provided for under section 1886(d)(3)(E) of the Act, we collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program.

As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586), the FY 2013 wage index is based on data collected on the new 2010 Medicare Wage Index Occupational Mix Survey (Form CMS-10079 (2010)). The survey is available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/WIFN/list.asp and through the fiscal intermediaries/MACs. Hospitals were required to submit their completed 2010 surveys to their fiscal intermediaries/MACs by July 1, 2011. The preliminary, unaudited 2010 survey data will be released in early October 2012, along with the FY 2010 Worksheet S-3 wage data, for the FY 2014 wage index review and correction process.

2. Calculation of the Occupational Mix Adjustment for FY 2013

For FY 2013, we calculated the occupational mix adjustment factor using the same methodology that we used for the FY 2012 wage index (76 FR 51582 through 51586). As a result of applying this methodology, the FY 2013 occupational mix

adjusted national average hourly wage is $37.4608. The FY 2013 occupational mix adjusted Puerto Rico-specific average hourly wage is $15.9019.

Because the occupational mix adjustment is required by statute, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2013 wage index. For the FY 2010 survey, the response rate was 91.7 percent. In the FY 2013 wage index established in this final rule, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586).

In the FY 2011 IPPS/LTCH PPS proposed rule and final rule (75 FR 23943 and 75 FR 50167, respectively), we stated that, in order to gain a better understanding of why some hospitals are not submitting the occupational mix data, we will require hospitals that do not submit occupational mix data to provide an explanation for not complying. This requirement was effective beginning with the new 2010 occupational mix survey. We instructed fiscal intermediaries/MACs to begin gathering this information as part of the FY 2013 wage index desk review process. We will review these data for future analysis and consideration of potential penalties for noncompliant hospitals.

G. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2013 Occupational Mix Adjusted Wage Index

1. Analysis of the Occupational Mix Adjustment and the Occupational Mix Adjusted Wage Index

As discussed in section III.F. of this preamble, for FY 2013, we apply the occupational mix adjustment to 100 percent of the FY 2013 wage index. We calculated the final occupational mix adjustment using data from the 2010 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2013 wage index results in a national average hourly wage of $37.4608 and a Puerto-Rico specific average hourly wage of $15.9019. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2009 Worksheet S-3, Parts II and III, cost report data for use in calculating the FY 2013 wage index, we calculated the FY 2013 wage index using the occupational mix survey data from 3,192 hospitals. Using the Worksheet S-3, Parts II and III, cost report data of 3,447 hospitals and occupational mix survey data from 3,192 hospitals represents a 92.6 percent survey response rate. The FY 2013 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	37.435806262
National LPN and Surgical Technician	21.779745192
National Nurse Aide, Orderly, and Attendant	15.334363984

Occupational Mix Nursing Subcategory	Average Hourly Wage
National Medical Assistant	17.232523608
National Nurse Category	31.852574284

The national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $31.852574284. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2010 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 43.47 percent, and the national percentage of hospital employees in the all other occupations category is 56.53 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 21.9 percent in one CBSA, to a high of 62.0 percent in another CBSA.

We also compared the FY 2013 wage data adjusted for occupational mix from the 2010 survey to the FY 2013 wage data adjusted for occupational mix from the 2007-2008 survey. This analysis illustrates the effect on area wage indices of using the 2010 survey data compared to the 2007-2008 survey data; that is, it shows whether hospitals' wage indices are increasing or decreasing under the current survey data as compared to the prior survey data. Our analysis shows that the FY 2013 wage index values for 189

(48.3 percent) urban areas and 14 (29.2 percent) rural areas will increase. Fifty three (13.6 percent) urban areas will increase by 1 percent or more, and no urban areas will increase by 5 percent or more. Three (6.3 percent) rural areas will increase by 1 percent or more, and no rural areas will increase by 5 percent or more. However, the wage index values for 199 (50.9 percent) urban areas and 34 (70.8 percent) rural areas will decrease using the 2010 data. Sixty-three (16.1 percent) urban areas will decrease by 1 percent or more, and no urban areas will decrease by 5 percent or more. Three (6.3 percent) rural areas will decrease by 1 percent or more, and no rural areas will decrease by 5 percent or more. The largest positive impacts using the 2010 data compared to the 2007-2008 data are 4.34 percent for an urban area and 3.20 percent for a rural area. The largest negative impacts are 4.91 percent for an urban area and 2.26 percent for a rural area. Three urban areas and no rural areas will be unaffected. These results indicate that the wage indices of more CBSAs overall (53.1 percent) will be decreasing due to application of the 2010 occupational mix survey data as compared to the 2007-2008 survey data to the wage index. Further, a larger percentage of urban areas (48.3 percent) will benefit from the 2010 occupational mix survey as compared to the 2007-2008 survey than will rural areas (29.2 percent).

We compared the FY 2013 occupational mix adjusted wage indices for each CBSA to the unadjusted wage indices for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the wage index values for 206 (52.7 percent) urban areas and 34 (70.8 percent) rural areas will increase. One hundred fifteen (29.4 percent) urban areas will increase by 1 percent or more, and 3 (0.77 percent)

urban areas will increase by 5 percent or more. Fourteen (29.2 percent) rural areas will increase by 1 percent or more, and no rural areas will increase by 5 percent or more. However, the wage index values for 185 (47.3 percent) urban areas and 14 (29.2 percent) rural areas will decrease. Eighty-one (20.7 percent) urban areas will decrease by 1 percent or more, and one urban area will decrease by 5 percent or more (0.26 percent). Seven (14.6 percent) rural areas will decrease by 1 percent or more, and no rural areas will decrease by 5 percent or more. The largest positive impacts are 6.68 percent for an urban area and 2.62 percent for a rural area. The largest negative impacts are 5.26 percent for an urban area and 3.14 percent for a rural area. No urban or rural areas are unaffected. These results indicate that a larger percentage of rural areas (70.8 percent) will benefit from the occupational mix adjustment than do urban areas (52.7 percent). While these results are more positive overall for rural areas than under the previous occupational mix adjustment that used survey data from 2007-2008, almost one-third (29.2 percent) of rural CBSAs will still experience a decrease in their wage indices as a result of the occupational mix adjustment.

2. Application of the Rural, Imputed, and Frontier Floors

a. Rural Floor

Section 4410 of Pub. L. 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the "rural floor." Section 3141 of Pub. L. 111-148 also requires that a national budget neutrality adjustment be applied in

implementing the rural floor. In the FY 2013 proposed wage index, we estimated that 393 hospitals would receive an increase in their FY 2013 proposed wage index due to the application of the rural floor. In the FY 2013 final wage index associated with this final rule and available on the CMS Web site, 454 hospitals are receiving an increase in their FY 2013 wage index due to the application of the rural floor.

Comment: We did not make any proposals in the FY 2013 proposed rule pertaining to the rural floor. However, several commenters opposed the application of the national budget neutrality adjustment for the rural floor. The commenters noted our discussion of the impacts of the policy in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28170 through 28172) and, in particular, the table in the Addendum at 77 FR 28171 shows Massachusetts would receive significant extra IPPS payments alone for FY 2013, due, in part, to this policy. The commenters opined that the national rural floor budget neutrality policy "unfairly skews Medicare payments, reducing payments to thousands of hospitals across the nation while benefitting a few dozen hospitals in one State." The commenters requested that CMS reassess the national rural floor budget neutrality provision and recommended that CMS reverse the provision.

Response: As discussed above, the national rural floor budget neutrality adjustment for the IPPS is required by section 3141 of Pub. L. 111-148.

b. Imputed Floor and Alternative, Temporary Methodology for Computing the Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109), we adopted the "imputed floor" policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy three times, the last of which was adopted in the FY 2012 IPPS/LTCH PPS final rule and is set to expire on September 30, 2013 (we refer readers to the discussion in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593)). There are currently two all-urban States, New Jersey and Rhode Island, that have a range of wage indices assigned to hospitals in the State, including through reclassification or redesignation (we refer readers to discussions of geographic reclassifications and redesignations in section III.H. of this preamble). However, as we explain below, the current method for computing the imputed floor benefits only New Jersey, and not Rhode Island.

The current methodology for computing the imputed floor is specified in our regulations at 42 CFR 412.64(h)(4). In computing the imputed floor for an all-urban State, we calculate the ratio of the lowest-to-highest CBSA wage index for each all-urban State (that is, New Jersey and Rhode Island) as well as the average of the ratios of lowest-to-highest CBSA wage indices of those all-urban States. We compare the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State--the product of which establishes the imputed floor for the State. Rhode Island has only one CBSA (Providence-New Bedford-Fall River, RI-MA); therefore, Rhode Island's own ratio equals 1.0, and its imputed floor

is equal to its original CBSA wage index value. Conversely, New Jersey has 10 CBSAs. Because the average ratio of New Jersey and Rhode Island is higher than New Jersey's own ratio, the current methodology provides a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27950), for the FY 2013 wage index, the final year of the extension of the imputed floor policy under § 412.64(h)(4), we proposed an alternative, temporary methodology for computing the imputed floor wage index to address the concern that the current imputed floor methodology guarantees a benefit for one all-urban State with multiple wage indices but cannot benefit the other. We proposed that this proposed alternative methodology for calculating the imputed floor would be established using data from the application of the rural floor policy for FY 2013. We proposed that we would first determine the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with the proposed rule and available on the CMS Web site included the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values would then be increased by this factor, the result of which would establish the State's alternative imputed floor. We proposed to amend § 412.64(h)(4) to add new paragraphs (v)(A) and (B) to incorporate this proposed alternative methodology, and to make conforming references.

In addition, for the FY 2013 wage index, we did not propose any changes to the current imputed floor methodology at § 412.64(h)(4) and, therefore, no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we proposed a second, alternative methodology that would be used in cases where an all-urban State has a range of wage indices assigned to its hospitals, but the State cannot benefit from the methodology in existing § 412.64(h)(4). We stated that we intended to further evaluate the need, applicability, and methodology for the imputed floor before the September 30, 2013 expiration of the imputed floor policy and address these issues in the FY 2014 proposed rule.

Comment: A few commenters addressed our proposal for an alternative, temporary methodology for calculating the imputed floor. Some of the commenters supported the proposal. One commenter also urged CMS to adopt the alternative methodology for 3 consecutive fiscal years rather than the proposed 1-year period. Another commenter, a State hospital association, urged CMS to make the imputed floor a permanent policy in the FY 2013 final rule. Two State hospital associations opposed the proposal. One association agreed with the rationale that CMS had previously provided in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25878 through 25879) for not proposing to extend the imputed floor policy. The association urged CMS to allow the imputed floor policy to expire and not to finalize the proposed alternative methodology that would allow additional hospitals to benefit from the imputed floor. Another association suggested that CMS should provide additional information and consider the effects on all States, not just the benefits that may apply to one or two specific States.

Additionally, the national hospital association stated that it would be premature for it to comment on the proposal at this time due to its ongoing analysis of wage index reform.

Response: As discussed above and in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed the alternative methodology for only the one remaining year of the imputed floor policy, which expires on September 30, 2013. We made no proposal for extending the general imputed floor policy beyond FY 2013; therefore, we do not agree with the suggestion to adopt a final policy that would extend the alternative, temporary policy for 3 years, beyond FY 2013. As proposed, we are adopting as final for the FY 2013 wage index the alternative, temporary methodology for computing the imputed floor wage index, as well as the proposal to amend § 412.64(h)(4) to add new paragraphs (v)(A) and (B) to incorporate the alternative methodology. In addition, as we stated above, we plan to further evaluate the need, applicability, and methodology for the imputed floor policy and will address these issues in the FY 2014 proposed rule.

The wage index and impact tables associated with this FY 2013 final rule that are available on the CMS Web site include the application of the imputed floor policy at § 412.64(h)(4) and a national budget neutrality adjustment for the imputed floor. There are 29 providers in New Jersey that will receive an increase in their FY 2013 wage index due to the imputed floor policy. The wage index and impact tables for this final rule also reflect the application of the second alternative methodology for computing the imputed floor, which we will benefit four hospitals in Rhode Island.

c. Frontier Floor

Section 10324 of Pub. L. 111-148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000 (we refer readers to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160). Four States in the FY 2013 wage index are receiving the frontier State wage index: Montana, North Dakota, South Dakota, and Wyoming; 45 providers in these States are receiving the frontier floor value of 1.0000 in the FY 2013 wage index associated with this final rule. Although Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, its FY 2013 rural floor value of 1.0256 is greater than the frontier floor value (that is, 1.0000) and, therefore, is the State's minimum wage index for FY 2013.

We did not receive any public comments on the frontier floor policy.

The areas affected by the rural, imputed, and frontier floor policies for the FY 2013 wage index are identified in Table 4D associated with this final rule and available on the CMS Web site.

3. FY 2013 Wage Index Tables

The wage index values for FY 2013 (except those for hospitals receiving wage index adjustments under section 1886(d)(13) of the Act), included in Tables 4A, 4B, 4C, and 4F, available on the CMS Web site, include the occupational mix adjustment, geographic reclassification or redesignation as discussed in section III.H. of this preamble, and the application of the rural, imputed, and frontier State floors as discussed in section III.G.2. of this preamble.

Tables 3A and 3B, available on the CMS Web site, list the 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2007, 2008, and 2009 cost reporting periods. Table 3A lists these data for urban areas, and Table 3B lists these data for rural areas. In addition, Table 2, which is available on the CMS Web site, includes the adjusted average hourly wage for each hospital from the FY 2007 and FY 2008 cost reporting periods, as well as the FY 2009 period used to calculate the FY 2013 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period. The average hourly wages in Tables 2, 3A, and 3B, which are available on the CMS Web site, include the occupational mix adjustment. The wage index values in Tables 4A, 4B, 4C, and 4D also include the national rural and imputed floor budget neutrality adjustment. The wage index values in Table 2 also include the out-migration adjustment for eligible hospitals.

H. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify 13 months prior to the start of the fiscal year for which reclassification is sought (generally by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and

must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion of the proximity requirements in the FY 2002 IPPS final rule (66 FR 39874 and 39875).) The general policies for reclassifications and redesignations that we proposed, and are adopting, for FY 2013, and the policies for the effects of hospitals' reclassifications and redesignations on the wage index, are the same as those discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). Also, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification pursuant to 42 CFR 412.103.

2. FY 2013 MGCRB Reclassifications

a. FY 2013 Reclassification Requirements and Approvals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this final rule was constructed, the MGCRB had completed its review of FY 2013 reclassification requests. Based on such reviews, there were 193 hospitals approved for wage index reclassifications by the MGCRB for FY 2013. Because

MGCRB wage index reclassifications are effective for 3 years, for FY 2013, hospitals reclassified during FY 2011 or FY 2012 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications. There were 265 hospitals approved for wage index reclassifications in FY 2011, and 205 hospitals approved for wage index reclassifications in FY 2012. Of all the hospitals approved for reclassification for FY 2011, FY 2012, and FY 2013, based upon the review at the time of this final rule, 663 hospitals are in a reclassification status for FY 2013.

Under 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to 42 CFR 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887) and the FY 2003 IPPS final rule (67 FR 50065). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and "fallback" reclassifications, were included in the FY 2008 IPPS final rule (72 FR 47333).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2013 are incorporated into the wage index values published in this FY 2013 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further,

the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

b. Applications for Reclassifications for FY 2014

Applications for FY 2014 reclassifications are due to the MGCRB by September 4, 2012 (the first working day of September 2012). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2012, via the Internet on the CMS Web site at: http://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html?redirect=/MGCRB/02_instructions_and_applications.asp, or by calling the MGCRB at (410) 786-1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244-2670.

3. Redesignations of Hospitals under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B) of the Act requires us to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA if certain criteria are met. Effective beginning FY 2005, we use OMB's 2000 CBSA standards and the Census 2000 data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties have been known as "Lugar" hospitals and the counties themselves are often referred to as "Lugar" counties. The FY 2013 chart with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act is available via the Internet on the CMS Web site.

4. Reclassifications under Section 1886(d)(8)(B) of the Act

As in the past, hospitals redesignated under section 1886(d)(8)(B) of the Act are also eligible to be reclassified to a different area by the MGCRB. Affected hospitals were permitted to compare the reclassified wage index for the labor market area in Table 4C associated with the proposed rule (which was available on the CMS Web site) into which they would be reclassified by the MGCRB to the wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals could have withdrawn from an MGCRB reclassification within 45 days of the publication of the FY 2013 proposed rule. (We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51598 through 51599) for the procedural rules and requirements for a hospital that is redesignated under section 1886(d)(8)(B) of the Act and seeking reclassification under the MGCRB, as well as our policy of measuring the urban area, exclusive of the Lugar County, for purposes of meeting proximity requirements.) We treat New England deemed counties in a manner consistent with how we treat Lugar counties. (We refer readers to FY 2008 IPPS final rule with comment period (72 FR 47337) for a discussion of this policy.)

5. Reclassifications under Section 508 of Pub. L. 108-173

Section 508 of Pub. L. 108-173 allowed certain qualifying hospitals to receive wage index reclassifications and assignments that they otherwise would not have been eligible to receive under the law. Although section 508 originally was scheduled to expire after a 3-year period, Congress extended the provision several times, as well as certain special exceptions that would have otherwise expired. For a discussion of the

original section 508 provision and its various extensions, we refer readers to the FY 2012 notice, CMS-1442-N, which went on public display at the Office of the Federal Register on April 19, 2012, and was published in the **Federal Register** on April 20, 2012 (77 FR 23722). The most recent extension of the provision was included in section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112-78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96), which extended certain section 508 reclassifications and special exception wage indices for a 6-month period during FY 2012, from October 1, 2011 through March 31, 2012. Section 508 reclassifications and certain special exceptions have not been extended for FY 2013. Therefore, the FY 2013 wage index associated with this final rule does not reflect any section 508 reclassifications or special exception wage indices.

6. Waiving Lugar Redesignation for the Out-Migration Adjustment

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.G. of this preamble.)

In addition, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written

notification to CMS within the requisite number of days from the publication of the proposed rule[49]) to automatically waive its urban status for the 3-year period for which its out-migration adjustment is effective. That is, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the adjustment. Thus, under the procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless, prior to its second or third year of eligibility, the hospital explicitly notifies CMS in writing, within the required period (generally 45 days from the publication of the proposed rule), that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) for a detailed discussion of the policy and process for waiving Lugar status for the out-migration adjustment.

7. Cancellation of Acquired Rural Status Due to MDH Expiration

As we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50286 and 50287) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (for discharges occurring before October 1, 2011) to the end of FY 2012 (for

[49] Hospitals generally have 45 days from publication of the proposed rule to request an out-migration adjustment in lieu of the section 1886(d)(8) deemed urban status.

discharges occurring before October 1, 2012). Accordingly, beginning with FY 2013, there will no longer be an MDH designation, and those hospitals that were formerly MDHs will be paid based solely on the Federal rate.

Comment: Several commenters requested CMS to permit hospitals to revisit any geographic reclassification decisions that would impact their ability to qualify for MDH status in the event that the Congress extends the MDH program. In particular, in anticipation of the September 30, 2012 expiration of the MDH program, the commenters stated that some urban hospitals that became rural under section 1886(d)(8)(E) of the Act in order to qualify for MDH status had canceled their rural status so that they could instead receive their urban area wage index or reclassify for a higher wage index under section 1886(d)(10) of the Act for FY 2013. The commenters further stated that if the MDH program is extended, such hospital would no longer be qualified for MDH status because the hospital is no longer a rural provider.

Response: Although we understand the commenters' concerns, we believe it would be imprudent for CMS in this FY 2013 final rule to revise existing Medicare regulations and procedural rules around actions that the Congress may take in the future. If legislation is passed to continue the MDH program, CMS will develop policies and procedures to implement the specific provisions of such legislation.

I. FY 2013 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with the broad discretion granted to the Secretary under section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, beginning with

FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the "out-migration" adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. The FY 2013 out-migration adjustment is based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment (we refer readers to a full discussion of the adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602)). Table 4J, available via the Internet on the CMS Web site, lists the out-migration adjustments for the FY 2013 wage index.

We did not receive any public comments on our proposals for the out-migration adjustment for FY 2013.

J. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S-3 wage data and occupational mix survey data files for the proposed FY 2013 wage index were made available on October 4, 2011, through the Internet on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/WIFN/list.asp.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional public use file on our Web site that

reflects the actual data that are used in computing the proposed wage index. The release of this new file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and the scheduling of the Hospital Open Door forums at the CMS Web site at: http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html.

In a memorandum dated September 29, 2011, we instructed all fiscal intermediaries/MACs to inform the IPPS hospitals they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the fiscal intermediaries/MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in the October 4, 2011 wage and occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its fiscal intermediary/MAC by December 5, 2011. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted on the preliminary wage index data files on the Internet, through the September 29, 2011 memorandum referenced above.

In the September 29, 2011 memorandum, we also specified that a hospital requesting revisions to its occupational mix survey data was to copy its record(s) from the

CY 2010 occupational mix preliminary files posted to the CMS Web site in October, highlight the revised cells on its spreadsheet, and submit its spreadsheet(s) and complete documentation to its fiscal intermediary/MAC no later than December 5, 2011.

The fiscal intermediaries/MACs notified the hospitals by mid-February 2012 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' early-December revision requests. The fiscal intermediaries/MACs also submitted the revised data to CMS by mid-February 2012. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 21, 2012. Hospitals had until March 5, 2012, to submit requests to the fiscal intermediaries/MACs for reconsideration of adjustments made by the fiscal intermediaries/MACs as a result of the desk review, and to correct errors due to CMS' or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal intermediaries/MACs were required to transmit any additional revisions resulting from the hospitals' reconsideration requests by April 11, 2012. The deadline for a hospital to request CMS intervention in cases where the hospital disagreed with the fiscal intermediary's (or, if applicable, the MAC's) policy interpretations was April 18, 2012.

Hospitals were given the opportunity to examine Table 2, which was listed in section VI. of the Addendum to the proposed rule and available on the CMS Web site at: http://www.cms.gov. Table 2 contained each hospital's adjusted average hourly wage

used to construct the wage index values for the past 3 years, including the FY 2009 data used to construct the proposed FY 2013 wage index. We noted that the hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by March 2, 2012.

We released the final wage index data public use files in early May 2012 on the Internet at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/WIFN/list.asp. The May 2012 public use files were made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary/MAC in the entry of the final wage index data that resulted from the correction process described above (revisions submitted to CMS by the fiscal intermediaries/MACs by April 11, 2012). If, after reviewing the May 2012 final public use files, a hospital believed that its wage or occupational mix data were incorrect due to a fiscal intermediary/MAC or CMS error in the entry or tabulation of the final data, the hospital had to send a letter to both its fiscal intermediary/MAC and CMS that outlined why the hospital believed an error existed and provided all supporting information, including relevant dates (for example, when it first became aware of the error). CMS and the fiscal intermediaries (or, if applicable, the MACs) had to receive these requests no later than June 4, 2012.

Each request also had to be sent to the fiscal intermediary/MAC. The fiscal intermediary/MAC reviewed requests upon receipt and contacted CMS immediately to discuss any findings.

After the release of the May 2012 wage index data files, changes to the wage and occupational mix data were only made in those very limited situations involving an error by the fiscal intermediary/MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the fiscal intermediary/MAC nor CMS approved the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by fiscal intermediaries or the MACs on or before April 11, 2012.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 21, 2012 wage index public use files.
- Requests to revisit factual determinations or policy interpretations made by the fiscal intermediary or the MAC or CMS during the wage index data correction process.

Verified corrections to the wage index data received timely by CMS and the fiscal intermediaries or the MACs (that is, by June 4, 2012) were incorporated into the final wage index in this FY 2013 IPPS/LTCH PPS final rule, which will be effective October 1, 2012.

We created the processes described above to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2013 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the fiscal intermediary's (or, if applicable, the MAC's) decision with respect to requested changes. Specifically, our policy is that hospitals that

do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the Provider Reimbursement Review Board, the failure of CMS to make a requested data revision. (See W. A. Foote Memorial Hospital v. Shalala, No. 99-CV-75202-DT (E.D. Mich. 2001) and Palisades General Hospital v. Thompson, No. 99-1230 (D.D.C. 2003).) We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the fiscal intermediary's (or, if applicable, the MAC's) attention. Moreover, because hospitals have access to the final wage index data by early May 2012, they have the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or the MAC or CMS before the development and publication of the final FY 2013 wage index by August 2012, and the implementation of the FY 2013 wage index on October 1, 2012. If hospitals availed themselves of the opportunities afforded to provide and make corrections to the wage and occupational mix data, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after June 4, 2012, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our existing regulations, we make midyear corrections to the wage index for an area only if a hospital can show

that: (1) the fiscal intermediary or the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, "before the beginning of the fiscal year" means by the June 4 deadline for making corrections to the wage data for the following fiscal year's wage index. This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the fiscal intermediaries or the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when: (1) the fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the fiscal intermediary (or, if applicable, the MAC) and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the

fiscal year for the applicable IPPS update (that is, by the June 4, 2012 deadline for the FY 2013 wage index); and (3) CMS agreed that the fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the June 4, 2012 deadline), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a judicial decision reverses a CMS denial of a hospital's wage index data revision request.

K. Labor-Related Share for the FY 2013 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related: "The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates…." We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Pub. L. 108-173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this "would result in lower payments to a hospital than would otherwise be made." However, this provision of Pub. L. 108-173 did not change the legal requirement that the Secretary estimate "from time to time" the proportion of hospitals' costs that are "attributable to wages and wage-related costs." Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43856), we rebased and revised the hospital market basket for operating costs. We established a FY 2006-based IPPS hospital market basket to replace the FY 2002-based IPPS hospital market basket, effective October 1, 2009. In that final rule, we presented

our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2010. We also recalculated a labor-related share of 68.8 percent, using the FY 2006-based IPPS market basket, for discharges occurring on or after October 1, 2009. In addition, we implemented this revised and rebased labor-related share in a budget neutral manner, but consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. In this FY 2013 final rule, as we proposed, we are not making any further changes to the national average proportion of operating costs that are attributable to wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market basket as labor-intensive).

We did not receive any public comments on the application of the labor-related share to the wage index for FY 2013. Therefore, for FY 2013, we are continuing to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2012. Tables 1A and 1B, which are published in section VI. of the Addendum to this final rule and available via the Internet, reflect this labor-related share. We note that section 403 of Pub. L. 108-173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to

provide that the Secretary must employ 62 percent as the labor-related share unless this employment "would result in lower payments to a hospital than would otherwise be made." Therefore, for all IPPS hospitals whose wage indices are less than 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indices are greater than 1.0000, we are applying the wage index to a labor-related share of 68.8 percent of the national standardized amount.

For Puerto Rico hospitals, the national labor-related share is 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0. As we proposed in the FY 2013 proposed rule, we are continuing to use a labor-related share for the Puerto Rico-specific standardized amounts of 62.1 percent for discharges occurring on or after October 1, 2012. This Puerto Rico labor-related share of 62.1 percent was also adopted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43857) at the time the FY 2006-based hospital market basket was established, effective October 1, 2009. Consistent with our methodology for determining the national labor-related share, we added the Puerto Rico-specific relative weights for wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market basket as labor-intensive) to determine the labor-related share. Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. The labor-related share of a hospital's Puerto Rico-specific rate will be either the Puerto Rico-specific labor-related

share of 62.1 percent or 62 percent, depending on which results in higher payments to the hospital. If the hospital has a Puerto Rico-specific wage index of greater than 1.0, we will set the hospital's rates using a labor-related share of 62.1 percent for the 25 percent portion of the hospital's payment determined by the Puerto Rico standardized amounts because this amount will result in higher payments. Conversely, a hospital with a Puerto Rico-specific wage index of less than 1.0 will be paid using the Puerto Rico-specific labor-related share of 62 percent of the Puerto Rico-specific rates because the lower labor-related share will result in higher payments. The Puerto Rico labor-related share of 62.1 percent for FY 2013 is reflected in Table 1C, which is published in section VI. of the Addendum to this final rule and available via the Internet.

IV. Other Decisions and Changes to the IPPS for Operating Costs and Graduate Medical Education (GME) Costs

A. Hospital Readmissions Reduction Program

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new subsection (q) to section 1886 of the Act. Section 1886(q) of the Act establishes the "Hospital Readmissions Reduction Program," effective for discharges from an "applicable hospital" beginning on or after October 1, 2012, under which payments to those applicable hospitals may be reduced to account for certain excess readmissions.

Section 1886(q)(1) of the Act sets forth the methodology by which payments to "applicable hospitals" will be adjusted to account for excess readmissions. Pursuant to section 1886(q)(1) of the Act, payments for discharges from an "applicable hospital" will be an amount equal to the product of the "base operating DRG payment amount" and the adjustment factor for the hospital for the fiscal year. That is, "base operating DRG payments" are reduced by an adjustment factor that accounts for excess readmissions. Section 1886(q)(2) of the Act defines the base operating DRG payment amount as "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by . . . any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d)."

Paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection(d) refer to outlier payments, IME payments, DSH payments, and payments for low-volume hospitals, respectively.

Furthermore, section 1886(q)(2)(B) of the Act specifies special rules for defining "the payment amount that would otherwise be made under subsection (d)" for certain hospitals. Specifically, section 1886(q)(2)(B) of the Act states that "[i]n the case of a Medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital . . . the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5)." We are finalizing policies to implement the statutory provisions related to the definition of "base operating DRG payment amount" in this FY 2013 IPPS/LTCH PPS final rule.

Section 1886(q)(3)(A) of the Act defines the "adjustment factor" for an applicable hospital for a fiscal year as equal to the greater of "(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C)." Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. It states that the ratio is "equal to 1 minus the ratio of – (i) the aggregate payments for excess readmissions…; and (ii) the aggregate payments for all discharges…." Section 1886(q)(3)(C) of the Act describes the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act sets forth the definitions of "aggregate payments for excess readmissions" and "aggregate payments for all discharges" for an applicable hospital for the applicable period. The term "aggregate payments for excess readmissions" is defined in section 1886(q)(4)(A) of the Act as "the sum, for applicable conditions . . . of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the "Excess Readmission Ratio… for such hospital for such applicable period minus 1." The "excess readmission ratio" is a hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmission ratio as the ratio of "risk-adjusted readmissions based on actual readmissions" for an applicable hospital for each applicable condition, to the "risk-adjusted expected readmissions" for the applicable hospital for the applicable condition.

Section 1886(q)(5) of the Act provides definitions of "applicable condition," "expansion of applicable conditions," "applicable hospital," "applicable period," and "readmission." The term "applicable condition," this is addressed in detail in section IV.C.3.a. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666), is defined as a "condition or procedure selected by the Secretary among conditions and procedures for which: (i) readmissions… represent conditions or procedures that are high volume or high expenditures…and (ii) measures of such readmissions . . . have been endorsed by the entity with a contract under section 1890(a)…and such endorsed

measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)." Section 1886(q)(5)(B) of the Act also requires the Secretary, beginning in FY 2015, "to the extent practicable, [to] expand the applicable conditions beyond the 3 conditions for which measures have been endorsed…to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary."

Section 1886(q)(5)(C) of the Act defines "applicable hospital," that is, a hospital subject to the Hospital Readmissions Reduction Program, as a "subsection (d) hospital or a hospital that is paid under section 1814(b)(3) [of the Act], as the case may be." The term "applicable period," as defined under section 1886(q)(5)(D) of the Act, "means, with respect to a fiscal year, such period as the Secretary shall specify." As explained in the FY 2012 IPPS/LTCH PPS final rule, the "applicable period" is the period from which data are collected in order to calculate various ratios and adjustments under the Hospital Readmissions Reduction Program.

Section 1886(q)(6) of the Act sets forth the public reporting requirements for hospital-specific readmission rates. Section 1886(q)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(q) of the Act. Finally, section 1886(q)(8) of the Act requires the Secretary to collect data on readmission rates for all hospital inpatients for "specified hospitals" in order to calculate the hospital-specific readmission rates for all hospital inpatients and to publicly report these readmission rates.

2. Overview

As we stated in the FY 2012 IPPS/LTCH PPS final rule, we intend to implement the requirements of the Hospital Readmissions Reduction Program in the FY 2012, FY 2013, and future IPPS/LTCH PPS rulemaking cycles.

As explained above, the payment adjustment factor set forth in section 1886(q) of the Act does not apply to discharges until FY 2013. Therefore, we elected to implement the Hospital Readmissions Reduction Program over a 2-year period, beginning in FY 2012. In the FY 2012 IPPS/LTCH PPS final rule, we addressed the issues of the selection of readmission measures and the calculation of the excess readmission ratio, which will be used, in part, to calculate the readmission adjustment factor. Specifically, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed portions of section 1886(q) of the Act related to the following provisions:

- Selection of applicable conditions;
- Definition of "readmission;"
- Measures for the applicable conditions chosen for readmission;
- Methodology for calculating the excess readmission ratio; and
- Definition of "applicable period."

With respect to the topics of "measures for readmission" for the applicable conditions, and "methodology for calculating the excess readmission ratio," we specifically addressed the following:

- Index hospitalizations;
- Risk adjustment;

- Risk standardized readmission rate;
- Data sources; and
- Exclusion of certain readmissions.

We are providing below a summary of the provisions of section 1886(q) of the Act that were finalized in the FY 2012 IPPS/LTCH PPS final rule.

Applicable conditions: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666), we finalized the applicable conditions for the FY 2013 Hospital Readmissions Reduction Program as heart failure (HF), acute myocardial infarction (AMI), and pneumonia (PN). Section 1886(q)(5)(A) of the Act requires that the "applicable conditions" be conditions or procedures for which readmissions are "high volume or high expenditure" and that "measures of such readmissions" have been endorsed by the entity with a contract under section 1890(a) of the Act (currently National Quality Forum (NQF)) and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27956), we proposed to codify this definition of "applicable conditions" in the regulations we proposed at 42 CFR 412.152.

Comment: One commenter stated that the Hospital Readmissions Reduction Program measures were not reviewed by the Measure Application Partnership (MAP) in 2011. The commenter urged CMS to coordinate MAP review of the Hospital Readmissions Reduction Program and related measures.

Response: We thank the commenter for the suggestion. The three measures to be used in the Hospital Readmissions Reduction Program were finalized in the FY 2012

IPPS/LTCH Final Rule posted at the Office of the Federal Register on August 1, 2011, which pre-dated the requirement and establishment of the pre-rulemaking process as described under section 3014(b) of the Affordable Care Act, which amended section 1890A of the Act. This provision of the Affordable Care Act requires the Secretary to submit measures to a multi-stakeholder group, currently the Measure Application Partnership (MAP) for pre-rulemaking review. CMS established this pre-rulemaking process in December 2011. Because the statutory language at section 1886(q)(1) of the Act, as amended by section 3025 of the Affordable Care Act, refers to FY 2013 "and subsequent Fiscal Years" but authorizes expansion of the conditions (and hence measures) to be used in the program beginning with FY 2015, we believe the statute implies that the measures adopted for use in FY 2013 would also be used in FY 2014. In the future, if we consider proposing any new measures for future expansion of the Hospital Readmissions Reduction Program beyond these three measures, which we have the authority to do beginning with in FY 2015, we plan to submit them to the MAP for pre-rulemaking review.

Comment: Several commenters expressed concerns that the Hospital Readmissions Reduction Program may induce unintended consequences of overcrowding hospital emergency departments, as hospitals may believe they are compelled to avoid readmitting patients.

Response: We recognize that performance-based payment penalty or incentive programs may have the potential for unintended consequences. We are committed to monitoring the measures and assessing unintended consequences over time, such as the

inappropriate shifting of care, increased patient morbidity and mortality, and other negative unintended consequences for patients.

After consideration of the public comments we received, we are finalizing our proposal to codify the definition of "applicable condition" at 42 CFR 412.152 without modification.

In the FY 2012 IPPS/LTCH PPS final rule, we discussed how each of the finalized "applicable conditions" for FY 2013 meets these statutory requirements. We noted that section 1886(q)(5)(B) of the Act allows for the Secretary to expand the conditions for the Hospital Readmissions Reduction Program starting in FY 2015.

Comment: Several commenters addressed the expansion of conditions to be included in the program. Some commenters urged that CMS not include the hospital-wide readmission measure, currently proposed for the Hospital IQR program, in future HRRP program expansion. Commenters believed it would result in double counting of AMI, HF, and PN patients, and that condition-specific measures were more actionable and understandable for hospitals subject to this provision. Other commenters encouraged CMS to include the following conditions in future program expansions: atrial fibrillation (as one of other vascular conditions); chronic obstructive pulmonary disease; coronary artery bypass grafting; and percutaneous transluminal angioplasty. One commenter suggested that CMS delay the expansion of the program until such time as hospitals gain familiarity with the first three conditions used in the program.

Response: We thank the commenters for these suggestions and will take them into consideration when we address the expansion of the applicable conditions in future rulemaking.

Readmission: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666), we finalized a definition of "readmission" as occurring when a patient is discharged from an applicable hospital and then admitted to the same or another acute care hospital, that is, another applicable hospital, within a specified time period (30 days) from the date of discharge from the initial index hospitalization. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27956), we proposed to codify this definition of "readmission" under the regulations we proposed at 42 CFR 412.152. As we also discussed in the FY 2012 IPPS/LTCH PPS final rule, only one readmission during the 30 days following the discharge from the initial hospitalization will count as a readmission for purposes of calculating the ratios set forth in section 1886(q)(3) of the Act. For any given patient, none of the subsequent readmissions he or she experiences within 30 days after discharge would be counted as a new "index" admission (that is, an admission evaluated for a subsequent readmission).

Comment: Several commenters did not believe that the readmissions measures adequately measures quality. Commenters noted that it is difficult to determine which readmissions are preventable, and questioned whether reducing readmissions is a desirable outcome because increased mortality could lead to decreased readmission rates. One commenter cited research that higher readmission rates occur in communities with more physicians and hospital beds and in areas with high poverty and large minority or

older populations to demonstrate that it is unclear whether readmissions always reflect poor quality.

Response: We believe that risk-standardized readmission rates provide an important quality indicator to hospitals, CMS, patients, policymakers, and insurers. Readmission of patients who were recently discharged after hospitalization with AMI, HF, or pneumonia represents an important, expensive, and often avoidable adverse outcome. The risk of readmission can be avoided by improving the quality and type of care provided to these patients. There is ample evidence[50,51,52] that hospitals can reduce their readmission rates through such efforts as ensuring patients are clinically ready at discharge, reducing risk of infection, reconciling medications, improving communication with community providers participating in transitions of care, educating patients adequately upon discharge, and assuring patients understand follow-up care upon discharge. These interventions are aligned with efforts to improve mortality and are not at odds with the goal of survival. Moreover, the results of public reporting of the measures indicate that hospitals can do well on both mortality and readmission rates.

Comment: One commenter recommended a 7-day to 15-day readmission timeframe instead of 30 days, stating that a 30-day measure may be appropriate for assessing a community's ability to work together to provide the best care and services for

---

[50] Jack BW, Chetty VK, Anthony D et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med*. Feb 3, 2009;150(3):178-187.

[51] Coleman EA, Perry C, Chalmers S, Min SJ. The care transitions intervention: results of a randomized controlled trial. *Arch Intern Med*. Sep 25 2006;166(17):1822-1828.

[52] Hernandez AF, Greiner MA, Fonarow GC, et al. Relationship between early physician follow-up and 30-day readmission among Medicare beneficiaries hospitalized for heart failure. JAMA, May 5 2010:303(17):1716-1722.

patients, but may attribute more responsibility to the hospital than might otherwise be warranted.

Response: In the FY 2012 IPPS/LTCH PPS final rule, we finalized 30 days as the time period specified from the date of discharge for the purpose of defining readmission for the Hospital Readmissions Reduction Program. The 30-day time period meets the requirement set forth in section 1886(q)(5)(E) of the Act that the time period specified by the Secretary for defining a readmission be consistent with the time period specified for the endorsed measures. Furthermore, the timeframe of 30 days is a clinically meaningful period for hospitals to collaborate with their communities in an effort to reduce readmissions.

Comment: One commenter expressed specific concerns that the list of planned readmissions in the AMI measure does not account for all planned readmissions. Specifically, the commenter recommended the inclusion of AMI codes with "0" in the fifth digit, indicating "episode of care unspecified." The commenter noted that if the episode of care is unspecified, it could be outside the 30-day readmission timeframe. The commenter added that under the ICD-9-CM guidelines, the ICD-9-CM codes 410.XX for AMI are used for "acute" condition for up to 8 weeks duration.

Response: We thank the commenter for the suggestion. However, the AMI ICD-9-CM codes described by the commenter are used to identify index hospitalizations, not readmissions. The measures only identify the index admissions based on the use of the principal discharge diagnosis, which should represent the reason the patient was admitted to the hospital. Therefore, despite the use of the word "unspecified," in most

cases the AMI will have been the primary reason for admission and appropriately included as an index case.

Comment: One commenter stated the 30-day timeframe may be appropriate for assessing a community's ability to collaborate and provide the best care and services for discharged patients, but 30 days is too long a timeframe to fairly assess the attribution of the hospital's direct care of a patient.

Response: The 30-day time period that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666) meets the requirement set forth in section 1886(q)(5)(E) of the Act that the time period specified by the Secretary for defining a readmission be consistent with the time period specified for the endorsed measures. We disagree with the commenter that a much shorter timeframe is fairer, and believe that the timeframe of 30 days is a clinically meaningful period for hospitals to collaborate with their communities in an effort to reduce readmissions. This approach would ensure patients are clinically ready at discharge, reducing risk of infection, reconciling medications, improving communication with community providers participating in transitions of care, educating patients adequately upon discharge, and assuring patients understand follow-up care upon discharge.

Comment: One commenter requested clarification whether transfers from short-term acute care hospitals to LTCHs are excluded from the definition of readmissions.

Response: As defined in section 1886(q)(5)(E) of the Act, and finalized in the FY 2012 IPPS/LTCH PPS final rule, only readmissions to a subsection (d) hospital or a

hospital that is paid under section 1814(b)(3) [of the Act] will be counted as readmissions. Readmissions to LTCHs will not be counted as readmissions.

After consideration of the public comments we received, we are finalizing our proposal to codify the definition of "readmission" at 42 CFR 412.152 without modification.

Measures for applicable conditions: As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666 and 51667), we will use three NQF-endorsed, hospital risk-standardized readmission measures for FY 2013, which are currently in the Hospital IQR Program: Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure (NQF #0505); Heart Failure 30-Day Risk Standardized Readmission Measure (NQF #0330); and Pneumonia 30-day Risk Standardized Readmission Measure (NQF #0506). The measures, as endorsed by the NQF, include the 30-day time window, risk-adjustment methodology, and exclusions for certain readmissions.

As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673), we will use the risk-standardized readmission ratio of the NQF-endorsed readmission measures as the excess readmission ratio. The ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than 1.0. If a hospital performs worse than average, the ratio will be greater than 1.0.

Measure methodology: In the FY 2012 IPPS/ LTCH PPS final rule (76 FR 51668 through 51669), we finalized the methodology of the measures and are summarizing it briefly below.

Index hospitalizations included in the measure calculation: We finalized the definition of "index hospitalization" consistent with the NQF-endorsed definition. The measures define an index hospitalization as a hospitalization evaluated in the measure for a possible readmission within 30 days after discharge (that is, a hospitalization included in the measure calculation). The measures exclude as index hospitalizations patients who died during the first admission, patients who have not spent at least 30 days post-discharge enrolled in Medicare fee-for-service (FFS), patients who are discharged against medical advice, and patients who are under the age of 65.

Comment: Several commenters suggested exclusions from the index hospitalizations included in the measures, which included exclusions for patients under "extreme circumstances" such as transplants, end-stage renal disease, burn, trauma, psychosis and substance abuse.

Response: We appreciate the concern expressed by the commenters that patients of these "extreme circumstances" clinically could be sicker and more likely to be readmitted. The measures address clinical differences in hospitals' case-mix through risk adjustment rather than through excluding patients from the measure as suggested by the commenter. The goal in developing outcomes measures is to create a clinically cohesive cohort that includes as many patients as possible admitted with the given condition. Greatly expanding our list of exclusions would result in a measure that was less useful

and meaningful, because it would reflect the care of fewer patients. In addition, we believe that by excluding patients with significant comorbidities, the measure would not assess of the quality of care for those patients. To fairly profile hospitals' performance, it is critical to place hospitals on a level playing field and account for their differences in the patients that present for care. This is accomplished through adequate risk-adjustment for patients' clinical presentation rather than exclusion of patients.

Risk adjustment: The three measures, as endorsed by the NQF and finalized in the FY 2012 IPPS/LTCH PPS final rule, adjust for key factors that are clinically relevant and have strong relationships with the outcome (for example, patient demographic factors, patient coexisting medical conditions, and indicators of patient frailty). Under the current NQF-endorsed methodology, these covariates are obtained from Medicare claims extending 12 months prior to, and including, the index admission. This risk-adjustment approach adjusts for differences in the clinical status of the patient at the time of the index admission as well as for demographic variables. A complete list of the variables used for risk adjustment and the clinical and statistical process for selecting the variables for each NQF-endorsed measure, as proposed, is available at the Web site: http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.

Comment: Several commenters suggested that the readmission measures include adjustments for socioeconomic status and other factors that are either outside the hospitals' immediate control or that may adversely affect certain types of hospitals more than others. Suggestions for variables to include in either the patient level or the hospital-

level model included: patient race, ethnicity, language, income, lifestyle, health literacy, dual-eligible status (that is, eligibility for both Medicare and Medicaid), insurance status, functional status, cognitive impairment, post-discharge care support structure, and access to primary care. Two commenters suggested stratification of the hospital calculations by the percentage of dual-eligible patients. Other commenters suggested accounting for societal factors such as housing stability, food scarcity, and chronic unemployment.

Response: We have continued to consider and evaluate stakeholder concerns regarding the influence of patient socioeconomic status on readmission rates. In our analyses (http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HospitalChartBook2011.pdf), we consistently find that hospitals that care for large proportions of patients of low socioeconomic status are capable of performing well on readmission measures. Many safety-net providers and teaching hospitals do as well or better on the measures than hospitals without substantial numbers of patients of low socioeconomic status. The measures include rigorous risk-adjustment for differences in patient illness, and this likely incorporates some of the patient differences due to socioeconomic status (to the extent that patients of low socioeconomic status present to the hospital with greater level of disease). The risk adjustment for clinical factors likely captures much of the variation due to socioeconomic status, thus leading to more modest impact of socioeconomic status on hospital readmissions than stakeholders expect. We note that the goal of risk adjustment is to account for factors that are inherent to the patient at the time of admission, such as severity of disease, so as to put hospitals on a level playing field. The

measures should not be risk-adjusted to account for differences in practice patterns that lead to lower or higher risk for patients to be readmitted. The measures aim to reveal differences related to the patterns of care. Furthermore, the statutory language in section 1886(q)(5)(A)(ii)(I) of the Act requires that the measures included in the Hospital Readmissions Reduction Program be consistent with measures that are NQF-endorsed. A change in the risk-adjustment methodology of the measures as they are currently endorsed by the NQF would take time and necessitate additional rulemaking to adopt such measures. The measures also do not adjust for socioeconomic status because the association between socioeconomic status and health outcomes can be due, in part, to differences in the quality of health care received by groups of patients with varying socioeconomic status. The measures do not adjust for socioeconomic status, or other patient factors such as race, both because we do not want to hold hospitals to different standards for the outcomes of their patients of low socioeconomic status (which would definitely occur if calculations were stratified by percent dual-eligible patients as suggested by two of the commenters), and because our analyses demonstrate that patient socioeconomic status does not determine hospital performance on the readmission measures. Finally, we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. This approach is also consistent with the guidance from the NQF, which states that risk models should not obscure disparities by adjusting for factors associated with inequality in case (such as race or socioeconomic status) as well as with the methodology finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676). However, we are committed

to tracking this issue and will continue to evaluate disparities in care and the impact of the Hospital Readmissions Reduction Program on providers of vulnerable populations, including teaching and safety-net hospitals.

Comment: Two commenters supported CMS' decisions not to risk-adjust for socioeconomic status and urged CMS to resist making any changes to the Hospital Readmissions Reduction Program based on socioeconomic status, because the same care protocols that work with a different population may also work with patients of lower socioeconomic circumstances. One commenter appreciated the justification for the continued exclusion of patient-level socioeconomic status covariates—that doing so would impose different performance expectations based on the income distribution of patients and would also result in overfitting the risk adjustment models, in that it would result in an overly complex and possibly multicollinear model that yields inaccurate predictions.

Response: We thank the commenters for their support of our approach to risk-adjustment.

Comment: One commenter believed that the risk adjustment variables used to calculate readmission rates are not transparent to hospitals and urged CMS to ensure they are publicly and easily accessible.

Response: The risk adjustment variables that will be used to calculate readmission rates can be found in the readmission measure methodology reports found on the Web site at:

http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQn

etTier4&cid=1219069855841. Some of the patient risk factors are grouped using the CMS Condition Categories (CC) classification. A crosswalk of CCs to ICD-9-CM codes is available at: http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694.

Comment: One commenter stated that the comorbidities included in the risk-adjustment variables may not all be consistently coded at the present time.

Response: We have validated the 30-day readmission measures with models that use medical record-abstracted data for risk adjustment. This validation supported the use of the administrative claims data on comorbidities and demonstrated that the estimates of hospitals' risk-standardized readmission rates (RSRRs) based on administrative data are very similar to the rates estimated by models based on medical record data. This high level of agreement in the results based on the two different approaches supports the use of the administrative claims-based models for public reporting. Our approach to gathering risk factors for patients also mitigates the potential limitations of claims data. Because not every diagnosis is coded at every visit, we use inpatient, outpatient, and physician claims data for the 12 months prior to admission, and secondary diagnosis codes during the index admission, for risk adjustment.

Data sources: The finalized measures use Medicare inpatient claims data for Medicare FFS patients 65 years and older to identify index hospitalizations and readmissions. For risk adjustment, the measures use Part A and Part B claims for the 12 months prior to the index hospitalization as well as index hospitalization claims.

Exclusion of certain readmissions: The NQF-endorsed measures of readmissions finalized in the FY 2012 IPPS/LTCH PPS final rule include exclusions of readmissions consistent with the statutory requirement that all measures exclude certain readmissions that are unrelated to the prior discharge, such as transfers to other acute care facilities and planned readmissions.

Comment: Some commenters urged CMS to identify and exclude planned readmissions for the AMI, HF, and PN readmission measures. The commenters stated that failure to do so may encourage providers to delay necessary follow-up procedures. Two commenters urged CMS to explore common reasons for planned readmissions, bring them to the NQF for review for continued endorsement for the AMI, HF, and PN measures, and use these planned readmissions for the measures in subsequent rulemaking. A few commenters recommended that CMS also consider implementing codes that hospitals can use to designate when a readmission is planned so that these cases can be excluded from the readmission measure, and recommended using the NUBC Committee's proposed discharge status codes to identify planned readmissions.

Response: Our contractor engaged multiple clinical experts to develop a list of planned readmissions which was made part of a hospital-wide readmission measure that recently obtained NQF endorsement. During the development of this hospital-wide readmission measure, there was a 2-week informal public comment period in order to receive feedback on the measure and its planned readmission algorithm. The list of planned readmissions also underwent a 2-week informal public comment period when the hospital-wide readmission measure was evaluated at the NQF.

We maintain the measures annually and submit the updates to NQF for review. In response to stakeholder input, we intend to update the condition-specific measures to permit more planned readmissions for the condition-specific measures, which would not be counted as readmissions. Any NQF-approved changes to the measures will then be proposed for the Hospital Readmissions Reduction Program through future rulemaking. We are aware of the NUBC's intention to propose discharge status code on claims to identify planned readmissions. We would analyze its reliability, validity, and usability for identifying planned readmissions prior to considering the adoption of such a code for use in the readmission measures in the future.

Comment: Some commenters suggested that CMS exclude readmissions that occur for reasons such as transplants and device implantation, trauma, psychoses, substance use, end-stage renal disease, maternity and neonatal readmissions, rehabilitation, sepsis, natural disease or treatment progression, acute decompensated heart failure, the result of nonhospital community factors, and disaster relief.

Response: We thank the commenters for these suggestions. Many of these suggestions are among the planned readmission updates we intend to submit for the AMI, HF and PN measures as part of annual maintenance review by NQF. We perform measure maintenance reviews which include consideration of public comments, exploration and identification of any other exclusions for the measures; in this case, other types of readmissions, that would be excluded from the measures as planned readmissions would be considered during the maintenance review. If we determine certain readmissions should be excluded from the measures, we will revise the measures,

present them to NQF for endorsement, and update the Hospital Readmissions Reduction Program in future rulemaking.

Comment: Several commenters urged CMS to differentiate between related and unrelated readmissions. One suggestion to define "related readmissions" as any readmission for which the patient's primary diagnosis falls within the same MS-DRG or as the diagnosis for the initial admission, or to use the AHRQ CCs as a way to group diagnoses and procedure codes into clinically meaningful groups.

Response: We do not seek to differentiate between related and unrelated readmissions, or to identify preventable readmissions or "necessary" readmissions for several reasons. First, from the patient perspective, an unplanned readmission for any reason is likely to be an undesirable outcome of care after an acute hospitalization. Second, readmissions not directly related to the index condition may still be a result of the care received during the index hospitalization. For example, a patient hospitalized for heart failure who develops a hospital-acquired infection may ultimately be readmitted for sepsis. It would be inappropriate to treat this readmission as unrelated to the care the patient received during the index hospitalization. Furthermore, the range of potentially avoidable readmissions also includes those not directly related to the initial hospitalization, such as those resulting from poor communication at discharge or inadequate follow-up. As such, creating a comprehensive list of potential complications related to the index hospitalization would be arbitrary, incomplete, and, ultimately, impossible to implement. The measures are not meant to suggest that the appropriate

readmission rate is zero, but rather to identify hospitals that have a higher rate of readmissions than would be expected given their case mix.

Minimum number of discharges for applicable conditions: Section 1886(q)(4)(C)(ii) of the Act allows the Secretary discretion to determine the minimum number of discharges for the applicable condition. We finalized a policy in the FY 2012 IPPS/LTCH PPS final rule that the minimum number of discharges for applicable conditions is 25 for each condition for the FY 2013 Hospital Readmissions Reduction Program.

Comment: Several commenters urged CMS to raise the minimum case threshold to qualify for the Hospital Readmissions Reduction Program to improve the reliability of the measures.

Response: We determined the 25-case threshold for public reporting based on a reliability statistic that is calculated from the intercluster correlation, a parameter of the model. We are maintaining the minimum 25-case threshold that we adopted through rulemaking last year.

Applicable period: Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year. In the FY 2012 IPPS/LTCH PPS final rule, we finalized our policy to use 3 years of claims data to calculate the proposed readmission measures. Specifically, we finalized the policy to use claims data from July 1, 2008, to June 30, 2011, to calculate the excess readmission ratios and to calculate the FY 2013 Hospital Readmissions Reduction Program payment adjustment. As we discussed in section IV.A.3.d. of the preamble of the FY 2013

IPPS/LTCH PPS proposed rule (77 FR 27957), the excess readmission ratios used to model our proposed methodology to calculate the Hospital Readmissions Reduction Program payment adjustment were based on the 3-year time period of July 1, 2007 to June 30, 2010. However, we indicated that, for the final rule, we intended to use excess readmission ratios based on the applicable period of July 1, 2008 to June 30, 2011, as finalized in the FY 2012 IPPS/LTCH PPS final rule. In the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to codify the definition of "applicable period" at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmission ratios and adjustments for the fiscal year.

Comment: Several commenters urged CMS to consider a shorter timeframe for measuring performance for readmissions such as a 1-year or 2-year period. The commenters believed that hospitals should not be assessed on readmissions that occurred during 2008, long before the policy addressing this provision was passed in the Affordable Care Act.

Response: In the FY 2012 IPPS/LTCH PPS final rule, we finalized 3 years as the applicable period for the FY 2013 payment adjustment. We use a 3-year period of index admissions to increase the number of cases per hospital used for measure calculation, which improves the precision of each hospital's readmission estimate. Although this approach utilizes older data, it also identifies more variation in hospital performance and still allows for improvement from one year of reporting to the next. We are maintaining the 3-year period as previously adopted.

Comment: One commenter stated that, although data from across a 3-year period helps to identify significant improvements over time, there is a huge lag in the end of the 3-year period and the commencements of penalties (approximately 15 months).

Response: We decided to use the current timeframe because it balances the needs for the most recent claims and for sufficient time to process the claims data and calculate the measures to meet the program implementation timeline. We will continue to explore the feasibility of using more up-to-date data sources.

After consideration of the public comments we received, we are finalizing our proposal to codify our definition of "applicable period" under the regulations at 42 CFR 412.152 without modification.

Excess Readmission Ratio Calculation: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673 through 51676), we finalized the excess readmission ratio pursuant to section 1886(q)(4)(C) of the Act. We established the excess readmission ratio as the risk-adjusted readmission ratio from the NQF-endorsed measures. The ratio is calculated using hierarchical logistic regression. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore variation in hospital patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal difference in quality. The method produces an adjusted actual (or "predicted") number in the numerator and an "expected" number in the denominator. The expected calculation is similar to that for logistic regression--it is the sum of all patients' expected probabilities of readmission, given their risk factors and the risk of readmission at an average hospital.

For each hospital, the numerator of the ratio used in the NQF-endorsed methodology (actual adjusted readmissions) is calculated by estimating the probability of readmission for each patient at that hospital and summing up over all the hospital's patients to get the actual adjusted number of readmissions for that hospital. Mathematically, the numerator equation can be expressed as:

Numerator: Adjusted Actual Readmissions

Step 1:

Calculate each patient's predicted probability of readmission = $\frac{1}{1 + e^{-Z_a}}$

Z_a = hospital-specific effect + Xβ

intercept + risk-adjustment coefficients

Step 2:

To get the numerator result, add all patients' predicted probabilities of readmission

The denominator of the risk-standardized ratio (excess readmission ratio) under this NQF-endorsed methodology sums the probability of readmission for each patient at an average hospital. This can be expressed mathematically as:

Denominator: Expected Readmissions

Step 1:

Calculate each patient's expected probability of readmission = $\frac{1}{1 + e^{-Ze}}$

$Z_e = X\beta$

intercept + risk-adjustment coefficients

Step 2:

To get the denominator result, add all patients' expected probabilities of readmission

Thus, the ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (excess readmission ratio) greater than one. In summary, in the FY 2012 IPPS/LTCH PPS final rule, we defined the "excess readmission ratio" as the risk-standardized readmission ratio of the NQF-endorsed readmission measures. More in-depth detail surrounding the methodology of excess readmission ratio calculation can be accessed on the Web site at: http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27958), we proposed to codify the definition of "excess readmission ratio" under the regulations we proposed at 42 CFR 412.152 as a hospital-specific ratio for each applicable condition for an

applicable period, which is the ratio (but not less than 1.0) of (1) risk-adjusted readmissions based on actual readmissions for an applicable hospital for each applicable condition to (2) the risk-adjusted expected readmissions for the applicable hospital for the applicable condition.

Comment: Two commenters indicated that almost no hospitals are statistically significantly different from the U.S. average because the hierarchical logistic regression model shrinks the coefficients of small hospitals towards the mean. One commenter expressed concern that the methodology relies excessively on the ability of the model to correct for hospital-specific characteristics and may be at odds with the observed rate. Another commenter suggested that alternatives to the current method could include looking at more conditions over several years which would increase the sample size, reduce random variation, and reduce the need to shrink estimates toward the national mean.

Response: The modeling of the readmission rates takes into account hospitals' case-mix as well as the sample size of the hospital. For both of these reasons, the risk-standardized rate may appropriately differ from the observed rates. These differences are important in leveling the playing field for hospitals and accounting for uncertainty in small volume estimates. The hierarchical logistic regression model that we use to calculate the 30-day measures allows the inclusion of hospitals with relatively few observations but takes into account the uncertainty associated with sample size.

Comment: One commenter believed that the statute requires that CMS calculate an Observed-to-Expected (O/E) ratio for each readmission condition by hospital and to

use that ratio to determine the payment penalty. The commenter requested that CMS revise its methodology so that it calculates hospital-specific observed and expected readmission rates and reports them on Hospital Compare.

Response: We disagree with the commenter's assessment that the statute requires that we use an observed to expected ratio. Rather, the statute at section 1886(q)(4)(C) of the Act defines the excess readmission ratio as the ratio of "the risk adjusted readmissions based on actual readmissions," and "the risk adjusted expected readmissions" as "determined consistent with a readmission methodology that has been endorsed" by an entity with a contract under section 1890(a) of the Act (currently the NQF). The readmission measures that we are using for the Hospital Readmissions Reduction Program have numerators and denominators consistent with these definitions. The measures have been endorsed by the NQF, and we finalized use of these NQF-endorsed readmission measures in the FY 2012 IPPS LTCH PPS final rule.

Comment: One commenter asked for clarification on the calculation of the readmission rates for multiple readmissions, particularly where one or more readmissions might be unrelated to the index admission.

Response: As finalized in the FY 2012 IPPS/LTCH PPS final rule, the readmissions measures are designed to measure whether a patient experienced at least one readmission within 30 days of an initial (or "index") discharge as a single binary (yes/no) event, rather than counting the number of readmissions experienced within 30 days of discharge as a separate readmissions. For any given patient, only one readmission during the 30 days following the discharge from the initial hospitalization

will count as a readmission for purposes of calculating the ratios set forth in section 1886(q) of the Act. For any given patient, none of the subsequent readmissions he or she experiences within 30 days after discharge would be counted as a new "index" admission within the same measure (that is, an admission evaluated in the measure for a subsequent readmission). Any eligible admission after the 30-day time period will be considered a new index admission. For example, if a patient's index admission was for heart failure and the patient was readmitted with a primary diagnosis of pneumonia, that hospitalization could count as both a readmission for the health failure measure and an index admission for the pneumonia measure.

We do not seek to differentiate between related and unrelated readmissions, or to identify preventable readmissions or "necessary" readmissions for several reasons. First, from the patient perspective, a readmission for any reason is likely to be an undesirable outcome of care after an acute hospitalization. Second, readmissions not directly related to the index condition may still be a result of the care received during the index hospitalization.

After consideration of the public comments we received, we are finalizing our proposal to codify the definition of "excess readmission ratio" under the regulations at 42 CFR 412.152 without modification.

3. FY 2013 Proposed and Final Policies for the Hospital Readmissions Reduction Program

a. Overview

In this final rule, we are addressing the provisions in section 1886(q) of the Act that are related to the Hospital Readmissions Reduction Program payment adjustment, as well as any other provisions in section 1886(q) of the Act that were not addressed in the FY 2012 IPPS/LTCH PPS final rule that are effective for discharges beginning on or after October 1, 2012. Specifically, in this final rule (as we did in the FY 2013 IPPS/LTCH PPS proposed rule), we are addressing section 1886(q) of the Act related to the following provisions:

- Base operating DRG payment amount, including policies for SCHs and MDHs and hospitals paid under section 1814(b) of the Act;
- Adjustment factor (both the ratio and floor adjustment factor);
- Aggregate payments for excess readmissions and aggregate payments for all discharges;
- Applicable hospital;
- Limitations on review;
- Reporting of hospital-specific information, including the process for hospitals to review and submit corrections.

b. Base Operating DRG Payment Amount, Including Special Rules for SCHs and MDHs and Hospitals Paid under Section 1814 of the Act

(1) Definition of Base Operating DRG Payment Amount (§ 412.152)

Under the Hospital Readmissions Reduction Program at section 1886(q) of the Act, payments for discharges from an "applicable hospital" will be an amount equal to the product of the "base operating DRG payment amount" and an "adjustment factor" that accounts for excess readmissions for the hospital for the fiscal year, for discharges beginning on or after October 1, 2012. Specifically, section 1886(q)(1) of the Act requires the Secretary to base payments for a discharge on an amount equal to the product of "the base operating DRG payment amount" and "the adjustment factor" for the hospital in a given fiscal year. The "base operating DRG payment amount" is defined under section 1886(q)(2) of the Act as "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by . . . any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d)." Paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d) of section 1886 of the Act refer to outlier payments, indirect medical education (IME) payments, disproportionate share (DSH) payments, and low-volume hospital payments, respectively.

In general, "the payment amount that would otherwise be made under subsection (d) … for a discharge" (that is, the discharge payment amount made under section 1886(d) of the Act) determined without consideration of the adjustments to payments made under the Hospital VBP Program (section 1886(o) of the Act) or under the Hospital Readmissions Reduction Program (section 1886(q) of the Act) is the applicable average standardized amount adjusted for resource utilization by the

applicable MS-DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment (COLA) for hospitals located in Alaska and Hawaii), which is often referred to as the "wage-adjusted DRG operating payment." This payment amount may then be further adjusted if the hospital qualifies for an IME adjustment (under section 1886(d)(5)(B) of the Act), a DSH payment adjustment (under section 1886(d)(5)(F) of the Act), and/or a low-volume payment adjustment (under section 1886(d)(12) of the Act), or if the discharge qualifies for an outlier payment (under section 1886(d)(5)(A) of the Act). Furthermore, certain discharges may qualify for an additional payment for new medical services or technologies under section 1886(d)(5)(K) of the Act (often referred to as a "new technology add-on payment").

Consistent with section 1886(q)(2) of the Act, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27959), under the regulations we proposed at 42 CFR 412.152, we proposed to define the "base operating DRG payment amount" under the Hospital Readmissions Reduction Program as the wage-adjusted DRG operating payment plus any applicable new technology add-on payments. As required by the statute, we stated that the proposed definition of "base operating DRG payment amount" does not include adjustments or add-on payments for IME, DSH, outliers and low-volume hospitals provided for under sections 1886(d)(5)(B), (d)(5)(F), (d)(5)(A), and (d)(12) of the Act, respectively. Section 1886(q)(2) of the Act does not exclude new technology payments made under section 1886(d)(5)(K) of the Act in the definition of "base operating DRG payment amount"; therefore, any payments made under section 1886(d)(5)(K) of the Act

are included in the definition of "base operating DRG payment amount." In addition, under the regulations we proposed at 42 CFR 412.152, we proposed to define "wage-adjusted DRG operating payment" as the applicable average standardized amount adjusted for resource utilization by the applicable MS-DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii). We proposed that, under § 412.154(b)(1), to account for excess readmissions, an applicable hospital's base operating DRG payment amount would be adjusted for each discharge occurring during the fiscal year. The payment adjustment for each discharge is determined by subtracting the product of the base operating DRG payment amount for such discharge and the hospital's readmission payment adjustment factor for the fiscal year from the base operating DRG payment amount for such discharge.

Under this proposal, consistent with section 1886(q)(2)(B)(i) of the Act and proposed § 412.154(b)(2), for SCHs that receive payments based on their hospital-specific payment rate, we also proposed to exclude the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate from the definition of "base operating DRG payment amount." We noted that, under the Hospital Readmissions Reduction Program at section 1886(q) of the Act, the proposed definition of "base operating DRG payment amount" would be used to calculate both the "aggregate payments for excess readmissions" and "aggregate payments for all discharges" under sections 1886(q)(4)(A) and (B) of the Act, which would then be used to determine the readmission adjustment factor that accounts for excess readmissions

under section 1886(q)(3) of the Act (as discussed in greater detail in section IV.A.3.c. of the preamble of the proposed rule and this final rule), and would also be used to determine which payment amounts will be adjusted to account for excess readmissions. (We note that, as discussed in section IV.G. of the preamble of the proposed rule and this final rule, under current law, the MDH program expires at the end of FY 2012 (that is, the MDH program is currently only applicable to discharges occurring before October 1, 2012). Therefore, due to the expiration of the MDH program beginning with FY 2013, we did not include MDHs in the discussion of our proposals regarding the base operating DRG payment amount in the proposed rule.)

Comment: Commenters supported the proposed definition of the base operating DRG payment amount. Commenters also supported our proposal to exclude IME, DSH, outliers, low-volume adjustment, and additional payments made due to status as an SCH from the definition of the base operating DRG payment amount.

Commenters both supported and opposed our proposed inclusion of new technology payments in the definition of the base operating DRG payment amount. Commenters recommended that CMS exclude the new technology payment from the definition of "base operating DRG payment amount" because, like payment adjustments for IME and DSH, it is extrinsic to the base rate. In addition, without any known association between the use of new technology and the quality and efficiency of care provided by a hospital, one commenter did not believe there was justification to incorporate the use of new technology into the structure of a quality program. Some commenters asserted that the inclusion of the new technology payments in the base DRG

operating payment definition for the determination of payment reduction adjustments conflicts with the primary principle of identifying and ensuring adequate payment for new medical services and technologies for a brief 2- to 3-year period and should not be altered by our other required initiatives.

Response: We believe the statute is specific with regards to the definition of base operating DRG payment amount at section 1886(q)(2) of the Act, which explicitly specifies that any additional payments for IME, DSH, outliers, and low-volume hospitals provided for under sections 1886(d)(5)(B), (d)(5)(F), (d)(5)(A), and (d)(12) of the Act, respectively, are to be excluded. Section 1886(q)(2) of the Act does not specify an exclusion for new technology payments made under section 1886(d)(5)(K) of the Act, and therefore, we do not believe we have the flexibility to exclude new technology payments in the definition of base operating DRG payment amount under the Hospital Readmissions Reduction Program. We are finalizing our definition of "base operating DRG payment," as proposed, without modification.

Comment: One commenter stated that cases that receive transfer adjustments when determining their payment should be accounted for in the proposed definition of base operating DRG payment amount. The commenter specified that the base operating DRG payment amount should also include any payment reductions for patients covered under the transfer policy as it applies to both post-acute and short-stay acute hospitals.

Response: We are clarifying that the base operating DRG payment amount accounts for any applicable transfer adjustment for cases that are paid under as either an acute care transfer or post-acute care transfer. In other words, if a case is paid as a

transfer in accordance with our transfer payment policy at 42 CFR 412.4(f), resulting in a reduced IPPS payment, the reduced transfer-adjusted payment amount is also reflected in the base operating DRG payment amount. For the FY 2013 IPPS/LTCH PPS proposed rule, the data used to model the proposed readmission payment adjustment factors actually reflected transfer adjusted base operating DRG payment amounts, where applicable. As discussed earlier, the "base operating DRG payment amount" would be used to calculate both the "aggregate payments for excess readmissions" and "aggregate payments for all discharges" under sections 1886(q)(4)(A) and (q)(4)(B) of the Act, which would then be used to determine the readmissions payment adjustment, and would also be used to determine which payment amounts will be adjusted to account for excess readmissions. We are finalizing that the definition of "base operating DRG payment amount" includes any applicable payment adjustments for transfer cases under 42 CFR 412.4(f). In addition, in this final rule, we are revising the definition of "wage-adjusted DRG operating payment" in the regulations we proposed at 42 CFR 412.152 to specify that any applicable payment adjustment for transfers under § 412.4(f) is included. Accordingly, we are finalizing the definition of "wage adjusted DRG operating payment" as the applicable average standardized amount adjusted for resource utilization by the applicable MS-DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii). This amount includes an applicable payment adjustment for transfers under § 412.4(f).

Comment: Commenters recommended that the proposed definition of base operating DRG payment should be refined to account for the special payment status of MDHs that are paid under the hospital-specific rate should the MDH payment status be extended under legislation. In addition, commenters suggested that CMS make a proposal to exclude the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate from its definition of "base operating DRG amount" for MDHs, similar to our proposal made for SCHs, which can also be paid under the hospital-specific payment rate.

Response: As stated earlier, under current law, the MDH program expires at the end of FY 2012 (that is, the MDH program is currently only applicable to discharges occurring before October 1, 2012). MDHs are paid the sum of the Federal payment amount plus 75 percent of the amount by which their hospital-specific rate exceeds the Federal payment amount. As discussed later in this section, we had proposed to exclude hospital-specific payments from the definition of base operating DRG payments in the calculation of a hospital's readmission payment adjustment factor. Specifically, we stated that because we are using historical data to determine the base operating DRG payments to calculate the adjustment factor, we proposed to model their base operating DRG payment amount as they would have been paid under the Federal standardized amount, rather than using the information on the claim (which may represent a payment either made under the hospital-specific rate or the Federal rate) so that their payments are consistent with our proposed definition of "base operating DRG payment."

For MDHs, the payment difference between the payment made under the hospital-specific rate and the payment made under the Federal rate is not included in the base operating DRG payment amount to determine the readmissions adjustment factor; that is, it is neither included in the numerator of the aggregate dollars for excess readmissions nor in the denominator of the aggregate dollars for all discharges.

Furthermore, we are clarifying that the difference between the applicable hospital-specific payment rate and the Federal payment rate for both SCHs and for MDHs, should the MDH provision be extended beyond FY 2012, is excluded from base operating DRG payment amount for these hospitals. This means that, for an SCH or an MDH, the readmissions payment adjustment under Hospital Readmissions Reduction Program for each discharge will be calculated by multiplying the SCH's or MDH's readmission payment adjustment factor by the base-operating DRG payment amount that is exclusive of the amount by which the hospital-specific rate payment exceeds the Federal payment rate, where applicable. The resulting payment adjustment will then be subtracted from the hospital's payment for the discharge, regardless of whether the hospital is paid based on the Federal rate or its hospital-specific rate.

After consideration of the public comments we received, we are finalizing the proposed definition of "base operating DRG payment amount" at 42 CFR 412.152, noting that it includes any applicable payment adjustments for transfer cases under 42 CFR 412.4(f). In addition, we are revising the definition of "wage-adjusted DRG operating payment" in the regulations we proposed at 42 CFR 412.152 to specify that any applicable payment adjustment for transfers under § 412.4(f) is included.

(2) Special Rules for Certain Hospitals: Hospitals Paid under Section 1814(b)(3) of the Act (§ 412.154(d))

Although the definition of "applicable hospital" under section 1886(q)(5)(C) of the Act also includes hospitals paid under section 1814(b)(3) of the Act (that is, certain Maryland hospitals), section 1886(q)(2)(B)(ii) of the Act allows the Secretary to exempt such hospitals from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings established by Congress for the program as applied to "subsection (d) hospitals." Accordingly, a program established by the State of Maryland that could serve to exempt the State from the Hospital Readmissions Reduction program would focus on those "applicable" Maryland hospitals operating under the "waiver" provided by section 1814(b)(3) of the Act, that is, those hospitals that would otherwise have been paid by Medicare under the IPPS, absent the provision.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27960), we proposed to establish criteria for evaluation of an annual report to CMS to determine whether Maryland should be exempted from the program each year. Accordingly, we proposed to evaluate a report submitted by the State of Maryland documenting how its program (described below) meets those criteria. Based on the information in the report, we proposed to determine whether or not Maryland's readmission program met our criteria to be exempt from the Hospital Readmissions Reduction Program for FY 2013. We noted that our proposed criteria to evaluate Maryland's program is for FY 2013, the first

year of the program, and our evaluation criteria may change through notice-and-comment rulemaking as the Hospital Readmissions Reduction Program evolves. We proposed to codify this requirement at § 412.154(d) of the regulations.

Based on preliminary discussions with the State, we understand that, effective July 1, 2011, Maryland has established the Admission-Readmission Revenue (ARR) Program. The State has described its program as a voluntary program for acute care hospitals, of which 30 out of the 46 acute care hospitals in the State are currently enrolled. Under the program, the State pays hospitals under a case-mix adjusted bundled payment per episode of care, where the episode of care is defined as the initial admission and any subsequent readmissions to the same hospital or linked hospital system that occur within 30 days of the original discharge. According to the State, an initial admission with no readmissions provides the hospital with the same weight as an initial admission with multiple readmissions. Therefore, hospitals receive a financial reward for decreased readmissions (as determined through the case mix adjusted, episode of care weights). Unlike the Hospital Readmissions Reduction Program under section 1886(q) of the Act, which is currently based on measures for three conditions (HF, AMI, and PN) for the Medicare FFS population and only adjusts the IPPS operating payments, Maryland's program applies to all conditions for all patients. In addition, while the Hospital Readmissions Reduction Program considers a readmission to be a subsequent admission to either the original acute care hospital from where the patient was initially discharged or an admission to another acute care hospital, currently Maryland only tracks readmissions to the same acute care hospital (or linked hospital system) from which the patient was

originally discharged. The State had noted that, under its ARR program, the readmission rates for the hospitals participating in the ARR program for the first quarter of its fiscal year compared to the first quarter of its previous fiscal year decreased from 9.86 percent to 8.96 percent.

In the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to evaluate Maryland's ARR program based on whether the State could demonstrate that cost savings under its program achieved or exceeded the savings to the Medicare program due to the Hospital Readmissions Reduction Program under section 1886(q) of the Act. We also proposed to evaluate whether Maryland's program could demonstrate similar results in reducing unnecessary readmissions among hospitals in the State, as described in more detail below. With specific regard to Maryland's demonstration of cost savings, we proposed to evaluate whether Maryland's ARR program could demonstrate savings to the Medicare program that are at least similar to those expected under the Hospital Readmissions Reduction Program. As discussed in this proposed rule, we estimated that, under the Hospital Readmissions Reduction Program, for FY 2013, Medicare IPPS operating payments would decrease by approximately $300 million (or 0.3 percent) of total Medicare IPPS operating payments. Maryland has indicated that it believes it can achieve comparable savings because it intends to reduce the rate update factor for all hospitals by 0.3 percent, regardless of a hospital's performance on readmissions.

In addition, we indicated in the proposed rule that we plan to propose, in future rulemaking, to evaluate whether Maryland's ARR program can meet or exceed health outcomes that we expect to improve under the Hospital Readmissions Reduction

Program. Because the Hospital Readmissions Reduction Program is not effective until October 1, 2012, we indicated that we do not yet have measured health outcomes against which we can evaluate Maryland's ARR program. However, we intend to have outcomes data in the future with which to evaluate Maryland's ARR program. We anticipate that, under the Hospital Readmissions Reduction Program, hospitals will experience a reduction in unnecessary readmissions. Therefore, in future rulemaking, we intend to propose to evaluate whether Maryland's ARR program can demonstrate similar decreases in potential preventable readmissions among hospitals in the State. Furthermore, in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed that the State's annual report and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually in accordance with the statute and as proposed at § 412.154(d)(2).

Based on preliminary information provided by Maryland, the State believes that its program can meet our evaluation criteria and demonstrate that its program achieves or surpasses the measured results in terms of health outcomes and cost savings. We indicated in the proposed rule that we are reviewing whether the Maryland's ARR program, which currently cannot monitor readmissions to other hospitals and provide a financial reward for hospitals that reduce within-hospital readmissions, but provides for an across-the-board 0.3 percent reduction to the annual rate update to account for comparable savings to the Hospital Readmissions Reduction Program, meets the criteria to exempt Maryland hospitals from the Hospital Readmissions Reduction Program. We welcomed public comments on whether the Maryland ARR program meets the

requirements for exemption from the Hospital Readmissions Reduction Program set forth in section 1886(q)(2)(B)(ii) of the Act.

Comment: Commenters requested that Maryland hospitals be exempt from the Hospital Readmissions Reduction Program. Commenters contended that Maryland's readmissions program meets the criteria for Maryland hospitals to be waived from the Hospital Readmissions Reduction Program. One commenter stated that Maryland has already demonstrated successful reductions in readmissions as a result of the Admission-Readmission Revenue (ARR) and Total Patient Revenue (TPR) programs. The commenter described the TPR program as a global budget payment program, designed to reduce overall volumes and, thus, reduce readmissions. ARR hospitals have seen a 7.1 percent reduction in Medicare readmissions since the inception of the program; TPR hospitals have experienced a 6.4 percent decline in readmissions from FY 2009 to FY 2011. The commenter sought more information on how CMS plans to measure Maryland's performance relative to the nation prior to implementation in order to ensure that Maryland's hospitals are prepared to meet our expectations, and can make the appropriate adjustments in advance of submitting an exemption request.

Commenters acknowledged that the ARR program provides a financial incentive for hospitals to reduce readmissions and improve the quality of care and that the ARR program established a 30-day episode of care payment instead of a payment per admission, so a hospital that reduces readmissions keeps the same revenue and increases profits by reducing costs. However, one commenter suggested that savings are generated by reducing inter-hospital readmissions and outpatient visits. The commenter stated that

the TPR program generates savings by restricting revenues and, therefore, providing an incentive for hospitals to reduce volumes. The commenter stated that this mechanism allows participating hospitals to focus on patient care and improved outcomes, rather than generating volume. Furthermore, the commenter pointed out that Maryland's Health Services Cost Review Commission reduced hospitals' FY 2013 rate update by 0.58 percentage points to guarantee readmissions savings.

Finally, the State of Maryland also commented that, in future years, it will work with us to demonstrate cost savings and improved outcomes, over a multiyear period.

Response: We appreciate the commenters' requests to exempt Maryland from the Hospital Readmissions Reduction Program for FY 2013. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27959), we proposed to establish an annual process by which to evaluate Maryland's readmission program to determine whether the State's program meets or exceeds measured results in terms of health outcomes and cost savings as compared to the Hospital Readmissions Reduction Program. For FY 2013, we indicated that the Hospital Readmissions Reduction Program would result in an estimated savings of $300 million (-0.3 percent), and we proposed to evaluate whether Maryland's program could have comparable savings. As commenters acknowledged, Maryland's readmissions program provides a financial incentive, not penalty, to hospitals that reduce their readmissions. Furthermore, commenters acknowledged that the State has guaranteed savings by reducing the FY 2013 rate by 0.58 percent. We understand that this is a uniform rate reduction for all hospitals, regardless of an individual hospital's performance on readmissions. We understand that the acute care hospitals in Maryland

are included either in the ARR program or the TPR program, which provides incentives for hospitals to reduce readmissions.

With respect to health outcomes, we proposed that since this is the first year of the Hospital Readmissions Reduction Program, we do not have a measured health outcomes by which to evaluate Maryland against. Thus, for the first year, we would not evaluate Maryland's program with respect to health outcomes. In the future, we intend to have national outcomes data to evaluate Maryland's program, and we will work with the State to measure those outcomes. Similarly, after considering the commenters' comments, we believe it would be premature to evaluate Maryland's readmissions program on cost savings, as it is the first year of the Hospital Readmissions Reduction Program, and Maryland's ARR Program just completed its first year. As such, we are finalizing to not evaluate Maryland's ARR Program on measureable health outcomes and cost savings for the first year. For FY 2013, we are exempting hospitals paid under section 1814(b)(3) of the Act from the Hospital Readmissions Reduction Program under our authority under section 1886(q)(2)(B)(ii) of the Act. We are finalizing, as proposed, our plan to evaluate whether Maryland's readmissions program can demonstrate similar decreases in potential preventable readmissions and similar cost savings on an annual basis. However, that evaluation will not begin until FY 2014. We intend to work with Maryland next year as the State develops its readmissions programs to be able to measure health outcomes and to have demonstrable savings. We are finalizing, as proposed, our requirement that the State's annual report and request for exemption from the Hospital Readmissions

Reduction Program be resubmitted and reconsidered annually in accordance with the statute, as finalized at § 412.154(d)(2).

Comment: Commenters sought clarification as to whether an exemption for Maryland hospitals from the payment requirements under the Hospital Readmissions Reduction Program would apply to all section 1814(b) hospitals in Maryland or all of Maryland's acute care hospitals. The commenters requested that the waiver be applied to all Maryland acute care hospitals.

Response: Section 1886(q)(2)(B)(ii) of the Act allows the Secretary to exempt hospitals paid under the "waiver" provided by section 1814(b)(3) of the Act, that is, those hospitals that would otherwise have been paid by Medicare under the IPPS, absent the provision. Accordingly, we are finalizing that, for FY 2013, all acute care hospitals in Maryland, which are the hospitals that are paid under the waiver at section 1814(b)(3) of the Act, that otherwise would have been paid under the IPPS, are exempt from the Hospital Readmissions Reduction Program.

Comment: One commenter asked for a definition of base operating DRG payment for Maryland hospitals, considering that Maryland hospitals paid under section 1814(b)(3) of the Act are paid at 94 percent of their charges.

Response: In the FY 2013 IPPS/LTCH PPS proposed rule, we did not make a proposal regarding the definition of base operating DRG payment amount with regard to Maryland hospitals. Because we are finalizing our proposal to exempt Maryland hospitals from the Hospital Readmissions Reduction Program for FY 2013, we intend to

revisit the definition of base operating DRG payment amount for Maryland hospitals in future rulemaking.

Comment: Commenters asked that there be a combined exemption request for Maryland hospitals for the Hospital Readmissions Reduction Program, the HAC program, and the Hospital VBP Programs in order to be more efficient and to reduce the administrative burden at the State and Federal level.

Response: The Hospital Readmissions Reduction Program and the Hospital VBP Program, effective in FY 2013, are separate hospital payment programs with different purposes and policy goals. For example, the Hospital Readmissions Reduction Program reduces payments to hospitals for excess readmissions, while the Hospital VBP Program redistributes reductions made to the base operating DRG payment amount, based on certain performance measures. Because of the varying nature of these two programs, at this time, we do not believe it is appropriate for the State to submit one exemption request to determine whether certain Maryland hospitals should be waived from the requirements under both the Hospital Readmissions Reduction Program and the Hospital VBP Program. Because the HAC Program, established under section 1886(p) of the Act, is not effective until FY 2015, we believe it is premature to consider the process by which the State can request an exemption from the requirements of this Program.

For the purposes of modeling the impacts of our proposal, we modeled under the assumption that Maryland hospitals will not have Hospital Readmissions Reduction Program adjustment factors applied to them. Although the adjustment factors do not apply to these hospitals under our models, Maryland hospitals have excess readmission

ratios, consistent with the definition of excess readmission ratio. Any readmission to a Maryland hospital from a subsection(d) hospital in another State is still considered a readmission for purposes of the original hospital in another State. This is consistent with the definition of readmissions in section 1886(q)(5)(E) of the Act, which includes admissions to the same or another "applicable hospital." As discussed above, we interpret the definition of "applicable hospital" under section 1886(q)(5)(C) of the Act to include both subsection (d) hospitals and hospitals paid under section 1814(b)(3) of the Act that would, absent the provisions of section 1814(b)(3) of the Act, be paid under subsection (d).

Although we are exempting Maryland hospitals from the Hospital Readmissions Reduction Program, Maryland hospitals are still considered an "applicable hospital." As such, we are finalizing, as proposed, that we are calculating excess readmission ratios for Maryland hospitals, consistent with the definition of excess readmission ratio. In addition, any readmission to a Maryland hospital from a subsection(d) hospital in another State is still considered a readmission for purposes of the original hospital in another State, and we are finalizing, as proposed, to include data from Maryland hospitals in the calculation of the excess readmission ratios for all applicable hospitals.

c. Adjustment Factor (Both the Ratio and Floor Adjustment Factor) (§ 412.154(c))

Section 1886(q)(3)(A) of the Act defines the "adjustment factor" for an applicable hospital for a fiscal year as equal to the greater of "(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C)."

Section 1886(q)(3)(B) of the Act in turn describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is "equal to 1 minus the ratio of – (i) the aggregate payments for excess readmissions…; and (ii) the aggregate payments for all discharges…." In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27960), we proposed to codify the calculation of this ratio at § 412.154(c)(1) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years. We proposed to codify the floor adjustment factor at § 412.154(c)(2) of the regulations.

For FY 2013, under proposed §412.154(c), we proposed that an applicable hospital would receive an adjustment factor that is either the greater of the ratio described in section IV.A.3.d. of the preamble of the proposed rule or a floor adjustment factor of 0.99. We proposed that the ratio would be rounded to the fourth decimal place, consistent with the calculation of other IPPS payment adjustments such as the wage index, DSH adjustment, and the IME adjustment. In other words, a hospital included in this program can have an adjustment factor that is between 1.0 and 0.9900 for FY 2013. Consistent with section 1886(q)(3) of the Act , under proposed § 412.154(c), we proposed that, for FY 2013, the hospital will receive an adjustment factor under the Hospital Readmissions Reduction Program that is the greater of the ratio or the floor of 0.99. Consistent with this proposal, under the regulations we proposed at 42 CFR 412.152, we proposed to define the "floor adjustment factor" as the value that the readmissions adjustment factor cannot be less than for a given fiscal year. As noted

above, the floor adjustment factor is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Comment: Commenters supported our proposed calculation of the adjustment factor as 1 minus the ratio of the hospital's aggregate payments for excess readmissions for applicable conditions to the hospital's aggregate payments for all discharges for applicable conditions. Commenters also supported our proposal to determine a hospital's actual payment adjustment factor as the higher of its calculated factor or 0.99, resulting in a maximum reduction of 1 percent of base operating DRG payments for FY 2013.

Response: We thank the commenters for their support of these proposals.

In this final rule, we are finalizing our proposal to establish an applicable hospital's adjustment factor as the higher of a ratio or the floor adjustment factor of 0.99 for FY 2013. We are finalizing, as proposed, that the ratio will be rounded to the fourth decimal place. We also are finalizing our proposal to codify these policies in regulation at § 412.154(c) without modification.

d. Aggregate Payments for Excess Readmissions and Aggregate Payments for All Discharges (§ 412.152)

As discussed earlier, section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. It states that the ratio is "equal to 1 minus the ratio of – (i) the aggregate payments for excess readmissions…; and (ii) the aggregate payments for all discharges…." In the FY 2013 IPPS LTCH PPS proposed rule (77 FR 27961), we set forth proposals to define aggregate payments for excess readmissions and aggregate payments for all discharges,

as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges).

Section 1886(q)(4) of the Act sets forth the definitions of "aggregate payments for excess readmissions" and "aggregate payments for all discharges" for an applicable hospital for the applicable period. The term "aggregate payments for excess readmissions" is defined in section 1886(q)(4)(A) of the Act as "for a hospital for an applicable period, the sum, for applicable conditions . . . of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the 'Excess Readmission Ratio'… for such hospital for such applicable period minus 1." We proposed to include this definition of "aggregate payments for excess readmissions" under the regulations we proposed at 42 CFR 412.152.

We did not receive any public comments on the proposed definition of "aggregate payments for excess readmissions" and are finalizing our definition as proposed under the regulations at 42 CFR 412.152 without modification.

The "excess readmission ratio" is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmission ratio as the ratio of "risk-adjusted readmissions based on actual readmissions" for an applicable hospital for each applicable condition, to the "risk-adjusted expected readmissions" for the applicable hospital for the applicable

condition. The methodology for the calculation of the excess readmission ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673). "Aggregate payments for excess readmissions" is the numerator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The term "aggregate payments for all discharges" is defined at section 1886(q)(4)(B) of the Act as "for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period." "Aggregate payments for all discharges" is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. In the proposed rule, we proposed to include this definition of "aggregate payments for all discharges" under the regulations we proposed at § 412.152.

We did not receive any public comments on the proposed definition of "aggregate payments for all discharges" and are finalizing our definition as proposed under the regulations at 42 CFR 412.152 without modification.

As discussed above, when calculating the numerator (aggregate payments for excess readmissions), we determined the base operating DRG payments for the applicable period. "Aggregate payments for excess readmissions" (the numerator) is defined as "the sum, for applicable conditions . . . of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the 'Excess Readmission Ratio'… for such hospital for such applicable period minus 1."

We discussed above our proposed definition of "base operating DRG payment amount." When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we proposed to use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period that was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) to calculate the excess readmission ratio. We proposed to use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking to determine IPPS rates. For FY 2013, we proposed to use data from MedPAR claims with discharge dates that are on or after July 1, 2008, and no later than June 30, 2011, the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule. We proposed to use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source (that is, the March updates of the respective Federal fiscal year MedPAR files for the final rules, as described in greater detail below). These are the same MedPAR files that are used in the annual IPPS rulemaking for each Federal fiscal year.

In the FY 2013 IPPS/LTCH PPS proposed rule, for FY 2013, we proposed to use the March 2009 update of the FY 2008 MedPAR file to identify claims within FY 2008 with discharges dates that are on or after July 1, 2008, the March 2010 update of the FY 2009 MedPAR file to identify claims within FY 2009, the March 2011 update of the FY 2010 MedPAR file to identify claims within FY 2010, and the December 2011 update

of the FY 2011 MedPAR file to identify claims within FY 2011 with discharge dates no later than June 30, 2011. For the FY 2013 IPPS/LTCH PPS final rule, we proposed to use the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2011, as these would be the most recently available FY 2011 claims data used for FY 2013 rulemaking. These MedPAR data files are used each year in other areas of the IPPS, including calculating the IPPS relative weights, budget neutrality factors, outlier thresholds, and the standardized amount. Accordingly, we believe it is appropriate to use these same data files for the purpose of calculating the readmission adjustment factors. The FY 2008 through FY 2011 MedPAR data files can be purchased from CMS. Use of these files will allow the public to verify the readmission adjustment factors. Interested individuals may order these files through the Web site at: http://www.cms.hhs.gov/LimitedDataSets/ by clicking on the MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and further detailed instructions for how to order the data sets. Persons placing an order must send the following: a Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for $3,655 to:

Mailing address if using the U.S. Postal Service: Centers for Medicare and Medicaid Services, RDDC Account, Accounting Division, P.O Box 7520, Baltimore, MD 21207-0520.

Mailing address if using express mail: Centers for Medicare and Medicaid Services, OFM/Division of Accounting- RDDC, Mailstop C#-07-11, 7500 Security Boulevard, Baltimore, MD 21244-1850.

In the proposed rule, we proposed to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2008, and no later than June 30, 2011, which is the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule. However, we noted in the proposed rule, that for the purposes of modeling, we used excess readmission ratios based on an older performance period of July 1, 2007 to June 30, 2010. As we stated in the proposed rule, for this final rule, we are using both the excess readmission ratios and MedPAR claims data to calculate aggregate payments for excess readmissions and aggregate payments for all discharges based on the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule (July 1, 2008 to June 30, 2011).

Comment: Commenters supported the use of MedPAR claims data to determine base operating DRG payment amounts. However, several commenters opposed CMS' proposal to use 3 years of data from the period July 1, 2008 through June 30, 2011, for calculating hospital readmissions adjustment factors for FY 2013. The commenters stated that using older data did not reflect current practices of a hospital, and recommended that CMS use a 1-year period from July 1, 2010 to June 30, 2011, to accurately reflect a hospital's performance on readmissions.

Response: We appreciate the commenters' support for using the MedPAR data to determine base operating DRG payment amounts to calculate the readmission payment adjustment factors.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27961), we proposed to calculate the readmission payment adjustment factor using the same applicable period that is used to calculate the excess readmission ratios, as finalized in the FY 2012 IPPS/LTCH PPS final rule. The statute references "applicable period" in both the calculation of the readmissions measures and the readmission payment adjustment factor, such that it requires that the same time period be used for both the calculation of the measures and the adjustment factor. As finalized in the FY 2012 IPPS/LTCH PPS final rule, we use 3 years of data to calculate the readmissions measures (that is, for FY 2013, we are using discharge data from July 1, 2008 through June 30, 2011), and therefore, we are using data from the same time period to calculate the aggregate payments for excess readmissions and aggregate payments for all discharges. Using 3 years of claims data increases precision for the calculation of excess readmission ratios and the calculation of the readmissions payment adjustment factors.

In this final rule, we are finalizing our proposal to use MedPAR data from July 1, 2008 through June 30, 2011, and we are finalizing our proposal to use the March 2009 update of the FY 2008 MedPAR file to identify claims within FY 2008 with discharges dates that are on or after July 1, 2008, the March 2010 update of the FY 2009 MedPAR file to identify claims within FY 2009, the March 2011 update of the FY 2010 MedPAR file to identify claims within FY 2010, and the March 2012 update of the

FY 2011 MedPAR file to identify claims within FY 2011 with discharge dates no later than June 30, 2011.

Comment: One commenter asked CMS to ensure that outlier payments are correctly excluded from the base operating DRG amount using the MedPAR data source.

Response: We have ensured that we are correctly excluding outlier payments in the calculation of the base operating DRG amount using our MedPAR data source.

In order to identify the admissions for each condition for an individual hospital for calculating the aggregate payments for excess readmissions, we proposed to identify each applicable condition using the same ICD-9-CM codes used to identify applicable conditions to calculate the excess readmission ratios. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51669), in our discussion of the methodology of the readmissions measures, we stated that we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period. The discharge diagnoses for each applicable condition are based on a list of specific ICD-9-CM codes for that condition. These codes are listed in the 2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmission Measures. They also are posted on the Web site at: http://www.QualityNet.org > Hospital-Inpatient > Readmission Measures >methodologies.

In order to identify the applicable conditions to calculate the aggregate payments for excess readmissions, we proposed to identify the claim as an applicable condition if

the ICD-9-CM code for that condition is listed as the principal diagnosis on the claim, consistent with the methodology to identify conditions to calculate the excess readmission ratio. Furthermore, we proposed to only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Part C, Medicare Advantage, would not be included in this calculation), consistent with the methodology to calculate excess readmission ratios based on readmissions for Medicare FFS patients. The tables below list the ICD-9-CM codes we proposed to use to identify each applicable condition to calculate the aggregate payments for excess readmissions under this proposal. These ICD-9-CM codes will also be used to identify the applicable conditions to calculate the excess readmission ratios, consistent with our policy finalized in the FY 2012 IPPS/LTCH PPS final rule.

ICD-9-CM CODES TO IDENTIFY PNEUMONIA CASES

ICD-9-CM Code	Description of Code
480.0	Pneumonia due to adenovirus
480.1	Pneumonia due to respiratory syncytial virus
480.2	Pneumonia due to parainfluenza virus
480.3	Pneumonia due to SARS-associated coronavirus
480.8	Viral pneumonia: pneumonia due to other virus not elsewhere classified
480.9	Viral pneumonia unspecified
481	Pneumococcal pneumonia [streptococcus pneumoniae pneumonia]
482.0	Pneumonia due to klebsiella pneumoniae
482.1	Pneumonia due to pseudomonas
482.2	Pneumonia due to hemophilus influenzae [h. influenzae]
482.30	Pneumonia due to streptococcus unspecified
482.31	Pneumonia due to streptococcus group a
482.32	Pneumonia due to streptococcus group b
482.39	Pneumonia due to other streptococcus
482.40	Pneumonia due to staphylococcus unspecified
482.41	Pneumonia due to staphylococcus aureus
482.42	Methicillin Resistant Pneumonia due to Staphylococcus Aureus
482.49	Other staphylococcus pneumonia
482.81	Pneumonia due to anaerobes
482.82	Pneumonia due to escherichia coli [e.coli]
482.83	Pneumonia due to other gram-negative bacteria
482.84	Pneumonia due to legionnaires' disease
482.89	Pneumonia due to other specified bacteria
482.9	Bacterial pneumonia unspecified
483.0	Pneumonia due to mycoplasma pneumoniae
483.1	Pneumonia due to chlamydia
483.8	Pneumonia due to other specified organism
485	Bronchopneumonia organism unspecified
486	Pneumonia organism unspecified
487.0	Influenza with pneumonia
488.11	Influenza due to identified novel H1N1 influenza virus with pneumonia

ICD-9-CM CODES TO IDENTIFY HEART FAILURE CASES

ICD-9-CM Code	Code Description
402.01	Hypertensive heart disease, malignant, with heart failure
402.11	Hypertensive heart disease, benign, with heart failure
402.91	Hypertensive heart disease, unspecified, with heart failure
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified failure and chronic kidney disease stage V or end stage renal disease
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease
428.xx	Heart Failure

ICD-9-CM CODES TO IDENTIFY ACUTE MYOCARDIAL INFARCTION CASES

ICD-9-CM Code	**Description of Code**
410.00	AMI (anterolateral wall) – episode of care unspecified
410.01	AMI (anterolateral wall) – initial episode of care
410.10	AMI (other anterior wall) – episode of care unspecified
410.11	AMI (other anterior wall) – initial episode of care
410.20	AMI (inferolateral wall) – episode of care unspecified
410.21	AMI (inferolateral wall) – initial episode of care
410.30	AMI (inferoposterior wall) – episode of care unspecified

ICD-9-CM Code	Description of Code
410.31	AMI (inferoposterior wall) – initial episode of care
410.40	AMI (other inferior wall) – episode of care unspecified
410.41	AMI (other inferior wall) – initial episode of care
410.50	AMI (other lateral wall) – episode of care unspecified
410.51	AMI (other lateral wall) – initial episode of care
410.60	AMI (true posterior wall) – episode of care unspecified
410.61	AMI (true posterior wall) – initial episode of care
410.70	AMI (subendocardial) – episode of care unspecified
410.71	AMI (subendocardial) – initial episode of care
410.80	AMI (other specified site) – episode of care unspecified
410.81	AMI (other specified site) – initial episode of care
410.90	AMI (unspecified site) – episode of care unspecified
410.91	AMI (unspecified site) – initial episode of care

Comment: Several commenters requested that, in the calculation of aggregate payments for excess readmissions, CMS remove admissions for the applicable conditions that were not considered admissions for the purposes of the calculation of the excess readmission ratio. Specifically, commenters requested that CMS remove admissions for (1) index admissions for beneficiaries who die in the hospital; (2) admissions for beneficiaries who were transferred to another acute care hospital; (3) admissions for beneficiaries who were discharged against medical advice; (4) admissions for beneficiaries without at least 30 days post-discharge enrollment in Medicare Part A fee-for-service; and (5) multiple admissions within 30 days of a prior index admission. Commenters argued that these trims are made for the readmissions measures, and accordingly, they should also be made when determining which admissions are included in the calculation of aggregate payments for excess readmissions. One commenter

recognized that not all of these trims can be identified in our proposed data source, MedPAR, so the commenter requested that CMS estimate an "additional exclusions factor" for the exclusions that we cannot account for based on data from the Measures Maintenance Technical Report, which lists the percentage of admissions that are removed by exclusion. The commenter suggested that the "additional exclusions factor" for each exclusion that cannot be accounted for in our proposed data source be removed for every hospital. By not excluding these admissions, the commenters believed that CMS is erroneously inflating the calculation of aggregate payments for excess readmissions.

Response: In our proposal to calculate the excess payments for readmissions, we proposed to identify admissions for each condition for an individual hospital for calculating the aggregate payments for readmissions by using the same ICD-9-CM codes used to identify the applicable conditions to calculate the excess readmissions ratios. We proposed to identify the claim as an applicable condition if the ICD-9-CM code for that condition is listed as the principal diagnosis on the claim, consistent with the calculation of the excess readmission ratios. Similarly, we proposed to limit our admissions to Medicare FFS claims, consistent with the methodology to calculate the excess readmission ratios.

As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51669), the readmissions conditions of AMI, HF, and PN account for certain exclusions of admissions from being considered as an index admission. The NQF-endorsed readmission measures exclude from the group of index admission: (1) hospitalizations for patients with an in-hospital death; (2) hospitalizations for patients without at least 30

days post discharge enrollment in Medicare FFS; (3) hospitalizations for patients discharged against medical advice; (4) transfers; and (5) multiple admissions within 30 days of a prior index admission. In addition, for AMI, same day discharges are excluded as an index admission. Furthermore, we limit admissions to include Medicare Part A FFS enrollees who are 65 years or older.

We agree with the commenters that the index admissions that are not considered admissions for the purpose of the readmissions measures, thus excluded from the calculation of the excess readmission ratio, should also not be considered admissions for the purposes of determining a hospital's aggregate payments for excess readmissions. Accordingly, we are modifying our methodology to identify the admissions included in the calculation of "aggregate payments for excess readmissions." For this final rule, using our MedPAR data source, we will identify admissions for the purposes of calculating aggregate payments for excess readmissions as follows:

- We will exclude admissions that are identified as an applicable condition based on the ICD-9-CM code listed as the primary diagnosis, but where the patient had died, as identified by the discharge status code on the MedPAR claim.

- We will exclude admissions identified as an applicable condition based on the ICD-9-CM code listed as the primary diagnosis, but where the patient was transferred to another applicable hospital, as identified by the discharge status code on the MedPAR claim.

- We will eliminate admissions identified as an applicable condition based on the ICD-9-CM code listed as the primary diagnosis, but where the patient was discharged against medical advice as identified by the discharge status code on the MedPAR claim.

- We will exclude admissions identified as an applicable condition based on the ICD-9-CM code listed as the primary diagnosis for patients who are under the age of 65, as identified on the MedPAR claim.

- For conditions identified as AMI, we will exclude claims that are same day discharges, as identified by the admission date and discharge date on the MedPAR claim.

As the commenters acknowledged, the MedPAR proposed data set that we are using to calculate the aggregate payments for excess readmissions cannot identify all of the exclusions included in the readmissions measures. Specifically, at this time, we cannot identify directly multiple admissions within 30 days of a prior index admission and patients without at least 30 days post discharge enrollment in Medicare FFS in the MedPAR data. However, the suggestion that we develop an "additional exclusions factor" to apply to the calculation of the readmissions payment adjustment factor is not within the statutory authority under section 1886(q) of the Act. We do not believe we have the authority to calculate an "additional exclusions factor," which would be in lieu of the exclusion of admissions from the calculation of the aggregate payments for excess readmissions, and then uniformly applied that amount to all applicable hospitals. We believe that with the exclusions to the data for the scenarios discussed earlier, we will have accounted for nearly all of the admissions excluded in the calculation of the excess readmission ratios. We intend to work towards modifying our systems to identify these

claims for the two additional scenarios, and we will propose in future rulemaking to what extent we can include those exclusions from the calculation of the aggregate payments for excess readmissions.

For FY 2013, we are finalizing a methodology to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2008 to June 30, 2011, to identify applicable conditions based on same ICD-9CM codes used to identify the conditions for the readmissions measures and to apply the exclusions for the types of admissions discussed above, which are currently identifiable on the claim in MedPAR.

Comment: One commenter stated that a claim that the Recovery Audit Contractor (RAC) determines should have been provided in the outpatient setting and subsequently is denied as an inpatient should not be included in the calculation of a hospital's readmissions adjustment. The commenter sought clarification on whether the Common Working File (CWF) has been updated for RAC denials. The commenter stated that if a claim was subsequently denied for inpatient status, it should be removed from inpatient claims data set used to calculation of a hospital's readmission adjustment.

Response: In the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to use the MedPAR claims data as our data source to calculate the excess payments for readmissions and payments for all discharges. Specifically, we proposed to use MedPAR data for discharges from July 1, 2008 through June 30, 2011, and we proposed to use the March 2009 update of the FY 2008 MedPAR file to identify claims within FY 2008 with discharges dates that are on or after July 1, 2008, the March 2010 update of the FY 2009 MedPAR file to identify claims within FY 2009, the March 2011 update of the FY 2010

MedPAR file to identify claims within FY 2010, and the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2011. We proposed to use these MedPAR updates, as it is consistent with the inpatient claims data set used in IPPS ratesetting.

The RACs have up to 3 years to review claims to determine whether a claim was inappropriately billed as inpatient when it should have been an outpatient claim. If a claim is denied as an inpatient stay, the claim is adjusted through the standard Medicare claims processing systems, going through the CWF and MedPAR. However, given the timing of the RAC audits and the updates of the MedPAR used to calculate the readmissions payment adjustments, it is not certain that all denied claims will be reflected in MedPAR at the time of our analysis. To the extent that those RAC determinations are made within the timeframe of the updates of MedPAR, those denied inpatient claims will not be included the MedPAR or in the calculation of the readmissions payment adjustment. We believe that using the updates of the MedPAR used in annual IPPS rate setting allows for us to use a complete inpatient claims data set and allows for transparency for the public to obtain this dataset to replicate our calculations.

In this final rule, we are finalizing our proposal to use MedPAR to calculate the readmissions payment adjustment factors without modification.

Section 1886(q)(2) of the Act defines the base operating DRG payment amount as "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by . . . any portion of such payment amount that is

attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d)." Paragraphs (d)(5)(A), (d)(5)(B), (d)(5)(F), and (d)(12) of section 1886 refer to outlier payments, IME payments, DSH payments, and payments for low-volume hospitals, respectively.

As discussed earlier in section IV.A.3.b.(1) of the preamble of the proposed rule, we proposed to define "base operating DRG payment amount" under the Hospital Readmissions Reduction Program as the wage-adjusted DRG operating payment plus any new technology add-on payments. Thus, in order to calculate the base operating DRG payment amount for such condition for such hospital, we proposed to identify the base operating DRG payment amount for such conditions based on the payment amounts in the MedPAR files on the claims identified to meet those conditions based on their ICD-9-CM code.

As discussed in section IV.A.3.b. of the preamble of the proposed rule, applicable hospitals in the Hospital Readmissions Reduction Program include SCHs and current MDHs (whose status is set to expire at the end of FY 2012), as these hospitals meet the definition of subsection (d) hospitals. SCHs are paid in the interim (prior to cost report settlement) on a claim-by-claim basis at the amount that is the higher of the payment based on the hospital-specific rate or the IPPS Federal rate based on the standardized amount. At cost report settlement, the fiscal intermediary or MAC determines whether the hospital would receive higher IPPS payments in the aggregate using the hospital-specific rate (on all claims) or the Federal rate (on all claims). MDHs are paid the sum of the Federal payment amount plus 75 percent of the amount by which their hospital-

specific rate exceeds the Federal payment amount. Although MDH status is set to expire at the end of FY 2012, because we are using historical data to determine the base operating DRG payments to calculate adjustment factor, the payments reflected on claims for current MDHs may be based on the hospital-specific rate. For SCHs and current MDHs, we proposed to model their base operating DRG payment amount as they would have been paid under the Federal standardized amount, rather than using the information on the claim (which may represent a payment either made under the hospital-specific rate or the Federal rate) so that their payments are consistent with our proposed definition of base operating DRG payment. As such, the payment difference between the payment made under the hospital-specific rate and the payment made under the Federal rate is not included in the base operating DRG amount to determine the readmission adjustment factor; that is, it is neither included in the numerator of the aggregate dollars for excess readmissions nor in the denominator of the aggregate dollars for all discharges.

We did not receive public comments on our proposal for current MDHs and SCHs to model the "base operating DRG payments" as they would have been paid under the Federal standardized amount, rather than using the information on the claim in MedPAR (which may represent a payment either made under the hospital-specific rate or the Federal rate) to calculate their "aggregate payments for excess readmissions, so that their payments are consistent with our definition of base operating DRG payment.

As discussed earlier, we proposed to use data from the MedPAR files that contain claims from the 3-year applicable period of July 1, 2008, to June 30, 2011, for FY 2013 to calculate aggregate payments for excess readmissions (the numerator of the ratio). To

calculate aggregate payments for excess readmissions, we proposed to calculate the base operating DRG payment amounts for all the claims in the 3-year applicable period that list each applicable condition as the principal diagnosis (as described above). Once we have calculated the base operating DRG payment amounts for all the claims that list each condition as the principal diagnosis, we proposed to sum the base operating DRG payment amounts by each condition, resulting in three summed amounts, one amount for each of the three applicable conditions. We then proposed to multiply each amount for each condition by their respective excess readmission ratio minus 1. The methodology for the calculation of the excess readmission ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673). We proposed that the excess readmission ratios for each condition used to calculate the numerator of this ratio are excess readmission ratios that had gone through the proposed review and correction process described in the FY 2013 IPPS/LTCH PPS proposed rule. Each product in this computation represents the payment for excess readmissions for that condition. We proposed to then sum the resulting products, which represent a hospital's proposed "aggregate payments for excess readmissions" (the numerator of the ratio).

If a hospital has an excess readmission ratio that is greater than 1 for a condition, that hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. As such, it will have aggregate payments for excess readmissions. If a hospital has an excess readmission ratio that is less than (or equal) to one, that hospital has performed better (or on average), with respect to readmissions for that applicable condition, than an average hospital with

similar patients. As such, that hospital would not be considered to have "aggregate payments" for excess readmissions, and its payments would not be reduced under section 1886(q) of the Act. As described in section 1886(q)(4)(C) of the Act, and finalized in the FY 2012 IPPS/LTCH PPS final rule, the excess readmission ratio used cannot be less than 1 because the hospital will not have aggregate payments for excess readmissions and will not be subject to a readmission payment adjustment, as the hospital will have performed equal to or better than average. Because this calculation is performed separately for the three conditions, a hospital's excess readmission ratio must be less than or equal to 1 on each measure to avoid aggregate payments for excess readmissions.

Section 1886(q)(4)(B) of the Act defines "aggregate payments for all discharges" (the denominator of the ratio) as "for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period." In the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to use the same MedPAR files to calculate the denominator as we proposed to use to calculate the numerator, for the 3-year applicable period of July 1, 2008 to June 30, 2011, for FY 2013. We proposed to calculate base operating DRG payments in the same manner as we calculate base operating DRG payments for the numerator. We proposed to sum the base operating DRG payment amounts for all Medicare FFS claims for such hospital during the 3-year applicable period. We also proposed that we would model base operating DRG payment amount for SCHs and current MDHs as they would have been paid under the Federal standardized amount, rather than using the information on the claim (as described above).

We did not receive any public comments regarding our proposed calculation of "aggregate payments for all discharges" and we are finalizing it as proposed without modification.

We proposed that the ratio described in section 1886(q)(3)(B) of the Act is 1 minus the ratio of the numerator and denominator described above. In addition, we proposed that the readmission adjustment for an applicable hospital is the higher of this ratio under section 1886(q)(3)(B) of the Act or the floor of 0.99 for FY 2013. Consistent with this proposal, under the regulations we proposed at 42 CFR 412.152, we proposed to define "readmissions adjustment factor" as equal to the greater of: (i) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges or (ii) the floor adjustment factor.

For the proposed rule, for the purpose of modeling the proposed aggregate payments for excess readmissions and the proposed readmissions adjustment factors, we used excess readmission ratios for the applicable hospitals from the 3-year period of July 1, 2007 to June 30, 2010, because the underlying data from this period had already been available to the public on the Hospital Compare Web site (as of July 2011). The data from the 3-year applicable period for FY 2013 of July 1, 2008 to June 30, 2011, had not been through the review and correct process required by section 1886(q)(6) of the Act (as discussed below). As we stated in the proposed rule, for this final rule, we are using excess readmission ratios based on discharges for the finalized applicable period of July 1, 2008 to June 30, 2011, to calculate the aggregate payments for excess readmissions and, ultimately, to calculate the readmission adjustment factors. Applicable

hospitals had the opportunity to review and correct these data before they were made public under our proposal set forth below regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act.

Formulas to Calculate the Readmission Adjustment Factor

Aggregate payments for excess readmissions = [sum of base operating DRG payments for AMI x (Excess Readmission Ratio for AMI-1)] + [sum of base operating DRG payments for HF x (Excess Readmission Ratio for HF-1)] +[sum of base operating DRG payments for PN x (Excess Readmission Ratio for PN-1)].

Aggregate payments for all discharges = sum of base operating DRG payments for all discharges.

Ratio = 1-(Aggregate payments for excess readmissions/Aggregate payments for all discharges).

Readmissions Adjustment Factor for FY 2013 is the higher of the ratio or 0.99.

*Based on claims data from July 1, 2008 to June 30, 2011 for FY 2013.

Comment: Several commenters supported our methodology to calculate the readmissions payment adjustment factor. Commenters supported calculating the adjustment factor as 1 minus the ratio of the hospital's aggregate payments for excess readmissions for applicable conditions to the hospital's aggregate payments for all discharges for applicable conditions. Commenters supported determining the hospital's aggregate payments for all discharges for applicable conditions based on our proposed definition of the base operating DRG payment amount, and commenters supported our proposal to determine the hospital's aggregate payments for excess readmissions by multiplying the hospital's aggregate payments for all discharges for an applicable condition by 1, minus the hospital's excess readmissions ratio.

Some commenters stated that it is unclear why the proposed numerator of the readmission payment adjustment factor, or the calculation of the excess payments for readmissions, is based on total admissions for each condition, when the purpose of the Hospital Readmissions Reduction Program is to reduce only preventable readmissions. Commenters stated that our proposed methodology to calculate the readmission payment adjustment factor should amend the legislative language in the formula for calculating the readmissions adjustment factor. The formula as proposed stipulated that the amount of aggregate payments due to excess readmission is calculated by multiplying the number of admissions for the condition times the average base DRG payment for the condition and the "excess readmission ratio." The excess readmissions ratio is defined as the ratio of the number of actual readmissions as compared to the number of expected readmissions for the clinical condition. However, commenters contended that the formula should specify that the calculation should be based on the number of expected readmissions in each condition, not the total number of admissions. They urged that we replace the words "number of admissions" with "number of expected readmissions" so that the formula for the aggregate payments for excess readmissions calculates the number of expected readmissions for each condition and not the total number of admissions.

One commenter believed that the proposed formula produces penalties that are higher than Medicare payments for excess readmissions, although the full impact is mitigated because of the proposed maximum penalty for FY 2013 of 1 percent of base operating DRG payments. The commenter believed that our proposed methodology to calculate the readmissions payment adjustment factors conforms to the statute. However,

the commenter suggested long-term changes to the formula to be more proportionate to the cost of readmissions, such as examining the issue of shrinking excess readmission computations towards the national mean and appropriate changes to account for excess payments for readmissions.

Commenters believe that our proposed methodology to calculate the readmissions payment adjustment over estimates the excess payments for readmissions resulting in an excessive readmission payment adjustment and is not consistent with Congressional intent. Commenters believed our proposed readmissions payment adjustments are excessive as evident by the Congressional Budget Office (CBO) score for the provision at $100 million while our estimates of the Hospital Readmissions Reduction Program published in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28172) was approximately $300 million.

Response: We believe that the statute is prescriptive with respect to the calculation of "aggregate payments for excess readmissions" where the statute specifies that the "aggregate payments for excess readmissions" is the sum for each condition of the product of "the operating DRG payment amount for such hospital for such applicable period for such condition" and "the number of admissions for such condition" and "the excess readmission ratio" minus one. We believe that section 1886(q)(4)(A) of the Act requires us to include all admissions for a condition in the calculation of "aggregate payments for excess readmissions."

Our estimate of $300 million in savings associated with the Hospital Readmissions Reduction Program published in the FY 2013 IPPS/LTCH PPS proposed

rule was based on different data that were not available to the CBO at the time of the CBO estimate. Furthermore, we potentially used different assumptions in our methodology to estimate the savings of this Hospital Readmissions Reduction Program as compared to CBO. Our proposed readmission payment adjustment factors were calculated using excess readmission ratios based on hospitals' readmissions performance from July 1, 2007 to June 30, 2010, which was not available at the time of the CBO estimate. In addition, our calculation for "aggregate payments for excess readmissions" and "aggregate payments for all discharges" were based on MedPAR claims data from July 1, 2007 to June 30, 2010, which was also not available at the time of the CBO estimate. Finally, we applied the proposed readmission payment adjustment factor to our estimated FY 2013 IPPS base operating DRG payments to determine the savings associated with the Hospital Readmissions Reduction Program and our FY 2013 IPPS base operating DRG payments were likely based on different assumptions than the CBO's estimate published in 2010. Therefore, it is difficult to assess the precise differences between our estimate of this provision and the CBO's estimate. Nonetheless, we believe that we are implementing the provision as required by law.

Comment: Several commenters requested that CMS make additional adjustments to the calculation of the readmissions payment adjustment factor to account for differences in the readmissions payment adjustment factors for hospitals that treat a high proportion of patients of low socioeconomic status. Commenters made a number of suggestions as to how to modify the readmissions payment adjustment factors. One commenter suggested that CMS and Congress could apply a uniform percentage

reduction to all hospitals' expected readmission rates, which the commenter believed would be a budget neutral change. The commenter urged CMS and Congress to intervene somehow to correct an inequity affecting the nation's most vulnerable hospitals and Medicare beneficiaries.

Another commenter suggested that CMS offer a one-time opportunity to waive the payment reduction for safety net and other hospitals that serve a higher-than-average proportion of patients of low socioeconomic status and are found to be at risk of experiencing a payment reduction. In return, the commenter suggested that these hospitals would be required to submit a comprehensive and aggressive preventable readmission rate improvement plan that centers on collaboratively engaging with the patients, their families, consumer organizations and community supports, to address the various factors that are causing preventable readmissions in their local community. The commenter stated that this approach should have a time limit (for example, 6 months) on how long the hospital would have for submitting and implementing the plan and another well-defined (for example 6 months) timeframe for monitoring and reporting results to CMS.

Some commenters requested that CMS postpone implementation of the Hospital Readmissions Reduction Program until it has made adjustments to the measures to account for socioeconomic status. One commenter requested postponing the application of the readmissions payment reduction to safety net hospitals that serve a vulnerable population while these hospitals develop programs to reduce readmissions.

Commenters suggested that CMS make an adjustment to the readmission payment adjustment factors to account for a hospital's proportion of dual-eligible patients. Commenters contended that dual-eligible status is a better predictor of readmission rates because it reflects Medicare beneficiaries, which is what the readmissions measures are based on.

In addition, commenters suggested that CMS make a hospital-level adjustment based on DSH. Commenters asserted that because the number of hospitals that will receive the maximum penalty in the first year jumps sharply between the sixth and seventh deciles for hospital's DSH Patient Percentage, the commenters suggested that any hospital-level adjustment based on DSH be applied to the top four deciles.

Response: We thank the commenters for their suggestions on modifying the readmission payment adjustment to account for differences in the socioeconomic status of patients treated by hospitals. As stated earlier, we continue to believe that we need to examine the relationship of patient socioeconomic status and readmissions as it applies to the readmissions measures. As we have stated earlier, the readmissions measures, as endorsed by the NQF, do not include risk adjustments for socioeconomic status. Currently, the NQF does not support risk adjustments based on socioeconomic status, as the NQF believes itcan create different standards of quality for hospitals that treat a higher proportion of patients with low socioeconomic status. Risk adjusting the readmissions measures for socioeconomic status can obscure differences in the quality of health care. Similarly, applying an adjustment to the readmissions payment adjustment factors can also create different standards of quality for hospitals based on the

socioeconomic status of the patients treated. Applying an adjustment to the readmissions payment adjustment factors at this point to account for socioeconomic status rather than determining whether a risk adjustment for socioeconomic status would be appropriate for the readmissions measures could appear as circumventing the NQF's position on the application of a risk adjustment for socioeconomic status on the readmissions measures. We note that, to the extent that dual eligible patients or patients of low socioeconomic status have higher readmission rates because they are sicker or have more comorbidities, we already account for comorbidities in the risk adjustment for the excess readmission rations. Since, we believe that all hospitals should be working towards the goal of reducing readmissions, on an ongoing basis, regardless of their patient population, we believe that we do not need to postpone the implementation of the readmission payment adjustments in order to provide additional time to hospitals to implement readmission reduction programs. While we are not incorporating any special adjustments for SES in the readmissions reduction program at this time, we remain concerned about the impact of this provision on hospitals that serve a high proportion of low income patients. We will continue to monitor the issue of the relationship of a patient's socioeconomic status and a hospital's readmission performance, and how it affects payments to hospitals.

Comment: One commenter recommended that CMS apply the readmissions adjustment in a manner that norms the calculation of the adjustment factor on the risk-adjusted readmission rate that is achieved by at least 25 percent of hospitals rather than on the average readmission rate.

Response: The excess readmission ratio, finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673), measures a hospital's performance on readmissions for a specified condition relative to the national average. The methodology to calculate the excess readmission ratio is endorsed by the NQF, as required at section 1886(q)(5)(C) of the Act. We did not propose any changes to the methodology to calculate the excess readmission ratio. Accordingly, we are not modifying the methodology to calculate the excess readmission ratio to compare a hospital's performance on readmissions relative to the 25th percentile of national performance, as opposed to the average.

Comment: One commenter questioned the statistical difference in the excess readmission ratio for a hospital that has an excess readmission ratio slightly above 1 and thus, subject to the payment penalty, versus a hospital that has an excess readmission ratio slightly below 1, and not subject to the penalty. The commenter asked that CMS consider the equitability of this policy approach and recommended the remunerative framework account for the confidence intervals surrounding the estimated Risk Standardized Readmission Rates and Ratios in determining future penalties for excess readmissions. The commenters believed that omitting a control for statistical significance exposes a large number of hospitals to financial penalties based on random variation. They recommended that CMS account for the confidence intervals surrounding the estimated Risk Standardized Readmission Rates and Ratios in determining future penalties for excess readmissions.

Response: We thank the commenter for raising the issue of statistical reliability of the excess readmission ratio and for recommending the use of confidence intervals in

determining whether or not to use a hospital's excess readmission ratio in the calculation of a hospital's readmission payment adjustment factor. We finalized our methodology of the calculation of the excess readmission ratio in the FY 2012 IPPS/LTCH PPS final rule, which results in the use of the point estimate as a hospital's excess readmission ratio.

We will consider the role, if any, of confidence intervals in determining a hospital's excess readmission ratio. We recognize that because the excess readmission ratio is a statistical measure, there may be some degree of variation. However, there are other Medicare programs, not limited to the Hospital Readmissions Reduction Program, that use statistical measures as part of their program, so any consideration to confidence intervals made with respect to the Hospital Readmissions Reduction Program may have implications for other programs. We will evaluate this concern and address it in future rulemaking, if needed.

Comment: Several commenters suggested that CMS take into consideration a hospital's improvement on readmissions in the calculation of the readmissions payment adjustment factor. One commenter noted that because measurement is based on 3 years' worth of data, it will be difficult for low performing hospitals to move out of being penalized, and the Hospital Readmissions Reduction Program does not reward for improvement as the Hospital VBP Program does, but only measures achievement. The commenter noted that this could result in low performing hospitals being unable to ever get out of the penalty phase.

Response: We appreciate the concerns raised by the commenters. The Hospital Readmissions Reduction Program is structured to apply a payment reduction to hospitals

with excess readmissions, as measured by having worse performance on readmissions for certain conditions compared to the average hospital. The readmission payment adjustment under section 1886(q)(1) of the Act does not allow for us to provide a reward for quality improvement, which is allowed under section 1886(p) of the Act for the Hospital VBP Program. We believe that hospitals do have the opportunity to not be subject to a reduction to payments due to excess readmissions if they can perform better than the average hospital in the future. We update the data annually with the most recently available 3 years of data, and we use 3 years of data in order to have sufficient data to reliably measure a hospital's performance.

Comment: Commenters sought clarification on how the readmissions payment adjustment factors would be applied to a hospital's base operating DRG payment amount. Commenters asked whether the readmissions payment adjustment factors would be applied on a per claim basis or at cost report settlement. Commenters asked how the IME, DSH, and outlier payments would not be affected by the readmissions payment adjustment factor when the IME, DSH and outlier payments are adjustments are currently determined from the base operating DRG payment amount, and the readmissions payment adjustment factor reduces the base operating DRG payment amount. Commenters asked if there would be changes to the cost report and to the PS&R to account for the implementation of the payment adjustment for excess readmissions. In addition, commenters noted that the effective date of the Hospital Readmissions Reduction Program is October 1, 2012, which straddles the cost reporting period for

many hospitals, and asked for clarification on how that would be accounted for with respect to the Medicare hospital cost report.

Commenters also stated that the statutory intent of the readmissions payment adjustment factor is that the factor should not be applied to payments for all admissions, but rather to payments for initial admissions with at least one readmission. Commenters requested clarification whether the readmissions payment adjustment factors will apply to only Medicare discharges for AMI, PN or HF; or whether the readmissions payment adjustment factor will apply to all discharges. The commenters believed that the readmissions payment adjustment factor should only be applicable to the specific populations included in the program rather than the entire Medicare population.

Response: We are clarifying that, for FY 2013, a hospital's payments will be reduced by the amount of the product of the readmissions payment adjustment factor and the base operating DRG payment amount (as defined as the wage-adjusted DRG payment amount), on a per-claim basis for all Medicare FFS discharges occurring on or after October 1, 2012. In other words, the payment amount the hospital would otherwise receive in FY 2013 in absence of the Hospital Readmission Reduction Program will be reduced by the an amount for excess readmissions (determined as the product of the readmissions payment adjustment factor and the base operating DRG payment amount). Section 1886(q)(1) of the Act specifies that "the Secretary shall make payments . . . in an amount equal to the product of (A) the base operating DRG payment amount for the discharge; and (B) the adjustment factor...." Therefore, it requires us to apply the readmissions payment adjustment factor to all discharges, not just discharges for initial

admissions with a readmission or admissions for the applicable conditions. We note that the readmissions payment adjustment factor is inversely proportional to the aggregate payments for all discharges (in the formula determining the excess readmissions ratio) so the adjustment factor appropriately reflects the relation between payments for excess readmissions and aggregate payments for all discharges.

In addition, we intend to modify the Medicare hospital cost report and the corresponding cost reporting instructions, effective for FY 2013, to account for the reductions to payments under the Hospital Readmission Reduction Program required by section 1886(q) of the Act (that is, the payment adjustment for excess readmissions). The current calculation of the additional payments for IME, DSH, outliers, and low-volume hospitals will remain unchanged consistent with the statutory requirement that payments for outliers, IME, DSH, and low-volume adjustments are not affected by the adjustments made under the Hospital Readmissions Reduction Program.

Currently, the cost report includes the base operating DRG payment for the cost reporting period and we use that line to determine add-on payments including payments for indirect medical education and disproportionate share hospital payments. This line will remain unchanged and will continue to be used to determine IPPS add-on payments, consistent with our policy that add-on payments for outliers, IME, DSH, and low-volume adjustments are not affected by the adjustments made under the Hospital Readmissions Reduction Program. We intend to modify the Medicare hospital cost report to include lines for base operating DRG payments by Federal fiscal year. For example, we will have a line that represents base operating DRG payments prior to October 1, 2012 and a

line that represents base operating DRG payments after October 1, 2012. In addition, we intend to modify the Medicare hospital cost report with lines for the readmissions payment adjustment factor by Federal fiscal year and lines with the readmissions payment amount by Federal fiscal year that would be deducted from a hospital's Medicare payments. The readmissions payment amounts would be determined by applying the readmission payment adjustment factor to the base operating DRG payment amount by Federal fiscal year. We intend to modify the cost reporting instructions to account for these new calculations. In addition, for FY 2013, we will ensure that the cost reporting instructions account for the readmissions adjustment to only be made to base operating DRG payments for discharges on or after October 1, 2012. We intend to modify the PS&R to account for these changes as well.

Comment: One commenter sought clarification as to whether the Hospital Readmissions Reduction Program is intended to replace the existing readmission review at Internet Only Manual (IOM) 100-04, Chapter. 3, Section 40.2.5, or if both policies will exist together.

Response: The Hospital Readmissions Reduction Program is not intended to replace the existing readmission review under IOM 100-04, Chapter 3, Section 40.2.5. IOM 100-04, Chapter 3, Section 40.2.5 of the Inpatient Claims Processing Manual provides guidance on appropriate billing practices for repeat admissions. In accordance with the manual, "a patient who requires follow-up care or elective surgery may be discharged and readmitted or may be placed on a leave of absence. Hospitals may place a patient on a leave of absence when readmission is expected… and providers may not use the leave of absence billing procedure when the second admission is unexpected." If a hospital

uses the leave of absence billing code, two inpatient stay claims for the original admission and the repeat admissions are bundled as one inpatient claim with one DRG payment. These claims can be reviewed by a fiscal intermediary or MAC and referred to the QIOs. This is a separate billing procedure from the Hospital Readmissions Reduction Program and will continue to exist.

During the FY 2012 IPPS rulemaking cycle, we received public comments expressing concern that hospitals that treat a larger proportion of patients of lower socioeconomic circumstances may have higher readmission rates and could be unfairly penalized under the Hospital Readmissions Reduction Program. The table below shows, based on the excess readmission ratios and the proposed methodology to calculate the readmissions adjustment factor discussed in the proposed rule, the estimated distribution of the readmission adjustment factors among hospitals ranked by their DSH patient percentage (DPP). The DPP is used as a proxy for low-income patients and is the sum of the hospital's Medicare fraction and Medicaid fraction. The Medicare fraction is computed by dividing the number of a hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days. The DPP is used to determine a hospital's Medicare DSH payment adjustment. Thus, hospitals with higher percentages of Medicare patients entitled to SSI and higher percentages of Medicaid patients have higher

DPPs. In the table, the hospitals are ranked by their estimated DPP and categorized into deciles. The table shows the number of hospitals within each decile that are subject to no proposed readmission payment adjustment, the -1 percent floor readmission payment adjustment, and a readmission payment adjustment that is less than the -1 percent floor. We invited public comment on this analysis.

DISTRIBUTION OF HOSPITALS READMISSION ADJUSTMENT FACTOR BY DSH PATIENT PERCENTAGE (DPP)

Decile	Number of Hospitals	Payment Adjustment of less than -1 percent	-1 Percent Floor Adjustment	No Readmission Adjustment Factor
Lowest DPP	339	156	38	145
Second	339	164	57	118
Third	339	168	44	127
Fourth	339	170	48	121
Fifth	339	182	42	115
Sixth	339	171	43	125
Seventh	339	187	44	108
Eighth	339	182	43	114
Ninth	339	179	58	102
Highest DPP	342	185	61	96
Total	3,393	1,744	478	1,171

In addition, we examined the estimated distribution of the proposed readmissions adjustment factor based on the excess readmission ratios in this proposed rule (determined using the 2007-2010 data discussed above). The table below shows the number and percentage of hospitals ranked by the percent reduction received under the Hospital Readmissions Reduction Program. The table shows that about 71 percent of

hospitals would receive either no adjustment or a readmission adjustment factor that would reduce their base operating DRG payments by less than 0.5 percent.

DISTRIBUTION OF READMISSION ADJUSTMENT FACTORS

Percent Reduction	Number of Hospitals	Percent of Hospitals
No Adjustment	1,171	34.5%
Up to -.09 Percent	347	10.2%
-0.1 Percent to -0.19 Percent	280	8.3%
-0.20 Percent to -0.29 Percent	228	6.7%
-0.30 Percent to -0.39 Percent	196	5.8%
-0.40 Percent to -0.49 Percent	180	5.3%
-0.50 Percent to -0.59 Percent	129	3.8%
-0.60 Percent to -0.69 Percent	118	3.5%
-0.70 Percent to -0.79 Percent	110	3.2%
-0.80 Percent to -0.89 Percent	77	2.3%
-0.90 Percent to -0.99 Percent	76	2.2%
-1.0 Percent	481	14.2%
Total	3,393	100.0%

Comment: Several commenters addressed the Medicare DSH analysis that was presented in the proposed rule. Several commenters could not replicate the DSH analysis and produce the same results presented in the proposed rule. Some commenters presented different results where they found that high DSH hospitals are, in fact, subject to higher readmission penalties. In addition, several commenters contended that DSH was not a good proxy to determine socioeconomic status. Commenters indicated that it is not uncommon for hospitals in areas with relatively affluent Medicare beneficiaries to qualify for DSH reimbursement due to the high volume of labor and delivery services provided to non-resident aliens. One commenter asked why CMS did not present a comparison table of the impacts to the DSH hospitals (approximately 1,882 hospitals) instead of the entire hospital population.

Commenters indicated that hospitals with high disproportionate share patient percentages have higher excess readmission ratios. Commenters presented other analyses showing that hospitals with high DSH have higher readmission penalties. Commenters provided analyses where the results indicate that high DSH hospitals (defined as hospitals in the top 25th percentile for the DSH percentage) and hospitals located in large urban areas (defined as those Metropolitan Statistical Areas with more than one million population) are much more likely to receive a readmission penalty under the CMS proposal. The commenter found that high DSH hospitals located in large urban areas are 1.9954 times more likely to be penalized for heart attack than other hospitals, 2.5849 times more likely for heart failure, and 2.1915 times more likely for pneumonia.

Response: In the proposed rule, we used the proposed readmissions payment adjustment factors and the DSH disproportionate patient percentage (DPP) reported in the FY 2012 IPPS/LTCH PPS final rule Impact file, as it was the most recently available data at the time of our analysis. We note that, for hospitals that have a missing DPP, we assigned them a DPP of zero. We believe that may have been one potential source for differences in the results.

We understand that there are several ways to measure socioeconomic status of a hospital's patient population and as we continue to monitor the issue of the relationship of a patient's socioeconomic status and a hospital's readmission performance, and how it affects payments to hospitals, we also can explore different measures of socioeconomic status, such as dual-eligible status. To the extent differences in readmission rates among hospitals treating a significant number of patients with low socioeconomic status are

determined to inappropriately affect their readmission payment adjustment, we can work with NQF to explore options for improving the readmissions measures to promote high quality care, as appropriate.

We understand that there have been different conclusions drawn from review of these data, and we will continue to work with MedPAC and other stakeholders to complete a more sophisticated analysis.

Comment: One commenter suggested that CMS provide a level of statistical significance for our DSH analysis, as well as correlation factors between hospitals' actual DSH patient percentage (as opposed their national decile) and the likeliness of receiving a readmissions adjustment, the magnitude of a readmissions adjustment, and the likeliness of reaching the maximum readmissions penalty.

Response: At this time, we are unable to produce a rigorous analysis showing the relationship of a hospital's actual DSH patient percentage and their likeliness of receiving a readmissions adjustment, the magnitude of a readmissions adjustment, and the likeliness of receiving the maximum adjustment of -1.0 percent. However, we will research these issues in the upcoming year and, if significant, we will present our findings in future rulemaking.

e. Applicable Hospitals

An "applicable hospital," is defined at section 1886(q)(5)(C) of the Act as (1) "a subsection(d) hospital or (2) a hospital that is paid under section 1814(b)(3)." Specifically, hospitals subject to the Hospital Readmissions Reduction Program are hospitals paid under the IPPS and hospitals paid under the authority of section 1814(b)(3)

of the Act. We are interpreting this reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the "waiver" specified by section 1814(b)(3) of the Act, would have been paid under the IPPS. A subsection (d) hospital is defined in section 1886(d)(1)(B) of the Act, in part, as a "hospital located in one of the fifty States or the District of Columbia." The term subsection (d) hospital does not include hospitals located in the Territories or hospitals located in Puerto Rico. Section 1886(d)(9)(A) of the Act separately defines a "subsection (d) Puerto Rico hospital" as a hospital that is located in Puerto Rico and that "would be a subsection(d) hospital . . . if it were located in one of the 50 States." Therefore, Puerto Rico hospitals are not considered applicable hospitals under the Hospital Readmissions Reduction Program. An Indian Health Services hospital enrolled as a Medicare provider meets the definition of a subsection (d) hospital and, therefore, is considered an applicable hospital under the Hospital Readmissions Reduction Program, even if it is not paid under the IPPS. In addition, hospitals that are SCHs and current MDHs, although they may be paid under a hospital-specific rate instead of under the Federal rate under the IPPS, are subsection (d) hospitals and, therefore, are included in the definition of an applicable hospital under the Hospital Readmissions Reduction Program.

A subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, and IPFs, and, therefore, these hospitals are not considered "applicable hospitals." CAHs are not "applicable hospitals" because they do

not meet the definition of a "subsection (d) hospital," as they are separately defined under section 1886(mm) of the Act and are paid under a reasonable cost methodology under section 1814(l) of the Act. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27966), consistent with the statute, we proposed to define "applicable hospital" under the regulations at 42 CFR 412.152 to include both (1) subsection (d) hospitals, that is, hospitals paid under the IPPS and (2) hospitals in Maryland that are paid under section 1814(b)(3) of the Act and that, absent the "waiver" specified by section 1814(b)(3) of the Act, would have been paid under the IPPS.

The term "applicable hospital" is also referenced in the definition of readmission in section 1886(q)(5)(E) of the Act, which defines "readmission" as "in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge." In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666), we finalized the definition of readmission as "occurring when a patient is discharged from the applicable hospital and then is admitted to the same or another acute care hospital within a specified time period from the time of discharge from the index hospitalization." Furthermore, we finalized the time period specified for these readmission measures as 30 days. With our proposal to define an applicable hospital as a subsection (d) hospital or certain Maryland hospitals described above, we also proposed to refine the definition of readmission to only include admissions and readmissions occurring from an applicable hospital (that is, a subsection (d) hospital or certain Maryland hospitals) to the same or another applicable hospital (again, a subsection (d)

hospital or certain Maryland hospitals) (proposed § 412.152). Accordingly, excess readmission ratios calculated for the purpose of the Hospital Readmissions Reduction Program would include only admissions and readmissions to "applicable hospitals."

We note that because the Hospital Readmissions Reduction Program only includes admissions and readmissions to "applicable hospitals" to calculate the excess readmission ratios used under section 1886(q) of the Act, these excess readmission ratios will differ from the readmission rates reported on Hospital Compare for the purpose of the Hospital IQR Program. The excess readmission ratios for the purpose of the Hospital IQR Program were determined based on admissions and readmissions to all hospitals, not just hospitals specified in sections 1886(d) and 1814(b)(3) of the Act. Therefore, as discussed above, the excess readmission ratios used in the proposed rule used a subset of the claims used to calculate the readmission rates reported on Hospital Compare for the purpose of the Hospital IQR Program and are limited to admissions and readmissions to "applicable hospitals" and are based on the period of June 30, 2007 to July 1, 2010. In the proposed rule, we used these excess readmission ratios, as they were based on the most recent data available and would allow the public to replicate our methodology to understand how the readmission adjustment factor is calculated. We believe that the differences between these proposed excess readmission ratios and those excess readmission ratios currently published on Hospital Compare under the Hospital IQR Program are minimal, and it was helpful for hospitals to see the impact of our proposed methodology to calculate the readmission adjustment using excess readmission ratios calculated under our methodology finalized in the FY 2012 IPPS/LTCH PPS final rule.

As we stated in the proposed rule, for this final rule, we are using excess readmission ratios based on the applicable period of June 30, 2008 to July 1, 2011, as finalized in the FY 2012 IPPS/ LTCH PPS final rule, and hospitals have had the opportunity to review and correct their data related to their excess readmission ratios prior to the publication of those excess readmission ratios.

We specifically invited public comment on our readmissions proposal, including our proposed definition of base operating DRG payment, our proposed methodology to calculate the readmission adjustment factor, the minimum number of cases, and our proposed definition of applicable hospital.

Comment: Commenters urged CMS to align the Hospital Readmissions Reduction Program with the clinical quality measure requirements of the Hospital IQR Program.

Response: As discussed above, the excess readmission ratios for the purpose of the Hospital IQR Program were determined based on admissions and readmissions to all hospitals, not just hospitals specified in sections 1886(d) and 1814(b)(3) of the Act. Therefore, the excess readmission ratios used in the final rule use a subset of the claims used to calculate the readmission rates reported on Hospital Compare for the purpose of the Hospital IQR Program and would be limited to admissions and readmissions to "applicable hospitals." We have aligned the methodology for readmission measures in the Hospital IQR Program and the Hospital Readmissions Reduction Program as much as is allowed by statutory requirements.

Comment: Some commenters supported our proposal to include subsection (d) hospitals and Maryland hospitals in our definition of "applicable hospital" for the Hospital Readmissions Reduction Program. One commenter asked CMS to waive the requirements of the Hospital Readmissions Reduction Program for hospitals that participate in an accountable care organization (ACO) under the Medicare Shared Savings Program or the Pioneer ACO Model. The commenter argued that hospitals that participate in ACOs are already subject to incentives to reduce hospital readmissions, are already measured for their performance on all conditions for readmissions; therefore, to include these hospitals in the Hospital Readmissions Reduction Program is redundant. The commenter argued that CMS has the authority to waive Title XVIII requirements, including the requirements of the Hospital Readmission Reduction Program, for these hospitals under the waivers provided under sections 1115A(d)(1) and 1899(f) of the Act.

Response: We appreciate the suggestion submitted by the commenters to exempt hospitals from the Hospital Readmissions Reduction Program if they already participate in an ACO under the Medicare Shared Savings Program or the Pioneer ACO Model. We agree that ACOs are encouraged to improve quality of care and reduce the rate of growth in expenditures. We also agree that avoidable readmissions is an area in which we believe an ACO's coordination of care and accountability can have a significant impact in improving patient care. To that end, we finalized an all-condition readmission quality measure in the Medicare Shared Savings Program Final Rule. This measure is also used to assess quality of care furnished by ACOs participating in the Pioneer ACO Model. However, the waivers under sections 3021 and 3022 of the Affordable Care Act permit us

to waive provisions of Title XVIII only to the extent that such a waiver may be "necessary" in order to carry out those sections. In this case, because the incentives of the Hospital Readmissions Reduction Program and the Medicare ACO initiatives are aligned, we see no need to waive the requirements of the Hospital Readmissions Reduction Program in order to carry out either the Medicare Shared Savings Program or to test the Pioneer ACO Model.

Indeed, because the incentives of the two programs are aligned, we believe that hospitals successful in reducing avoidable readmissions could be important allies for ACOs who share similar goals. Because it is unlikely that the beneficiaries assigned to ACO will use only a single inpatient facility, ACOs will need to work effectively with all local hospitals that their Medicare FFS beneficiaries choose to use.

Finally, as we gain experience with the Shared Savings Program and other new payment incentives in the Medicare FFS program, we will monitor their interactions with the Hospital Readmissions Reduction Program and continue our efforts to align measures and incentives to achieve the best outcomes for our patients and the program.

Comment: One commenter requested clarification regarding how hospitals participating in the Rural Hospital Community Demonstration Program will be impacted by the Hospital Readmissions Reduction Program.

Response: As described, the applicable hospital is defined as a subsection (d) hospital or certain Maryland hospitals. Hospitals participating in the Rural Hospital Community Demonstration Program are subsection (d) hospitals and, thus, will be included in the Hospital Readmissions Reduction Program. Accordingly, we have

calculated excess readmission ratios and readmissions payment adjustment factor for hospitals in the Rural Hospital Community Demonstration Program. If hospitals in the Rural Hospital Community Demonstration Program are subject to a readmissions payment reduction, the reduction will be applied to their base operating DRG amount as if they were paid under the IPPS. At cost report settlement, the readmissions payment amount subtracted from the hospital's base operating DRG amount will be reduced from the payments received under the demonstration.

We are finalizing as proposed our definition of applicable hospitals under the regulations at 42 CFR 412.152 to include both (1) subsection (d) hospitals, that is, hospitals paid under the IPPS and (2) hospitals in Maryland that are paid under section 1814(b)(3) of the Act and that, absent the "waiver" specified by section 1814(b)(3) of the Act, would have been paid under the IPPS. Furthermore, we note that the Hospital Readmissions Reduction Program only includes admissions and readmissions to "applicable hospitals" to calculate the excess readmission ratios used under section 1886(q) of the Act.

4. Limitations on Review (§ 412.154(e))

Section 1886(q)(7) of the Act provides that there will be no administrative or judicial review under section 1869 of the Act, under section 1878 of the Act, or otherwise for any of the following:

- The determination of base operating DRG payment amounts.

- The methodology for determining the adjustment factor, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges, and applicable periods and applicable conditions.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR27966), we proposed to include under proposed § 412.154(e) that the provisions listed above will not be subject to administrative or judicial review, consistent with section 1886(q)(7) of the Act. We note that section 1886(q)(6) of the Act requires that the Secretary "make information available to the public regarding readmissions rates of each subsection (d) hospital under the [Hospital Readmissions Reduction Program]" and also requires the Secretary to "ensure that a subsection (d) hospital has the opportunity to review and submit corrections for, the information to be made public." Our proposal for reporting hospital-specific information, including a hospital's opportunity to review and submit corrections, consistent with section 1886(q)(7) of the Act, is discussed below.

We did not receive any public comments on our proposals regarding the Limitations for Review; therefore, we are finalizing our proposals without modification, including the regulatory text at § 412.154(e).

5. Reporting Hospital-Specific Information, Including Opportunity to Review and Submit Corrections (§ 412.154(f))

Section 1886(q)(6)(A) of the Act requires the Secretary to "make information available to the public regarding readmissions rates of each subsection (d) hospital under the [Hospital Readmissions Reduction Program]". Section 1886(q)(6)(B) of the Act also requires the Secretary to "ensure that a subsection (d) hospital has the opportunity to

review, and submit corrections for, the information to be made public with respect to the hospital." In addition, section 1886(q)(6)(C) of the Act requires the Secretary to post the hospital-specific readmission information for each subsection (d) hospital on the Hospital Compare Web site in an easily understood format.

As we stated in the proposed rule, for purposes of the Hospital Readmissions Reduction Program for FY 2013, we will calculate excess readmission ratios for each of the three conditions, AMI, HF, and PN, using the previously finalized 3-year applicable period for the FY 2013 payment determination that spans from July 1, 2008 through June 30, 2011 (76 FR 51671), data sources, and the minimum number of discharges previously finalized in the FY 2012 IPPS/LTCH PPS final rule for each applicable hospital (76 FR 51671 through 51672). We stated that we intended to make these excess readmission ratios available to the public, consistent with the requirements of section 1886(q)(6)(B) of the Act, as part of the FY 2013 rulemaking process, in addition to posting this information on the Hospital Compare Web site in a subsequent release.

In the FY 2012 IPPS/LTCH PPS final rule, we indicated that we would provide hospitals an opportunity to review and submit corrections using a process similar to what is currently used for posting results on Hospital Compare. We currently provide hospitals with the data elements necessary to verify the accuracy of their readmission rates for the Hospital IQR Program prior to posting their rates on Hospital Compare. Because we believe it is important to provide hospitals with relevant information available to hospitals for assessing payment impacts for purposes of the Hospital Readmissions Reduction Program, as we stated in the proposed rule, we plan to make the excess

readmission ratios used for the Hospital Readmissions Reduction Program adjustment factor calculation available during the rulemaking cycle. As a result, the timeline and details of this process must accommodate the rulemaking timeline in addition to posting on Hospital Compare. In the proposed rule, we set forth the following details regarding the process for hospitals to review and submit corrections to their excess readmission ratios prior to making this information available to the public in rulemaking and on Hospital Compare.

For FY 2013, we proposed to deliver confidential reports and accompanying confidential discharge-level information to applicable hospitals as defined in section IV.A.2. of this preamble, which contain their excess readmission ratios for the three applicable conditions by June 20, 2012. These reports will be delivered in hospitals' secure QualityNet accounts. The information in the confidential reports and accompanying confidential discharge-level information would be calculated using the claims information we had available approximately 90 days after the last discharge date in the applicable period, which is when we would create the data extract for the calculations (we discuss this practice in more detail later).

The discharge-level information accompanying the excess readmission ratios would include the risk-factors for the discharges that factor into the calculation of the excess readmission ratio, as well as information about the readmissions associated with these discharges (such as dates, provider numbers, and diagnosis upon readmission). Our intent in providing this information is twofold: (1) to facilitate hospitals' verification of the excess readmission ratio calculations we provide during the review and correction

period based upon the information CMS had available at the time our data extract was created; and (2) to facilitate hospitals' quality improvement efforts with respect to readmissions.

We proposed to provide hospitals with a period of 30 days to review and submit corrections for their excess readmission ratios for the Hospital Readmissions Reduction Program. This 30-day period would begin the day hospitals' confidential reports and accompanying discharge-level information are posted to their QualityNet accounts. Based on previous experience with public reporting of measures under the Hospital IQR program, including the 30-day risk standardized readmission rates, we believe this 30-day period would allow enough time for hospitals to review their data and notify CMS of calculation errors, and for CMS to incorporate appropriate corrections to the excess readmission ratio calculations prior to the publication of the final rule, at which time the excess readmission ratios would be made available to the public in a table to be cited in the final rule and available via the Internet on the CMS Web site. During the review and correction period, hospitals should notify CMS of suspected errors in their excess readmission ratio calculations using the technical assistance contact information provided in their confidential reports. In order to meet the timelines for this program, we delivered these confidential reports and discharge-level data files to hospitals for the review and correction period on June 20, 2012.

The review and correction process we proposed for the excess readmission ratios above would not allow hospitals to submit additional corrections related to the underlying claims data we used to calculate the ratios, or allow hospitals to add new claims to the

data extract we used to calculate the ratios. This is because it is necessary to take a static "snapshot" of the claims in order to perform the calculations. For purposes of this program, we would calculate the excess readmission ratios using a static snapshot (data extract) taken at the conclusion of the 90 day period following the last date of discharge used in the applicable period. We recognize that under our current timely claims filing policy, hospitals have up to 1 year from the date of discharge to submit a claim to CMS. However, in using claims data to calculate measures for this program, we proposed to create data extracts using claims in CMS' Common Working File (CWF) 90 days after the last discharge date in the applicable period which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is June 30, 2011, we would create the data extract on September 30, 2011 (90 days later), and use that data to calculate the ratios for that applicable period. Hospitals would then receive the excess readmission ratio calculations in their confidential reports and accompanying discharge-level information and they would have an opportunity to review and submit corrections for the calculations. As we stated above, hospitals would not be able to submit corrections to the underlying data that were extracted on September 30, 2011, and would also not be able to add claims to the data set. Therefore, we would consider hospitals' claims data to be complete for purposes of calculating the excess readmission ratios for the Hospital Readmissions Reduction Program at the conclusion of the 90-day period following the last date of discharge used in the applicable period.

We considered a number of factors in determining that a 90-day "run-out" period is appropriate for purposes of calculating claims based measures. First, we seek to provide timely quality data to hospitals for the purpose of quality improvement and to the public for the purpose of transparency. Next, we seek to make payment adjustments to hospitals based on their performance on measures as close in time to the performance period as possible. Finally, with respect to claims-based measures, we seek to have as complete a data set as possible, recognizing that hospitals have up to one year from the date of discharge to submit a claim under CMS' timely claims filing policy.

After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted, and/or episode-based measures). We then need to generate and check the calculations, as well as program, populate, and deliver the confidential reports and accompanying data to be delivered to hospitals. We also are aware that hospitals would prefer to receive the calculations to be used for the Hospital Readmissions Reduction Program as soon as possible. Because several months lead time is necessary after acquiring the data to generate these claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to hospitals sooner than 18 to 24 months after the last discharge date. We believe this would create an unacceptably long delay both for hospitals and for CMS to deliver timely calculations to hospitals for quality improvement and transparency, and ultimately timely readmission adjustment factors for purposes of this program. Therefore, we proposed to extract the data needed to calculate the excess

readmission ratios for this program 90 days after the last date of discharge for the applicable period so that we can balance the need to provide timely program information to hospitals with the need to calculate the claims-based measures using as complete a data set as possible.

During the 30-day review and correction process for the excess readmission ratios, if a subsection (d) hospital suspects that such discrepancies exist in the CMS application of the measures' methodology, it should notify CMS during the review and correction period using the technical support contacts provided in the hospital's confidential report. We would investigate the validity of each submitted correction and notify hospitals of the results. If we confirm that we made an error in creating the data extract or in calculating the excess readmission ratios, we would strive to correct the calculations, issue new confidential reports to subsection (d) hospitals, and then publicly report the corrected excess readmission ratios through the rulemaking process, and subsequently on Hospital Compare. However, if the errors take more time than anticipated to correct, not allowing for publication of the corrected ratios in the final rule, we would notify hospitals in the final rule that corrected ratios will be made available after the final rule through delivery of confidential reports followed by a second 30-day review and correction period, subsequent publication, and posting on Hospital Compare. In addition, we proposed that any corrections to a hospital's excess readmission ratios would then be used to recalculate a hospital's ratio under section 1886(q)(4)(B) of the Act in order to determine the hospital's adjustment factor in accordance with section 1886(q)(3) of the Act.

We believe that this proposed process would fulfill the statutory requirements at section 1886(q)(6)(A), section 1886(q)(6)(B), and section 1886(q)(6)(C) of the Act. We further believe that the proposed process would allow hospitals to review and correct their excess readmission ratios. We note that, under the proposed process, hospitals would retain the ability to submit new claims and corrections to submitted claims for payment purposes in line with CMS' timely claims filing policies. However, we emphasize that the administrative claims data used to calculate the excess readmission ratios reflect the state of the claims at the time of extraction from CMS' Common Working File. Under the proposed process, a hospital's opportunity to submit corrections to the calculation of the excess readmission ratios ends at the conclusion of the review and correction period. We welcomed public comments on the proposed review and corrections process for the Hospital Readmissions Reduction Program.

Comment: One commenter disagreed with the use of the Common Working File (CWF) to calculate the readmission measures, stating that it does not contain final-action claims for all of the discharges eligible to be used to calculate excess readmission ratios:

Response: The excess readmission ratios are calculated using only the final action claims (that is, we do not include canceled/edited claims) from the CWF available as of September 30, which are published in the Inpatient Standard Analytic File (SAF). Calculations include claims processed by CMS as of the following dates: June 26, 2009 for July 1, 2007 through June 30, 2008 claims; June 25, 2010 for July 1, 2008 through June 30, 2009 claims; June 24, 2011 for July 1, 2009 through June 30, 2010 claims; and September 30, 2011 for July l, 2010 through June 30, 2011 claims. Claims and

corrections processed after these dates are not reflected in the calculations. Thus data between 2008 and 2010 include more than 6 months of run-out period, and 2011 data contain a 3-month run-out period to allow as many corrected and final-action claims to be incorporated. These are the most recent final action data that can be used to meet the timeline of the program need. We encourage hospitals to submit claim corrections as early as possible and to ensure the quality of the data they submitted for reimbursements. If CMS waits for final-action claims for all eligible discharges to be included in the data, then the excess readmission ratios will be based on old data, which will limit its usefulness for hospitals to review and improve their care delivery processes. Therefore, we have encouraged hospitals to submit claim corrections as early as possible and to ensure the quality of the data they submitted for reimbursements. We will continue to research and seek public comments on alternative data sources that might provide measure results that are as accurate and are more timely than the CWF. The CWF will be used for the calculation of excess readmission ratios for the Hospital Readmissions Reduction Program as finalized in the FY 2012 IPPS/LTCH final rule (76 FR 51671 through 51672).

Comment: One commenter appreciated the release of additional hospital specific data and "excess readmission rates" data prior to the implementation of the program, as well as the readmission information and patient's risk factors.

Response: We thank the commenter for the recognition and we are committed to foster transparency, provide accurate data to hospitals for quality improvement, and,

ultimately, timely calculate readmission adjustment factors for base operating DRG payments.

Comment: One commenter thanked CMS for the 30-day review and correction period while one commenter requested the review and correction period be extended to 60 days.

Response: We appreciate the commenter's support of the 30-day review period. We note that, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51672 through 51673), we adopt the same preview and correction process and timeframe used for subsection (d) hospitals for the rates calculated for the Hospital Readmissions Reduction Program. That is, we provide hospitals with an opportunity to preview their readmission rates for 30 days prior to posting on the Hospital Compare webs site. This process meets the statutory requirement in section 1886(q)(6)(B) of the Act which requires the Secretary to ensure that a subsection (d) hospital has the opportunity to review and submit corrections before the information to be made public with respect to the hospital*** prior to such information being made public.

Aside from the statutory requirements, we also considered hospital experience with the measure and data production timeline in proposing the 30-day preview period. In terms of hospital experience with the measures, while the Hospital Readmissions Reduction Program is new, subsection (d) hospitals are already familiar with the three 30-day risk-standardized readmission measures that the Program uses to determine payment adjustment. In particular, these three measures were first publicly reported by the former Reporting of Hospital Quality Data for Annual Payment Update (RHQDAPU) program

(currently known as the Hospital IQR Program), back in 2009. The measure results have been reported annually since then and have recently been updated in July 2012. To help hospitals understand the methodology for these measures and the calculation and interpretation of measure results, we have made publicly available the latest version of the methodology reports, a Frequently-Asked-Question list, a mock hospital-specific report, and a mock discharge-level data file for these measures on the *QualityNet* website. The measures methodology for the Hospital Readmissions Reduction Program is the same as that for the Hospital IQR Program. Because hospitals are working with measures in which they have prior experience from the Hospital IQR Program, we believe that a 30-day preview period is sufficient for hospitals to review and correct their excess readmission ratios.

In terms of data production timeline, due to the complexity of these measures and the need for bootstrapping in measure calculations, a significant amount of programming resources is needed. It took several months to complete the production and extensive quality assurance procedures for the results for more than 3,500 hospitals. As a result, we will not be able to begin the preview period earlier than late June. Also, we will not be able to extend the preview period to more than 30 days. This is because if hospitals find data problems that we determine to be attributable to our calculation or programming errors, we will need adequate time between mid-July and the end of September to: (1) recalculate the excess readmission ratios; (2) regenerate and redisseminate corrected results to hospitals in time for payment adjustment in early October (the beginning of the subsequent fiscal year); and (3) publicly report the excess readmission ratios on the

Hospital Compare website in mid-October to meet the statutory reporting requirements under section 1886(q)(6) of the Act. Based on the above reasons, we cannot change the review and correction timeframe to 60 days.

Comment: One commenter requested that, for self-validation purposes, CMS provide each hospital with a downloadable database containing all of the claims data used to calculate the hospital's readmission rates. One commenter recommended that CMS provide hospitals with additional claim information documenting the first physician/licensed independent practitioner visit post index discharge and prior to readmit (days from discharge to first visit). The commenter stated that the first follow-up provider information is critical to decreasing readmissions. Another commenter was concerned that limited access to the claims data will impair hospitals' ability self-validate our results.

Response: We considered several factors in deciding the amount of information that CMS provides to hospitals for the review and correction process. These factors are: confidentiality of information, our resources, and feasibility for hospital providers to process the data.

For the purposes of the Hospital Readmissions Reduction Program data, we have decided to provide as much of the claims-based information that is pertinent to the calculation of the excess readmission ratio so that hospitals can verify the accuracy of these calculations and engage in outreach and coordination with readmitting hospitals. Providing the entire raw claims history for index admissions and for subsequent services after discharge would provide more information than would be necessary in hospitals'

effort to review their excess readmission ratios. To protect sensitive patient information, and to avoid burden and confusion to hospitals, we are careful not to include data elements that are not relevant for the review and correction process.

Furthermore, providing all subsection (d) and Maryland hospitals with all the claims data will require a large amount of resources, infrastructure changes and exert significant financial burden on these hospitals and on taxpayers. We have already provided supplemental discharge-level data to hospital providers to review qualified individual readmissions, including primary diagnosis at index and readmission stays, where the patient was readmitted, dates of index and readmission stays, and individual risk factors, and instructions for replicating their excess readmission ratios.

Additionally, we have also set up a Help Desk for hospitals to inquire about their results. This Help Desk has access to all the claims data used for the calculation of the hospitals' excess readmission ratios, and is highly experienced in assisting hospitals with the results of the 30-day risk-standardized readmission measures. Therefore, we believe that the proposed review correction policies are adequate. We are working to identify new methods to provide hospitals with accurate and timely data to improve their care delivery processes to reduce readmission rates. We encourage hospitals and other healthcare providers to provide us with recommendations for this effort.

After consideration of the public comments received, for the review and correction process, we are finalizing the policies of providing applicable hospitals with: (1) a period of 30 days to review and submit corrections for their excess readmission ratios for the Hospital Readmissions Reduction Program; and (2) confidential reports and

accompanying confidential discharge-level information (this includes the excess readmission ratios, the risk-factors for the discharges that factor into the calculation of the excess readmission ratio, as well as information about the readmissions associated with these discharges).

B. Sole Community Hospitals (SCHs) (§ 412.92)

1. Background

Section 1886(d)(5)(D)(iii) of the Act defines a sole community hospital (SCH) generally as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as a SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 463897).

2. Reporting Requirement and Clarification for Duration of Classification for Hospitals Incorrectly Classified as Sole Community Hospitals (§ 412.92(b)(3)(iv))

The regulations at § 412.92(b)(2) and (b)(3) address the effective dates of a classification as an SCH and the duration of this classification. Currently, a hospital's SCH classification status remains in effect without the need for reapproval unless there is a change in the circumstances under which the classification was approved. Section 412.92(b)(3) requires a hospital to notify the fiscal intermediary or Medicare administrative contractor (MAC) within 30 days of a change that could affect its

classification as an SCH. Specifically, the regulations require an SCH to notify its fiscal intermediary or MAC if any of the following changes specified in §§ 412.92(b)(3)(ii)(A) through (b)(3)(ii)(E) occur:

- The opening of a new hospital in its service area.
- The opening of a new road between itself and a like provider within 35 miles.
- An increase in the number of beds to more than 50, if the hospital qualifies as an SCH under § 412.92(a)(1)(ii).
- Its geographic classification changes.
- Any changes to the driving conditions that result in a decrease in the amount of travel time between itself and a like provider if the hospital qualifies as an SCH under § 412.92(a)(3).

As discussed in the FY 2007 IPPS final rule (71 FR 48060), in the context of CMS becoming aware of several hospitals that had been paid based on SCH status, even after the original circumstances of the classification changed, CMS determined that an SCH's classification status would generally end 30 days after CMS notifies the SCH that it no longer meets the requirements to be classified as an SCH. However, if a hospital does not report when any one of the changes listed above occurs, CMS will cancel the hospital's SCH classification effective with the date that the hospital no longer met the criteria for SCH classification, subject to the reopening rules at 42 CFR 405.1885 (§ 412.92(b)(3)(i)).

For any change that is not listed under § §412.92(b)(3)(ii)(A) through (b)(3)(ii)(E) that affects an SCH's classification status, CMS requires a hospital to report that change

to the fiscal intermediary or MAC if it "becomes aware" of the change. If a hospital does not report a change, other than those listed under §§ 412.92(b)(3)(ii)(A) through (b)(3)(ii)(E), and it becomes known to CMS that the hospital had knowledge of that change, CMS will cancel the hospital's SCH classification effective with the date the hospital became aware of the event. Specifically, § 412.92(b)(3)(iii) states that "a sole community hospital must report to the fiscal intermediary if it *becomes aware of any change* that would affect its classification as a sole community hospital beyond the events listed in paragraph (b)(3)(ii) of this section within 30 days of the event. If CMS determines that a sole community hospital has failed to comply with this requirement, CMS will cancel the hospital's classification as a sole community hospital effective with the date the hospital *became aware of the event* that resulted in the sole community hospital no longer meeting the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter." (Emphasis added.)

The existing language at § 412.92(b)(3)(iii) only refers to a hospital becoming aware of a "change," because it deals specifically with a situation where a hospital was appropriately classified as an SCH because it had previously met the requirements to become an SCH. We believe that this requirement was not intended to preclude situations where a hospital was incorrectly classified as an SCH. However, the regulations did not explicitly address the situation where a hospital never met the requirements to be classified as an SCH, but was incorrectly classified as an SCH. Therefore, we believe it would be prudent to explicitly address this situation in the regulations.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27968 and 27969), we proposed to add a new paragraph (b)(3)(iv) to § 412.92 to clarify our current authority that if CMS determines that the hospital was incorrectly classified as an SCH, SCH status could be cancelled retroactively, consistent with the provisions at § 405.1885. We proposed that any factor or information, not only a change or an event that could have affected a hospital's initial SCH classification must be reported by the SCH to its fiscal intermediary or MAC.

Our proposed regulation stated explicitly our current authority that if a determination is subsequently made that, in fact, a hospital did not ever qualify as an SCH, the withdrawal of SCH status could be made retroactively to revoke payments associated with the incorrect SCH classification for the entire time period, consistent with the reopening rules at § 405.1885.

Comment: Many commenters contended that a hospital should not be accountable for any errors it made inadvertently and is unaware of or for any errors made by CMS or the Medicare contractor. Commenters requested confirmation and clarification regarding a number of issues, such as: (1) the circumstances under which the reporting obligation is triggered; (2) the timeframe involved in making a report to CMS; and (3) what factor or information must be reported.

Response: We realize that a hospital could have been incorrectly classified as an SCH based on an inadvertent error by the hospital, CMS, or the contractor. However, an error is not adequate justification to maintain a hospital's SCH status and to provide higher payments under the Medicare program. However, in light of the public comments,

we are modifying our proposed change in this final rule so that, effective October 1, 2012, if a hospital reports any factor or information that could have affected its initial classification as an SCH, and CMS determines that, based on the additional information, the hospital should not have qualified for SCH status, we will only revoke SCH status prospectively, effective 30 days from CMS' date of determination. We note that this reopening limitation does not apply to situations where there was fraud involved. If a hospital knowingly misled CMS or deliberately submitted incorrect information in its initial classification, different procedures would apply. These procedures would include recouping incorrect payments associated with the fraudulently awarded SCH classification.

This policy, as revised in this final rule, will allow a hospital that reports to CMS any factor or information that could have affected its initial classification as an SCH to have its SCH classification removed prospectively only. A hospital is only required to report to CMS any available information that would have affected its initial classification as an SCH under the regulations that were effective at that time. We are not requiring hospitals to continuously monitor subsequent year data from other hospitals such as changes in patient origin data. However, information that could have affected its classification as an SCH at the time of its initial SCH determination is required to be reported to CMS.

For example, if hospital A is classified as an SCH and the distance between itself and hospital B is such that it may have been classified as an SCH in error, hospital A would be required to report this to CMS. If the hospital reports this issue to CMS, and

CMS determines in fact that the distance between hospital A and hospital B would have precluded hospital A from being classified as an SCH using the qualification criteria that were in place at the time of its initial classification, we would remove the hospital's SCH status effective 30 days from the date that CMS determines that Hospital A should not have qualified for SCH status. However, if hospital A does not report to CMS that hospital B's proximity to hospital A may have been overlooked in its initial classification as an SCH, and CMS finds that hospital A should never have qualified as an SCH, CMS has the discretion to recoup the overpayments associated with erroneous SCH status, in accordance with cost reporting reopening rules at § 405.1885, that is, for cost reporting periods that are within the 3-year reopening period. We believe this distinction between the effective date for hospitals that do and do not notify CMS of the possible error will encourage self-reporting of possible errors. In cases where hospitals fail to report, CMS would have the discretion to reopen back to the earliest date possible in accordance with § 405.1885. Such discretion would be available to rectify situations where hospitals were paid as SCHs even though they never initially met the classification standards for such status, and never reported the error to CMS.

Accordingly, if a hospital suspects that it should not have qualified as an SCH at the time of its initial classification and the hospitals comes to CMS and requests that CMS determine whether it meets all of the requirements for SCH status, if CMS confirms that suspicion and the hospital in fact should never have been approved as an SCH, CMS will remove SCH status effective 30 days from CMS' date of determination.

We note that this policy, as revised, is in addition to the requirements already in place in the regulations at §§ 412.92(b)(3)(i) through (b)(3)(iii) that require a hospital to notify CMS (that is, the fiscal intermediary or MAC servicing the hospital) of any changes that would affect its SCH status.

Comment: Several commenters were concerned that our proposal could potentially revoke SCH status from a hospital's initial classification as an SCH, which could potentially span a few decades. One commenter suggested that CMS establish a "look back" period on which hospitals can rely and that CMS not reopen a prior SCH classification more than 3 years after the initial determination simply because there is an open cost report due to an appeal or delayed payment. Many commenters objected to the retroactive cancellation of SCH classification claiming that this would be punitive.

Response: We understand and appreciate the need to establish a limit to how far back CMS may rescind SCH status. Our proposal clearly stated that the withdrawal of SCH status could be made retroactively, consistent with the provisions at § 405.1885, meaning that we may withdraw SCH status for cost reporting periods that are within the 3-year reopening period only. Therefore, if a hospital was incorrectly approved as an SCH and the effective date of the original classification is still within the 3-year cost report reopening period, we could withdraw SCH status for all those periods in which it was paid incorrectly as an SCH starting with its initial date of classification. However, if the effective date of the original classification as an SCH was not within the 3-year cost report reopening period, we could only withdraw SCH status and any payments associated with that SCH status for those cost reporting periods subject to the reopening

period. This is consistent with our reopening rules, and applies to any open cost report, regardless of the reason the report is still in an open cost reporting period. We note that our ordinary reopening rules do not distinguish the period available for reopening based on why a cost report may still be open. Finally, as stated above, CMS would have the discretion to reopen to the earliest date possible, consistent with § 405.1885.

Comment: Some commenters contended that the proposal undermines CMS' longstanding principle favoring prospective policy and that a hospital would never have total certainty that it qualifies as an SCH.

Response: While we appreciate the commenters' concerns, we also believe that overpaying hospitals based on an erroneous classification that should never have been awarded undermines a payment system, and could even encourage attempts at misclassification. Our reopening rules have always provided authority to revoke overpayments associated with an erroneous SCH classification retroactively and in accordance with the cost report reopening rules. Our clarification in the regulation is merely codifying this already existing authority. We are simply making explicit what is already implicit in our authority and is not introducing a change in policy.

Comment: Several commenters asserted that CMS' proposed regulation is unfair in that it would impose an unfair and burdensome obligation to continuously monitor data that may not be within a hospital's control. Other commenters suggested that CMS modify the proposed regulation to make it more consistent with the regulations at §§ 412.92(b)(3)(ii) and (b)(3)(iii) which describe the way CMS handles the cancellation

of SCH for a hospital where there was a change in circumstances under which the classification was approved.

Response: We are not requiring hospitals to continuously monitor data nor are we requiring hospitals to report data that may not be within their control. A hospital would only be required to report any factor or information that would have affected its initial classification. We note that this policy is in addition to the requirements already in place in the regulations at §§ 412.92(b)(3)(i) through (b)(3)(iii) that require a hospital to notify CMS (that is, the hospital's fiscal intermediary or MAC) of any changes that would affect its SCH status. The information in question is data that are germane to the information on which the SCH classification was based. The factors and information that a hospital must report are a limited universe of data that was used during the hospital's initial classification.

The modifications that we have made to the proposed regulation in this final rule would make the final regulation consistent with our existing regulations at §§ 412.92(b)(3)(i) and (b)(3)(ii) where CMS cancels SCH classification in accordance with our reopening rules when the SCH fails to disclose a change in circumstance.

Comment: Several commenters requested classification as to (1) whether the proposed regulation would apply to hospitals that were classified as SCHs before the implementation of IPPS; and (2) which standards and criteria would be used by CMS to determine whether or not the hospital qualified as an SCH in its initial classification.

Response: We note that there are a few types of SCHs that have been classified as such under different sets of requirements:

(1) A *hospital that was granted SCH status and was granted an exemption from cost limits pre-IPPS*. Our regulations at § 412.92 (b)(5) state that a hospital that has been granted an exemption from the hospital cost limits before October 1,1983, or whose request for the exemption was received by the appropriate intermediary before October 1, 1983, and was subsequently approved, is automatically classified as an SCH. In the September 1, 1983 final rule (48 FR 39780), we stated that a hospital would be classified as an SCH for purposes of the IPPS if the hospital has an approved exemption from hospital cost limits as an SCH prior to October 1, 1983, and that the hospital would retain SCH status unless there was a change in the circumstances affecting this classification under the cost limits.

(2) A *hospital that was classified as an SCH before the change in the law under section 6003(e)(3) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239).* In the August 18, 2006 final rule (71 FR 48061), we discussed that changes in criteria for being eligible for SCH status that were made by section 6003(e)(3) of Pub. L. 101-239. The law changed SCH criteria by reducing the number of miles between providers from 50 to 35 and by requiring the Secretary to establish a criterion that takes into consideration the travel time between two providers. Section 6003(e)(3) of Pub. L. 101-239 exempted hospitals that already had SCH status from meeting either of these requirements. In other words, any hospital that was correctly an SCH in 1989 is protected under this grandfathering provision from the new mileage criterion and whether or not it meets the new criterion for classification concerning travel time at § 412.92(a)(3). However, we noted that this grandfathering provision is limited to these

two circumstances. Hospitals with SCH designations in effect prior to 1989 can lose SCH status if they fail to meet any of the other eligibility criteria.

(3) A *hospital that was designated as an EACH prior to October 1, 1997.* Under the regulations at § 412.109, a hospital designated as an EACH is paid as an SCH as long as the hospital continues to comply with the terms, conditions, and limitations that were applicable at the time of designation.

These hospitals are grandfathered in and are protected against later changes to SCH criteria or new interpretations of those criteria. Accordingly, these grandfathered SCHs would maintain their SCH status as long as they continue to meet the criteria under which they classified for payments as SCHs.

In this final rule, we also are clarifying that we would apply the standards and regulations that were in effect at the time the hospital was initially classified as an SCH. That is, when CMS determines that a hospital never met the requirements to be classified as an SCH, we are referring to the requirements that were in place during the hospital's initial classification as an SCH. However, we note that the criteria for SCH classification have not been modified since we made changes to implement section 6003(e)(3) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239). Since that time, we have issued minimal reinterpretations in the actual criteria for classification. Therefore, we are confirming that we would not apply SCH criteria, standards, or interpretations that were not effective at the time of initial SCH classification to any hospital.

Comment: Some commenters argued that the proposed regulation change is irreconcilable with our existing regulation which states that a hospital retains SCH status

unless there is a change in the circumstances under which the classification was approved.

Response: The commenters' argument is based on an incorrect assumption about the applicability of the existing regulations. That is, the existing regulations only address situations where a hospital was correctly classified as an SCH. The regulations were silent on hospitals that were initially classified incorrectly. If a hospital was classified as an SCH in error, clearly it would not take a "change in circumstances" to revoke SCH status.

After consideration of the public comments we received, we are finalizing our proposed codification of our current authority to recoup any overpayments associated with incorrect SCH classification, consistent with cost report reopening rules at § 405.1885. We also are making one modification to specify that, effective October 1, 2012, if a hospital subsequently reports any factors or information to CMS that could have affected its initial classification as an SCH and CMS determines that, based on the additional information, the hospital should not have qualified for SCH status, CMS will cancel SCH status effective 30 days from CMS' date of determination.

As stated above, we also note that reopening limitation does not apply to situations where there was fraud involved. If a hospital knowingly misled CMS or deliberately submitted incorrect information in its initial classification, CMS will recoup incorrectly paid amounts from the date of the hospital's initial SCH classification.

3. Change to Effective Date of Classification for MDHs Applying for SCH Status Upon the Expiration of the MDH Program (§ 412.92(b)(2)(v))

Under existing regulations at § 412.92(b)(2), an SCH's status is generally effective 30 days after CMS's written notification of approval. It has come to our attention that there may be a number of hospitals currently classified as MDHs, under § 412.108 of the regulations, that intend to apply for classification as SCHs, under § 412.92 of the regulations, upon the expiration of the MDH program provision on September 30, 2012. Those hospitals may be reluctant to apply for SCH classification status well before the expiration of their MDH status because they would prefer to maintain their MDH status for as long as possible. Conversely, if those hospitals were to wait to apply for SCH classification status after expiration of their MDH status, they could experience a financial hardship if there were a delay in the approval for SCH classification status. In order to facilitate a seamless transition for hospitals that are currently classified as MDHs and that will qualify as SCHs, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27969), we proposed to add an exception to the effective dates of SCH classification by adding a new paragraph (v) under § 412.92(b)(2). We proposed that for any MDH that applies for SCH classification status at least 30 days prior to the expiration of the MDH program provision and requests that SCH classification status be effective with the expiration of the MDH program provision, and the MDH is approved for SCH classification status, the effective date of the hospital's classification as an SCH would be the day following the expiration date of the MDH program provision (that is, October 1, 2012). For example, Hospital A is an MDH that would like to maintain its MDH status for as long as possible and be classified as an SCH only after its MDH status expires. In order to seamlessly transition from MDH status to SCH status, Hospital A

must apply for SCH status by August 31, 2012, and must request that, if approved, SCH classification status be effective with the expiration of the MDH program provision. If CMS determines that Hospital A qualifies for SCH status, the effective date of its SCH classification will be October 1, 2012.

Comment: Commenters supported the proposal to provide for a seamless transition for MDHs than can qualify as SCHs, in anticipation of the expiration of the MDH program. Commenters also requested that CMS provide hospitals with the ability to, in turn, rescind their new SCH status retroactively and reinstate their MDH status in a seamless manner if a retroactive extension to the MDH program is made.

Response: We appreciate the commenters' support. The commenters' request that CMS make provisions for hospitals to transition from SCH status back to MDH status depends on legislation being passed for the MDH program. We typically do not create policy around actions that Congress may take in the future. However, if legislation is passed to continue the MDH program, we will develop policy to implement the specific provisions of such legislation.

After consideration of the public comments received, we are finalizing our proposed change to the effective date of SCH status for MDHs losing their MDH status with the expiration of the MDH program. In order for an MDH to receive SCH status effective October 1, 2012, it must apply for SCH status at least 30 days before the end of the MDH program; that is, the MDH must apply for SCH status by August 31, 2012. The MDH also must request that, if approved as an SCH, the SCH status be effective with the expiration of the MDH program provision; that is, MDH must request that the SCH

status, if approved, be effective October 1, 2012, immediately after its MDH status expires with the expiration of the MDH program at the end of FY 2012, on September 30, 2012.

C. Rural Referral Centers (RRCs): Annual Update to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Pub. L. 108-173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs are also not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area where the hospital is located.

Section 4202(b) of Pub. L. 105-33 states, in part, "[a]ny hospital classified as an RRC by the Secretary . . . for fiscal year 1991 shall be classified as such an RRC for fiscal year 1998 and each subsequent year." In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), CMS reinstated RRC status for all hospitals that lost the status due to triennial review or MGCRB reclassification. However, CMS did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban.

Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of "urban" and "rural" specified in Subpart D of 42 CFR Part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum CMI and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513).) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if--

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and

- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.)

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The national median CMI value for FY 2013 includes data from all urban hospitals nationwide, and the regional values for FY 2013 are the median CMI values of urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These values are based on discharges occurring during FY 2011 (October 1, 2010 through September 30, 2011), and include bills posted to CMS' records through March 2012.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27969), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2012, they must have a CMI value for FY 2011 that is at least--

- 1.5378; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2013 IPPS/LTCH PPS proposed rule at 77 FR 27970.)

The final CMI criteria for FY 2013 are based on the latest available data (FY 2011 bills received through March 2012). In addition to meeting other criteria, , if rural

hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2012, they must have a CMI value for FY 2011 that is at least--

- 1.5378; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final median CMI values by region are set forth in the following table:

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.3146
2. Middle Atlantic (PA, NJ, NY)	1.3744
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4640
4. East North Central (IL, IN, MI, OH, WI)	1.4533
5. East South Central (AL, KY, MS, TN)	1.4045
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.4899
7. West South Central (AR, LA, OK, TX)	1.5855
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6461
9. Pacific (AK, CA, HI, OR, WA)	1.5298

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its fiscal intermediary or MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS-DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. We would normally update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2010 (that is, October 1, 2009 through September 30, 2010), which would normally be the latest cost report data available at the time of the development of this final rule. However, due to a transition in our data system, in lieu of a full year of FY 2010 cost report data, we needed to use a combination of FY 2009 and FY 2010 cost report data in order to create a full fiscal year of cost report data for this analysis. Due to CMS' transition to a new cost reporting form effective for cost reporting periods beginning on or after May 1, 2010, cost reports with fiscal year begin dates of May 1, 2010 through September 30, 2010 were not accessible on our system for analysis at the time of the development of this final rule. Therefore, in order to have a complete fiscal year of cost report data, we utilized FY 2009 cost report data for providers with fiscal years beginning on or after May 1, 2010 and by September 30, 2010, in addition to the FY 2010 cost report data for providers with fiscal years beginning on or after October 1, 2009 and before May 1, 2010.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27970), we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2012, must have, as the number of discharges for its cost reporting period that began during FY 2010 (based on a

combination of FY 2009 and FY 2010 cost report data as explained in the preceding paragraph), at least-

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2013 IPPS/LTCH PPS proposed rule at 77 FR 27970.)

Based on the latest discharge data available at this time (that is, based on a combination of FY 2009 and FY 2010 cost report data as explained earlier in this section), the final median number of discharges for urban hospitals by census region are set forth in the following table:

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,159
2. Middle Atlantic (PA, NJ, NY)	11,448
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	11,755
4. East North Central (IL, IN, MI, OH, WI)	8,749
5. East South Central (AL, KY, MS, TN)	7,234
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	8,129
7. West South Central (AR, LA, OK, TX)	6,232
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,336
9. Pacific (AK, CA, HI, OR, WA)	8,745

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, 5,000 discharges is the minimum criterion for all hospitals under this final rule.

We reiterate that, if an osteopathic hospital is to qualify for RRC status for cost reporting periods beginning on or after October 1, 2012, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2010 (based on a combination of FY 2009 and FY 2010 cost report data as explained earlier in this section).

D. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Expiration of the Affordable Care Act Provisions for FYs 2011 and 2012

For FYs 2011 and 2012, the Affordable Care Act expanded the definition of low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition. Beginning with FY 2013, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. We discuss the payment policies for FY 2013 in section IV.D.4. of this preamble.

2. Background

Section 1886(d)(12) of the Act, as added by section 406(a) of Pub. L. 108-173, provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective beginning FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is "in addition to any payment calculated under this section." Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume payment amount is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outliers. For SCHs and MDHs, the low-volume payment amount is based on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

Section 1886(d)(12)(C)(i) of the Act defined a low-volume hospital as "a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is

located more than 25 road miles from another subsection (d) hospital and has less than 800 discharges during the fiscal year." Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term "discharge" means "an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under Part A." Therefore, the term "discharge" refers to total discharges, regardless of payer (that is, not only Medicare discharges). Furthermore, under section 406(a) of Pub. L. 108-173, which initially added subparagraph (12) to section 1886(d) of the Act, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the "empirical relationship" between "the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges." The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Therefore, the

low-volume adjustment of an additional 25 percent continues to be provided for qualifying hospitals with less than 200 discharges.

3. Affordable Care Act Provisions for FYs 2011 and 2012

Sections 3125 and 10314 of the Affordable Care Act amended section 1886(d)(12) of the Act, modifying the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals, effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume.

Sections 3125(3) and 10314(1) of the Affordable Care Act amended the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act to make it easier for hospitals to qualify for the low-volume adjustment. Specifically, the provision specifies that, for FYs 2011 and 2012, a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Part A during the fiscal year. In addition, section 1886(d)(12)(D) of the Act, as added by section 3125(4) and amended by section 10314 of the Affordable Care Act, provides that the payment adjustment (the applicable percentage increase) is to be determined "using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year."

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we revised our regulations at 42 CFR 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals according to the provisions of the Affordable Care Act. In addition to changing the regulations to conform them to the Affordable Care Act changes, we also defined, at § 412.101(a), the term "road miles" to mean "miles" as defined at § 412.92(c)(i). The definition of "road miles" continues to apply even after the Affordable Care Act provisions expire at the end of FY 2012. We also clarified the existing regulations to indicate that a hospital must continue to qualify as a low-volume hospital in order to receive the payment adjustment in that year; that is, it is not based on a one-time qualification. Furthermore, in that same final rule, we discussed the process for requesting and obtaining the low-volume hospital payment adjustment (75 FR 50240).

4. Payment Adjustment for FY 2013 and Subsequent Fiscal Years

As we discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27971 through 27973), in accordance with section 1886(d)(12) of the Act, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, as specified under the existing regulations at § 412.101, effective for FY 2013 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal

year. As discussed above, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year, but also requires that the applicable percentage increase for qualifying low-volume hospitals be based on the "empirical relationship" between "the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges." Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirements set forth in section 1886(d)(12)(B) of the Act to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

As described above, for FYs 2005 through 2010 and FY 2013 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 and 2012, CMS used the most recently available MedPAR data to determine the hospital's Medicare discharges because

only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

For FY 2013 and subsequent fiscal years, in addition to a discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion specified at § 412.101(b)(2)(i). Specifically, to meet the mileage criterion to qualify for the low-volume payment adjustment for FY 2013 and subsequent fiscal years, a hospital must be located more than 25 road miles from the nearest "subsection (d) hospital." As mentioned above, we define, at § 412.101(a), the term "road miles" to mean "miles" as defined at § 412.92(c)(i) (75 FR 50238 through 50275 and 50414).

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. In order to qualify for the low-volume hospital payment adjustment, a hospital must provide to its fiscal intermediary or MAC sufficient evidence to document that it meets the discharge and distance requirements. The fiscal intermediary or MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital will know in advance whether or not it will receive a payment adjustment. The fiscal intermediary or MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria.

In order to receive a low-volume hospital payment adjustment under § 412.101, a hospital must notify and provide documentation to its fiscal intermediary or MAC that it meets the mileage criterion. The use of a Web-based mapping tool, such as MapQuest, as part of documenting that the hospital meets the mileage criterion for low-volume hospitals, is acceptable. The fiscal intermediary or MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance (in road miles, as defined in the regulations at § 412.101(a)) from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the fiscal intermediary or MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the low-volume mileage criterion. In addition, the fiscal intermediary or MAC will refer to the hospital's most recently submitted cost report to determine whether or not the hospital meets the discharge criterion. A hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year. As noted previously, a hospital must continue to meet the qualifying criteria at § 412.101(b)(2)(i) as a low-volume hospital (that is, the discharge criterion and the mileage criterion) in order to receive the payment adjustment in that year; that is, low-volume hospital status is not based on a "one-time" qualification.

In order to be a low-volume hospital in FY 2013 and subsequent fiscal years, in accordance with our previously established procedure, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by

September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the 25 percent low-volume add-on payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the fiscal intermediary or MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the 25 percent low-volume add-on payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination.

Specifically, for FY 2013, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1, 2012, in order for the 25-percent low-volume add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2012 (through September 30, 2013). If a hospital's request for low-volume hospital status for FY 2013 is received after September 1, 2012, and if the fiscal intermediary or MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the 25 percent low-volume add-on payment adjustment to determine the payment for the hospital's FY 2013 discharges, effective prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination. For additional information on our established application process for the low-volume hospital payment adjustment, we refer readers to the FY 2011 IPPS/LTCH PPS final rule

(75 FR 50274 through 50275), Transmittal 2060 (Change Request 7134; October 1, 2010), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), in addition to implementing the Affordable Care Act provisions affecting low-volume hospitals for FYs 2011 and 2012, we also implemented changes to the regulations at 42 CFR 412.101 to conform them to the statutory requirements to require that, beginning with FY 2013, the low-volume hospital qualifying criteria and payment adjustment methodology will return to that which was in effect prior to the amendments made by the Affordable Care Act (that is, the low-volume hospital payment policy in effect for FYs 2005 through 2010). Therefore, no further revisions to the policy or to the regulations at § 412.101 are required to conform them to the statutory requirement that the low-volume hospital policy in effect prior to the Affordable Care Act returns for FY 2013 and subsequent years.

Comment: A few commenters expressed concern about the financial impact of the expiration of the temporary expansion of the low-volume hospital payment adjustment provided for by the Affordable Care Act. Some commenters encouraged CMS to promote legislative action that would continue the Affordable Care Act's modification of the low-volume hospital payment adjustment. Other commenters urged CMS to mitigate the impact of the expiration of the 2-year enhancement of the low-volume hospital payment adjustment provided for by the Affordable Care Act by using the existing statutory authority to make the low-volume adjustment to qualifying hospitals that have up to less than 800 total discharges rather than only to qualifying

hospitals that have less than 200 total discharges. The commenters provided no data analysis in support of their comments to expand the low-volume hospital adjustment to qualifying hospitals that have up to less than 800 total discharges.

Response: To implement the original low-volume hospital provision, and as mandated by statute, we developed an empirically justified adjustment based on the relationship between costs and total discharges of hospitals with less than 800 total (Medicare and non-Medicare) discharges. Specifically, we performed several regression analyses to evaluate the relationship between hospitals' costs per case and discharges, and found that an adjustment for hospitals with less than 200 total discharges is most consistent with the statutory requirement to provide for additional payments to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with lower numbers of discharges (69 FR 49101 through 49102). Based on these analyses, we established a low-volume hospital policy where qualifying hospitals with less than 200 total discharges receive a payment adjustment of an additional 25 percent. (Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.) We may, in the future, reevaluate the low-volume hospital adjustment policy, that is, the definition of a low-volume hospital and the payment adjustment. However, because we did not make any proposals regarding the low-volume hospital payment adjustment for FY 2013, we are not making any changes to the low-volume hospital payment adjustment policy in this final rule. As discussed above, the low-volume hospital definition and payment adjustment methodology will revert back to the policy established under statutory requirements that

were in effect prior to the amendments made by the Affordable Care Act, which is currently implemented in the existing regulations at § 412.101.

E. Indirect Medical Education (IME) Payment Adjustment (§ 412.105)

1. IME Adjustment Factor for FY 2013

Under the IPPS, an additional payment amount is made to hospitals that have residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B) of the Act states that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2013, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2013 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

Comment: One commenter supported the continuation of the IME adjustment factor because IME payments are an important part of guaranteeing a strong general surgery workforce in which there is currently a growing shortage. Another commenter stated that it supported the Nation's teaching hospitals and, therefore, supported continuation of the IME adjustment factor. A third commenter stated that, because of its

commitment to GME, academic medicine, and residency training in cardiothoracic surgery, it supported the continuation of the IME adjustment factor. The commenter stated that IME payments are an important part of guaranteeing a strong cardiothoracic surgery workforce "…which is currently experiencing a growing shortage as cited in the report *Shortage of Cardiothoracic Surgeons is Likely by 2020*, published in the journal Circulation, July 27, 2009."

Response: We appreciate the commenters' support. We note that the IME formula multiplier is set by Congress.

We are finalizing our proposal that the IME formula multiplier for FY 2013 be set at 1.35, which we estimate will result in an increase in IPPS payments of 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

2. Timely Filing Requirements under Fee-for-Service Medicare

a. IME and Direct GME

The Balanced Budget Act of 1997 (Pub. L. 105-33) amended sections 1886(d) and 1886(h) of the Act by adding paragraphs (d)(11) and (h)(3)(D), respectively, to establish payment provisions for IME and direct GME costs to hospitals providing services to Medicare + Choice (now Medicare Advantage) enrollees. Sections 1886(d)(11) and 1886(h)(3)(D) of the Act specify that the Secretary shall provide for an "additional payment amount" for services furnished to individuals who are enrolled in a Medicare Advantage plan under Medicare Part C. To implement sections 1886(d)(11) and 1886(h)(3)(D) of the Act, we issued two final rules in the **Federal Register** that specifically addressed IME and direct GME payments to teaching hospitals for services

provided to Medicare Advantage enrollees (the FY 1997 IPPS final rule (62 FR 46003) and the FY 1998 IPPS final rule (63 FR 26341)). Subsequent to the FY 1998 IPPS final rule, we (then HCFA) issued a Program Memorandum (PM), A-98-21, in July 1998, which outlined fiscal intermediary and standard system changes needed to process requests for IME and direct GME supplemental payments for services provided to Medicare Advantage enrollees. The PM explained that hospitals must submit their Medicare claims to the fiscal intermediary in UB-92 format in order for the standard system to process the claims so that hospitals may be paid the supplemental IME and direct GME payments for services provided to Medicare Advantage enrollees. It was always our intent that the claims filing requirements under 42 CFR Part 424, including the time limits at 42 CFR 424.44, fully applied to these claims submissions.

Existing § 424.44 of the regulations contains the time limits for filing all Medicare claims. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27973), we again included a clarification that the regulations governing time limits for filing claims at § 424.44 apply to claims submitted for IME and direct GME payments associated with services provided to Medicare Advantage enrollees. The process that was established by PM A-98-21 is within the same framework of the preexisting methodology for submitting claims under Medicare Part A. Therefore, because IME and direct GME payments for services provided to Medicare Advantage enrollees are also made under Medicare Part A, the same timely filing requirements that apply to other Part A claims for payments also apply to claims for IME and direct GME payments for services provided to Managed Advantage enrollees. We also clarified once again in the proposed rule that when

hospitals submit claims for services provided to Medicare Advantage enrollees for additional IME and direct GME payments, the hospitals must comply with the regulations governing time limits for filing claims at § 424.44.

b. Nursing and Allied Health Education

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106-113) further amended section 1886 of the Act by adding subsection (l) to provide for additional payments to hospitals that operate nursing or allied health education programs and incur costs associated with services provided to Medicare+Choice (now Medicare Advantage) enrollees. Section 512 of the Benefits Improvement and Protection Act (BIPA) (Pub. L. 106-554) changed the formula for determining the additional payment amount paid to hospitals that operate nursing or allied health education programs and incur costs for services provided to Medicare+Choice (now Medicare Advantage) enrollees. We issued several PMs (Transmittals A-00-86 on November 22, 2000, and A-03-043 on May 23, 2003) to implement section 541 of the BBRA and section 512 of the BIPA. We also issued related Transmittal A-03-007 on February 3, 2003, and Transmittal A-03-045 on May 30, 2003, to instruct hospitals that operate a nursing or allied health education program and that qualify for additional payment related to services provided to Medicare Advantage enrollees to also submit those claims for processing as no-pay bills in the UB-92 format. These transmittals also instructed hospitals that are not paid under the IPPS, hospitals with rehabilitation and psychiatric units, and hospitals that operate approved nursing or allied health education programs (but may not have approved GME residency programs)

to submit claims for services provided to Medicare Advantage enrollees to their fiscal intermediary in UB-92 format with specific condition codes present. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27973), we clarified that the regulations governing the time limits for filing claims at § 424.44 also apply to claims submitted for nursing or allied health education program payments for services provided to Medicare Advantage enrollees.

c. Disproportionate Share Hospital (DSH) Payments

On July 20, 2007, we issued Change Request 5647 instructing applicable hospitals to submit no pay bills for their Medicare Advantage patients for FY 2007 forward in order for these days to be captured in the DSH calculation. Because we issued this request in the middle of FY 2007, we extended the deadline for submission of FY 2007 and FY 2008 no pay Medicare Advantage bills to August 31, 2010.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27973), we proposed to adopt a policy that hospitals that are required to submit no pay bills for services furnished on a prepaid capitation basis by a Medicare Advantage organization, or through cost settlement with either a health maintenance organization (HMO), a competitive medical plan (CMP), a health care prepayment plan (HCPP), or a demonstration, for the purpose of calculating the DSH patient percentage (DPP) must also do so within the time limits for filing claims specified at § 424.44. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50282), we changed our methodology for calculating the SSI fraction of the DSH adjustment, in part, by using claims information that is updated 15 months after the close of each Federal fiscal year. We believed that allowing for a 15-month run-out period

would more closely align the timing of the match process with the requirements for the timely submission of claims. As we stated in that final rule, hospitals may not have an incentive to submit no pay bills in as timely a manner as they would for fee-for-service claims. In order to ensure that no pay claims are properly incorporated into the DSH calculation, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27973), we proposed to extend our rules regarding the timely submission of claims to no pay bills submitted for the purposes of calculating the DPP.

We proposed to revise the regulations at § 424.30 to (1) clarify our existing policy that hospitals must file timely claims in order to receive supplemental IME, direct GME, and/or nursing or allied health education payments for Medicare Advantage enrollees and (2) propose that hospitals that are required to submit no pay bills for the purpose of calculating the DPP must also follow the time limits for filing claims.

d. Summary of Public Comments, Our Responses, and Final Policies

Comment: Two commenters stated that, although it is more time consuming to submit no pay bills, it is reasonable to apply the same timely filing requirements to no pay bills for supplemental direct GME, IME, nursing and allied health education, and DSH payments that are applied to other Medicare Part A claims.

Response: We appreciate the commenters' support.

Comment: Several commenters specifically addressed the clarification concerning the timely filing requirements that need to be met to receive supplemental IME and direct GME payments for Medicare Advantage enrollees. The commenters asked that CMS recognize that there are nuances related to shadow billing and that

"inherent complexities" can delay the processing of these claims. The commenters requested CMS to include in the final rule "…an estimate of the administrative and cost burdens to hospitals that result from the requirement to file a second shadow bill for each Medicare managed care discharge." The commenters also urged CMS to recognize that the policy related to GME payments is a new rule rather than a clarification of existing policy.

Response: We do not agree with the commenters that the clarification related to the timely filing requirements for supplemental direct GME and IME payments is a new rule as opposed to a clarification. As noted earlier in this preamble and in the proposed rule (77 FR 27973), to implement sections 1886(d)(11) and 1886(h)(3)(D) of the Act, which provide for an "additional payment amount" for services furnished to individuals who are enrolled in a Medicare Advantage plan under Medicare Part C, we issued two final rules in the **Federal Register** that specifically addressed IME and direct GME payments to teaching hospitals for services provided to Medicare Advantage enrollees (the FY 1997 IPPS final rule (62 FR 46003) and the FY 1998 IPPS final rule (63 FR 26341)). In addition, in July 1998, we (then HCFA) issued a Program Memorandum (PM), A-98-21, which outlined fiscal intermediary and standard system changes needed to process requests for IME and direct GME supplemental payments for services provided to Medicare Advantage enrollees. The PM explained that hospitals must submit their Medicare claims to the fiscal intermediary in UB-92 format in order for the standard system to process the claims so that hospitals may be paid the supplemental IME and direct GME payments for services provided to Medicare Advantage enrollees.

All claims submitted in UB-92 format are subject to the timely filing regulations at § 424.44. Therefore, in accordance with PM A-98-21, UB-92 claims submitted on behalf of Medicare Advantage enrollees have always been subject to the timely filing regulations at § 424.44. In this final rule, as we did in the proposed rule, we are clarifying that in order for a hospital to receive supplemental direct GME, IME, and/or nursing and allied health payments for Medicare Advantage enrollees, it must follow the regulations governing time limits for filing claims at § 424.44.

In response to the commenters who requested an estimate of the administrative and cost burden associated with the submission of a no pay bill for Medicare Advantage enrollees, the requirement for hospitals to follow the timely filing requirements in order to receive supplemental direct GME, IME, and/or nursing and allied health education payments for Medicare Advantage enrollees is a clarification and not a new policy proposal. Because we are clarifying this requirement rather than implementing a new requirement, we have concluded that there is no new cost or administrative burden associated with this requirement.

Comment: One commenter asserted that the policy of treating the submission of Part C claims for purposes of calculating direct GME and IME payments as subject to the Part A regulations regarding timely filing constituted a substantive rule, rather than an interpretive rule. As a result, the commenter stated that CMS could not have imposed this requirement without first undertaking rulemaking, and, thus, it was inappropriate for CMS to attempt to clarify this policy in the FY 2013 IPPS/LTCH PPS proposed rule.

The commenter noted that this argument had also been raised in Loma Linda vs. Sebelius (D.D.C. (2010)).

Response: We disagree. As a preliminary matter, we note that this issue was not addressed directly in the court's decision in Loma Linda vs. Sebelius because the case was decided on other grounds. Furthermore, as discussed in more detail above, IME and direct GME payments for services provided to Medicare Advantage enrollees are made under Medicare Part A. It has always been CMS' intent that the claims filing requirements under 42 CFR 424, including the time limits at 42 CFR 424.44, apply to those claims. Thus, we continue to believe it was appropriate for CMS to characterize the discussion in the proposed rule as a clarification of an existing policy, rather than as a new proposal.

After consideration of the public comments we received, in this final rule, we are restating our clarifications that when hospitals submit claims for services provided to Medicare Advantage enrollees for additional IME and direct GME payments, and for claims for nursing or allied health education program payments, the hospital must comply with the regulations governing time limits for filing claims at § 424.44. In addition, we are finalizing our proposal that hospitals that are required to submit no pay bills for the purpose of calculating the DPP must also follow the time limits for filing claims, and the proposed amendments to the regulations at § 424.30 to incorporate these requirements. Further, in this final rule, we are making minor technical revisions to the regulations at § 424.30 in order to further clarify the claims submission requirements.

3. Other Related Policy Changes

In sections IV.F. and IV.I. of the preamble of the FY 2013 IPPS/LTCH PPS proposed rule, we present other proposed policy changes relating to determining labor and delivery bed counts for purposes of the DSH payment adjustment and relating to determining FTE resident caps for direct GME and IME payment purposes that would have an effect on the IME payment adjustment. We refer readers to these same two sections of the preamble of this final rule where we address any public comments received and present the final policies.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 412.106)

1. Background

For the most recent background discussion regarding the Medicare payment adjustment for subsection (d) hospitals that serve a significantly disproportionate number of low-income patients, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51681).

As we did in the FY 2012 IPPS/LTCH PPS final rule, we are combining, under section IV.F.2. of this preamble, our discussion of FY 2013 proposed and final changes to the policies for counting beds in relation to the calculations for the IME adjustment at § 412.105(b) and the DSH payment adjustment at § 412.106(a)(1)(i) because the underlying concepts are similar, and we believe they should generally be interpreted in a consistent manner for both purposes.

2. Policy Change Relating to Treatment of Labor and Delivery Beds in the Calculation of the Medicare DSH Payment Adjustment and the IME Payment Adjustment

a. Background

Medicare's policy with respect to the treatment of labor and delivery services in the calculation of the Medicare DSH payment adjustment has undergone a number of changes over the years. (We refer readers to the background discussion regarding these policy changes in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43899 through 43901)). The most recent change in policy was adopted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule. Prior to FY 2010, our policy was to exclude from the count of inpatient days, for purposes of the Medicare DSH calculation, labor and delivery patient days associated with beds used for ancillary labor and delivery services when the patient did not occupy a routine bed prior to occupying an ancillary labor and delivery bed. This policy applied whether the hospital maintained separate labor and delivery rooms and postpartum rooms, or whether it maintained "maternity suites" in which labor, delivery, and postpartum services all occurred in the same bed. However, in the latter case, patient days were counted proportionally based on the proportion of (routine/ancillary) services furnished. (We refer readers to the example provided in the FY 2004 IPPS final rule (68 FR 45420) that describes how routine and ancillary days are allocated under this policy.)

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we revised our regulations to include in the disproportionate patient percentage (DPP) of the Medicare DSH payment adjustment all patient days associated with patients occupying labor and delivery beds once the patient has been admitted to the hospital as an inpatient, regardless of whether the patient days are associated with patients who occupied a routine bed prior

to occupying an ancillary labor and delivery bed. Our rationale for adopting this change was that the costs associated with labor and delivery patient days are generally payable under the IPPS. Although we adopted this change with respect to labor and delivery *patient* days, we did not make a similar change to our policy for counting hospital beds.

b. Policy Change

As we stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51682), our policy for counting hospital beds is to include bed days available for IPPS-level acute care hospital services. In the FY 2004 IPPS final rule (68 FR 45417), we stated that beds in a particular unit would be considered available for IPPS-level acute care hospital services if the services furnished in that unit were generally payable under the IPPS. Moreover, as stated above, our policy for counting patient days with respect to the Medicare DSH payment adjustment is to include patient days in units that provide services that are generally payable under the IPPS. Under our current policy, the services furnished to a labor and delivery patient are considered to be generally payable under the IPPS (74 FR 43900).

We recognize that, under our current policy, while the services furnished to a labor and delivery patient are considered to be generally payable under the IPPS, under § 412.105(b)(4), the bed where the services are furnished is not considered to be available for IPPS-level acute care hospital services.

As we discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27974 through 27975), upon further examination of our existing policies, we believe that if a patient day is counted because the services furnished are generally payable under the

IPPS, the bed in which the services were furnished should also be considered to be available for IPPS-level acute care hospital services. Accordingly, we believe it is appropriate to extend our current approach of including labor and delivery patient days in the DPP of the Medicare DSH payment adjustment to our rules for counting hospital beds for purposes of both the IME payment adjustment and the Medicare DSH payment adjustment. Specifically, because we have described labor and delivery patient days as being generally payable under the IPPS (74 FR 43900), we believe that the bed in which such services are furnished should also be considered to be available for IPPS-level acute care hospital services, and should be included in the count of beds available for IPPS-level acute care hospital services. The rules for counting hospital beds for purposes of the IME payment adjustment are codified in the IME regulations at § 412.105(b), which are cross-referenced in § 412.106(a)(1)(i) for purposes of determining the DSH payment adjustment.

In light of the similar policy rationales for determining patient days in the calculation of the Medicare DSH payment adjustment, and for determining bed days for both the Medicare DSH payment adjustment and the IME payment adjustment, we proposed to include labor and delivery bed days in the count of available beds used in the IME and DSH calculations. Moreover, we stated that our proposal to treat labor and delivery patient days and bed days the same is consistent with our approach with respect to the observation, swing-bed, and hospice days, which are excluded from both the patient day count and the available bed count. Accordingly, we proposed to revise the regulations at § 412.105(b)(4) to remove from the list of currently excluded beds those

beds associated with "ancillary labor/delivery services." We proposed that this regulation change would be effective for cost reporting periods beginning on or after October 1, 2012.

As we noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43900), our policy for counting labor and delivery patient days does not allow for the inclusion of days of labor and delivery patients who are not admitted to the hospital as inpatients. For example, if a woman presents at a hospital for labor and delivery services, but is determined by medical staff to be in false labor and is sent home without ever being admitted to the hospital as an inpatient, any days associated with such services furnished by the hospital would not be included in the DPP for purposes of the calculation of the Medicare DSH payment adjustment. For the same reason, days on which labor and delivery beds are used for such services also would be excluded from the count of available bed days.

Comment: A number of commenters stated that the current discrepancy in the treatment of labor and delivery for purposes of the patient day count and the bed day count is appropriate because labor and delivery services are typically not paid for by the Medicare program. The commenters further stated that, to the extent Medicare does pay for labor and delivery services, the Medicare program only pays for 1 percent of all births in the United States, as opposed to Medicaid, which, according to the National Bureau of Economic Research, pays for 41 percent of all births in the country. The commenters also stated that the low volume of Medicare labor and delivery patients justifies

excluding labor and delivery beds from a hospital's bed count for purposes of determining a hospital's qualification for status as an MDH.

Response: As we stated in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43900), we believe that the costs associated with services provided in a labor and delivery room are generally payable under the IPPS. The volume of labor and delivery services paid under the Medicare program, regardless of whether it is as low as asserted by the commenters, does not alter the fact that patients receiving these services are inpatients who are receiving an IPPS-level of care, whether or not paid under the Medicare program. A policy to exclude beds from a hospital's number of available beds based on the volume of services paid for by Medicare would create unpredictability with respect to the DSH and IME payment adjustments and could impose an undue burden on the agency and hospitals to monitor the volume of individual services to determine appropriate exclusions.

Comment: Commenters pointed to CMS' current policy with respect to nursery days. Specifically, the commenters noted that, under CMS' current policy, patient stays in a newborn nursery unit are included in the patient day count for purposes of the DSH calculation but are excluded from the DSH and IME bed counts. The commenters believed that this distinction is appropriate and, therefore, believed it would be appropriate for CMS to take a similar approach with respect to labor and delivery days.

Response: As we stated above, we believe inconsistencies between the patient day policies and the bed count policies are generally an inappropriate approach for implementing the DSH and IME payment adjustments. We appreciate the commenters'

pointing out the potential inconsistency with respect to the treatment of newborn nursery units. We will review our current approach to newborn nursery units and will consider addressing this issue in future rulemaking.

Comment: Commenters expressed concern that the Medicare hospital cost report and the cost reporting instructions would need to be amended to implement the policy proposal. Specifically, the commenters noted that the current definition of a labor and delivery bed on the cost report is inconsistent with CMS' policy proposal. The commenters also stated that the current hospital cost report does not allow for hospitals to report excluded labor and delivery bed days such as an outpatient bed day in a labor and delivery room.

Response: We appreciate the commenters' information regarding the need for changes to the Medicare hospital cost report and the cost reporting instructions. We plan to amend the cost reporting instructions to reflect our finalized change in policy and to allow for the proper reporting of labor and delivery bed days.

Comment: A number of commenters requested additional clarity regarding beds that would be included in the bed count. Specifically, the commenters asked if "maternity suites" in which labor, delivery, and postpartum services all occur in the same bed would be counted and if so whether the bed count would be split in the same manner that costs are split for apportionment purposes. The commenters also expressed confusion regarding hospitals that maintain separate labor and delivery rooms and postpartum rooms. The commenters stated that, in these situations, providers are concerned that including the ancillary beds would result in a "double counting" of beds.

Additionally, the commenters asked CMS to specifically identify whether certain beds, such as triage labor and delivery beds used for preadmission evaluation and assessment, are to be included in the bed count. In addition to expressing confusion about CMS' proposal, the commenters stated that they believed labor and delivery beds should not be counted if they are not licensed as routine beds.

Response: As stated above, our policy is to include in the bed count the bed days available for IPPS-level acute care services, or more specifically, the bed days of a particular unit if the services furnished in that unit are generally payable under the IPPS. We do not consider whether a bed is licensed under State law as a routine or ancillary bed, but rather whether the unit in which the bed is located is providing services generally payable under the IPPS. To the extent that the beds in a particular unit, whether maternity suite beds or ancillary labor and delivery beds, are furnishing services that are generally payable under the IPPS, such beds should be included in the bed count under our proposal. Furthermore, as stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27974 through 27975), the bed days of a patient not admitted as an inpatient are not included in a hospital's bed count. Because our proposal is intended to align our patient day and bed day policies, we also refer readers to our discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43899 through 43901) for further information regarding our policy on counting labor and delivery patient days.

We also do not share the commenters' concern regarding the "double counting" of bed days for the IME and DSH payment adjustments. Under our existing policies, we include all beds in a unit that is providing services that are generally payable under the

IPPS because we believe such beds to be *available* for IPPS-level acute care hospital services. Therefore, unoccupied ancillary labor and delivery beds would still be included in a hospital's bed count under our proposal because they are available for IPPS-level acute care hospital services.

Comment: Commenters noted that currently the Medicare hospital cost report does not allow for labor and delivery patient days to be counted in the direct GME patient load. The commenters believed that, because these patient days are considered inpatient days, they should be considered a patient day for purposes of allocating costs for direct GME.

Response: We thank the commenters for bringing this issue to the agency's attention. We will undertake a further review to determine if it is necessary to make any changes to the way patient days are reported on the cost report, and whether those patient days should be included or excluded from the calculation of the Medicare patient load.

Comment: One commenter requested that CMS begin implementation of the Affordable Care Act amendments to the DSH payment adjustment provisions of the Act through this rulemaking.

Response: We believe that this comment is outside of the scope of the FY 2013 proposed rule. The statutory changes made by the Affordable Care Act relating to the DSH payment adjustment do not go into effect in FY 2013 and were not addressed in the FY 2013 proposed rule.

Comment: Commenters expressed concern about the impact of our proposal on the calculation of transitional corridor payments under the OPPS for SCHs. The

commenters noted that the outpatient hold harmless payments are derived by comparing Medicare payments to adjusted Medicare costs. Because these payments and costs do not reflect costs associated with labor and delivery beds, the commenters stated that they believe these costs should not count toward determining whether a hospital qualifies for hold harmless payments under the OPPS.

Response: We agree with the commenters that the revision to the regulations at § 412.105(b)(4) to remove from the list of currently excluded beds those beds associated with "ancillary labor/delivery services" could impact the qualification of certain hospitals for hold harmless payments under the OPPS, Under section 3002 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96), temporary outpatient hold harmless payments to small rural hospitals, small SCHs, and small Essential Access Community Hospitals (EACHs) are extended through the end of CY 2012. Under the hold harmless provisions at § 419.70(d), hospitals that have 100 or fewer beds, as defined in § 412.105(b), may result in bed counts for hospitals currently eligible for OPPS hold harmless payments going above the 100-bed limit. However, we do not agree with the commenters that labor and delivery beds should be excluded from the bed count under § 412.105(b) as it applies to the qualification for OPPS hold harmless payments. Rather, we believe that it is appropriate to continue to determine hospital size with regard to OPPS hold harmless eligibility based on the hospital's bed count as determined under § 412.105(b)(4).

After consideration of the public comments we received, we are adopting our proposed policy without modification. In summary, we are revising the regulations at

§ 412.105(b)(4) to remove from the list of currently excluded beds those beds associated with "ancillary labor/delivery services."

G. Expiration of the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

Under current law, separate special payment protections are provided to a Medicare-dependent, small rural hospital (MDH) under the IPPS through the end of FY 2012. (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684.) The provisions for MDHs at section 1886(d)(5) of the Act expire at the end of FY 2012 (that is, with discharges occurring on September 30, 2012). As we discussed in the FY 2012 IPPS/LTCH PPS final rule, section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). Under prior law, as specified in section 5003(a) of Pub. L. 109-171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only. Section 3124(a) of the Affordable Care Act amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to extend the MDH program and payment methodology from the end of FY 2011 to the end of FY 2012, by striking "October 1, 2011" and inserting "October 1, 2012". Section 3124(b) of the Affordable Care Act also made conforming amendments to sections 1886(b)(3)(D) and 1886(b)(3)(D)(iv) of the Act. Section 3124(b)(2) of the Affordable Care Act also amended section 13501(e)(2) of OBRA 1993 to extend the provision permitting hospitals

to decline reclassification through FY 2012. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287 and 50414), we amended the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the statutory extension of the MDH program through FY 2012. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), we did not make any additional changes to the MDH regulatory text for FY 2012.

Because the MDH program is not authorized by statute beyond FY 2012, beginning in FY 2013, all hospitals that previously qualified for MDH status will no longer have MDH status and will be paid based on the Federal rate. (We note that, in section IV.B.3. of this preamble, we are finalizing our proposal to revise our SCH policies to allow MDHs to apply for SCH status and be paid as such under certain proposed conditions, following expiration of the MDH program.) For the FY 2013 impact of the expiration of the MDH program at the end of FY 2012, we refer readers to section I.G.2.j. of Appendix A to this final rule.

Comment: Several commenters expressed concern with the expiration of the MDH program, citing serious detrimental effects that would result to patients, hospitals, and communities. The commenters strongly encouraged the continuation of the MDH program.

Response: The MDH program, which provides special treatment of and payment to small, rural, Medicare-dependent hospitals, was authorized by statute. In order for the MDH program to continue, or in order to reinstate it once it expires, legislation is required. CMS does not have the authority, without statutory provision, to continue the MDH program.

H. Changes in the Inpatient Hospital Update

1. FY 2013 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient operating costs by a factor called the "applicable percentage increase." Prior to enactment of the Affordable Care Act, section 1886(b)(3)(B)(i)(XX) of the Act set the applicable percentage increase equal to the rate-of-increase in the hospital market basket for subsection (d) hospitals (hereafter referred to as "IPPS hospitals") in all areas, subject to the hospital submitting quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act. For hospitals that did not provide these data, the update was equal to the market basket percentage increase less an additional 2.0 percentage points. The update for the hospital-specific rates for SCHs is set by section 1886(b)(3)(B)(iv) of the Act as discussed further below.

Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2013 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas (which is currently based on a forecast of the FY 2006-based IPPS market basket), subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.1 percentage point. Sections 1886(b)(3)(B)(xi) and

(b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2013 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27975 and 27976), we stated that, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. We also stated in the proposed rule that, for FY 2013, we were not proposing to make any change in our methodology for calculating and applying the MFP adjustment. Similar to the market basket increase, we are using the most recent data available for this final rule to compute the MFP adjustment. Using the methodology that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51690), in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27975), based on IHS Global Insight, Inc.'s (IGI's) first quarter 2012 forecast of multifactor productivity (MFP), we proposed an MFP adjustment (the 10-year moving average of MFP for the period ending FY 2013) of 0.8 percent.

Consistent with current law, and based on IGI's first quarter 2012 forecast of the FY 2013 market basket increase, we proposed an applicable percentage increase to the FY 2013 operating standardized amount of 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage points for economy-wide productivity (the MFP adjustment) and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance

with our rules. For hospitals that do not submit quality data, we proposed an applicable percentage increase to the operating standardized amount of 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.8 percentage points for economy-wide productivity, and less an additional adjustment of 0.1 percentage point). In the proposed rule, we stated that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2013 market basket update and MFP adjustment in the final rule.

We did not receive any public comments on these proposals to implement the applicable percentage increase. For this final rule, using the most recent data available, consistent with current law, and based on IGI's second quarter 2012 forecast of the FY 2013 market basket increase, we are finalizing an applicable percentage increase to the FY 2013 operating standardized amount of 1.8 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent less an adjustment of 0.7 percentage point for economy-wide productivity (that is, the MFP adjustment) and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data under rules established in accordance with section 1886(b)(3)(B)(viii) of the Act in accordance with our rules. For hospitals that do not submit these quality data, we are finalizing an applicable percentage increase to the operating standardized amount of -0.2 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent, less 2.0 percentage points for failure to submit quality data, less an

adjustment of 0.7 percentage point for the MFP adjustment, and less an additional adjustment of 0.1 percentage point).

In the proposed rule, we proposed to revise the existing regulations at 42 CFR 412.64(d)(1)(iv) to reflect the current law for the FY 2013 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we proposed to revise paragraph (d)(1)(iv) to reflect the applicable percentage increase to the FY 2013 operating standardized amount as the percentage increase in the market basket index, subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to a multifactor productivity adjustment and, lastly, subject to the additional reduction of 0.1 percentage point. We did not receive any public comments on this proposal. Therefore, in this final rule, we are adopting as final, without modification, the proposed changes to § 412.64(d)(1)(iv) to reflect current law.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27976), we proposed an update to the hospital-specific rates applicable to SCHs of 2.1 percent for hospitals that submit quality data or 0.1 percent for hospitals that fail to submit quality data. For FY 2013, the

regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e) and 412.78(e) already contain provisions that set the update factor for SCHs equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, we did not propose to make further changes to these four regulatory provisions to reflect the FY 2013 update factor for the hospital-specific rates of SCHs. We did not receive any public comments on this proposal. Therefore, for this final rule, we are finalizing an update to the hospital-specific rates applicable to SCHs of 1.8 percent for hospitals that submit quality data or -0.2 percent for hospitals that fail to submit quality data. As we noted above, for the proposed rule, we used the first quarter 2012 forecast of the FY 2006-based IPPS market basket with historical data through fourth quarter 2011. For this final rule, we used the most recent data available, which was the second quarter 2012 forecast of the FY 2006-based IPPS market basket with historical data through first quarter 2012. Similarly, for the proposed rule, we used IGI's first quarter 2012 forecast of MFP. For this final rule, we used the most recent data available, which was IGI's second quarter 2012 forecast of MFP.

We note that, as discussed in section IV.G. of this preamble, section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). Under prior law, the MDH program was to be in effect through the end of FY 2011 only. Absent additional legislation further extending the MDH program, the MDH program will expire for discharges beginning in

FY 2013. Accordingly, we are not including MDHs in our update to the hospital-specific rates for FY 2013.

2. FY 2013 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Pub. L. 108-173 amended section 1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27976), we proposed an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 2.1 percent for FY 2013. The regulations at § 412.211(c) already set the update factor for the Puerto Rico-specific operating standardized amount equal to the update factor applied to

the national standardized amount for all IPPS hospitals. Therefore, it is not necessary for us to make changes to the existing regulatory text.

We did not receive any public comments on this proposal. Therefore, for this final rule, we are finalizing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.8 percent for FY 2013. As we noted above, for the proposed rule, we used the first quarter 2012 forecast of the FY 2006-based IPPS market basket with historical data through fourth quarter 2011. For this final rule, we used the most recent data available, which was the second quarter 2012 forecast of the FY 2006-based IPPS market basket with historical data through first quarter 2012. Similarly, for the proposed rule, we used IGI's first quarter 2012 forecast of MFP. For this final rule, we used the most recent data available, which was IGI's second quarter 2012 forecast of MFP.

I. Payment for Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs (§§ 412.105, 413.75 through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base

period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the hospital inpatient prospective payment system (IPPS) for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and

osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident count for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than their caps, and to authorize the "redistribution" of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503 amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions "in the same manner" to the IME FTE resident caps. The regulations implementing section 5503 of the Affordable Care Act were included in the November 24, 2010 final rule with comment period (75 FR 72263).

2. Teaching Hospitals: Change in New Program Growth from 3 Years to 5 Years

Section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for calculating the direct GME caps of teaching hospitals training residents in new programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, these rules also apply to the establishment of a hospital's IME cap. CMS implemented these statutory requirements in the August 29, 1997 **Federal Register** (62 FR 46005) and in the May 12, 1998 **Federal Register** (63 FR 26333). Generally, under existing regulations at 42 CFR 413.79(e)(1) and 42 CFR 412.105(f)(1)(vii), if a hospital did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins to participate in training residents in a new residency program (allopathic or osteopathic) on or after January 1, 1995, the hospital's unweighted FTE resident cap (which would otherwise be zero) may be adjusted based on the sum of the product of the highest number of FTE residents in any program year during the third year of the first new program, for each new residency training programs established during that 3-year period, and the minimum accredited length for each type of program. The number of FTE resident cap slots that a teaching hospital receives for each new program may not exceed the number of accredited slots that are available for each new program. Once a hospital's FTE resident cap is established, no subsequent cap adjustments may be made for new programs unless the teaching hospital is a rural hospital. A rural hospital's FTE resident caps may be adjusted for participation in subsequent new residency training programs. As a reminder, a hospital that did not train any allopathic or osteopathic residents in its most recent cost

reporting period ending on or before December 31, 1996, may only receive a permanent FTE resident cap adjustment for training residents in a truly "new" residency training program; no permanent cap adjustment would be given for training residents associated with an existing program. That is, if a hospital that did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, serves as a training site for residents in a program that exists or existed previously at another teaching hospital that remains open, that "new" teaching hospital does not receive a "new program" cap adjustment because it is not participating in training residents in a truly "new" program. However, it is possible for that hospital to receive a temporary cap adjustment if it enters into a Medicare GME affiliation agreement with the existing teaching hospital as specified at 42 CFR 413.79(f) and 412.105(f)(1)(vi). (For a detailed discussion of the distinctions between a new residency program and an existing residency program, we refer readers to the August 27, 2009 final rule (74 FR 43908).)

As stated previously, the existing regulations provide for a 3-year period in which a teaching hospital can "grow" its programs, for the purpose of establishing its FTE resident caps. This 3-year period, which we will refer to as the "3-year window" for ease of reference, starts when the teaching hospital first begins to train residents in its first new program, typically on July 1, and it ends when the third program year of that first new program ends. For example, assume residents begin training in a new program for the first time on July 1, 2012. The 3-year window begins on July 1, 2012, and ends on June 30, 2015, the end of the third program year of that (first) new program. At this point in

time, regardless of the actual accredited length of the new program, or the number of new programs started, the teaching hospital's FTE resident caps are established permanently and are effective beginning with the fourth program year from the date the first new program started (using the same example, this would be July 1, 2015). We note that there are several "types" of hospitals that can receive a permanent cap adjustment for training FTE residents in a new program. A hospital that has never before trained any residents and begins training FTE residents in its first new program can receive a permanent cap adjustment. A hospital that previously trained FTE residents in an existing program(s) and begins training FTE residents in its first new program can receive a permanent cap adjustment. A rural hospital can always receive a permanent cap adjustment for each new program it begins. That is, a rural hospital enters a cap-building period for each new residency training program it begins, not just for its first new residency training program. Because all of these hospitals could qualify to receive a permanent cap adjustment for training FTE residents in a new residency training program, we refer to these hospitals as "qualifying" hospitals throughout the remainder of this preamble.

Prior to issuance of the proposed rule, the provider community expressed concerns that 3 years do not provide for a sufficient amount of time for a hospital to "grow" its new residency programs and to establish FTE resident caps that are properly reflective of the number of FTE residents that it will actually train, once the programs are fully grown. Providers explained that 3 years is an insufficient amount of time primarily because a period of 3 years is not compatible with program accreditation requirements, particularly in instances where the qualifying teaching hospital wishes to start more than

one new program. For example, we understand that a qualifying teaching hospital may not begin all of its new programs at the same time because of accreditation prerequisites; rather, a qualifying teaching hospital must wait until the first program is in place for a specified amount of time before it can begin training residents in a second or third program. This potential delay means that a qualifying teaching hospital may not be able to sufficiently "grow" all of its new programs by the end of the "3-year window." We understand, for example, that the Accreditation Council for Graduate Medical Education (ACGME) requires that, for a hospital to sponsor an anesthesiology program, the hospital must sponsor or be affiliated with at least one internal medicine program and one general surgery program. Furthermore, we understand that the ACGME can require new residency training programs to pass through an "initial" accreditation period of up to 3 years until they can be granted "continued" accreditation. During this initial accreditation period, a hospital is not allowed to add any additional positions to its new program. Therefore, even if a hospital has plans to expand its new training program beyond the number of positions for which it is initially accredited, it may not be possible for the hospital to actually do so until this initial period has expired. Lastly, we were made aware that providers may want to stagger the start dates for their residency training programs if they plan on training residents in several programs because they may want to gain some experience in residency training before they begin all of their new programs.

Given the concerns about teaching hospitals having insufficient time to "grow" their new residency training programs and to establish an appropriately reflective permanent FTE resident cap within a 3-year window, in the FY 2013 IPPS/LTCH PPS

proposed rule (77 FR 27978), we proposed that a teaching hospital will have 5 years, or a "5-year window," in which to establish and grow new programs. At the end of the fifth program year of the first new program in which the teaching hospital participates, the teaching hospital's FTE resident caps would be determined, and set permanently, effective with the beginning of the sixth program year. We proposed that this change would apply to teaching hospitals that begin training residents in new programs for the first time on or after October 1, 2012. Although we understand that many residency training programs begin July 1 of the calendar year, consistent with the proposed effective date of the FY 2013 IPPS provisions in the proposed rule, we proposed an effective date for this change of October 1, 2012. We proposed to amend the regulations at § 413.79(e)(1) to state that if a teaching hospital participates in training residents in a new program for the first time on or after October 1, 2012, the teaching hospital's FTE resident cap may be adjusted based on the product of the highest number of FTE residents training in any program year during the fifth year of the first program's existence for all new residency training program(s) and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. We proposed that this policy would apply to the establishment of a hospital's cap for both direct GME and IME payment purposes. The IME regulations at § 412.105(f)(1)(vii) refer to the direct GME regulations at § 413.79(e)(1) through (e)(4) for the rules for the establishment of a new teaching hospital's cap. As is required under existing regulations, the number of cap slots associated with each new

program cannot exceed the number of accredited slots available to the hospital for that new program.

We note that we did not propose to make any changes to regulations governing treatment of the rolling average and the intern and resident-to-bed (IRB) ratio for new programs. That is, new program FTE residents will continue to be exempt from the rolling average and the cap on the IRB ratio for the minimum accredited length for the specific type of residency training program. These exceptions are discussed in the regulations at §§ 412.105(a)(1)(i) through (a)(1)(ii) and 413.79(d)(5). The current cost report instructions for Form CMS-2552-10, Worksheet E-4, Line 6 (current year unweighted allopathic and osteopathic FTE count) instruct hospitals to contact their Medicare contractor for instructions on how to complete that line if the hospital has a new program for which the period of years is less than or greater than 3 years. Similarly, in the case of the proposed policy where the exemption from the rolling average for a new program could expire prior to the hospital's cap being set in the sixth year of the first new program, we stated that we would encourage hospitals to contact CMS if they have questions on the method of reporting FTE resident counts for FTE residents in new programs that are subject to the rolling average but not subject to the cap.

We also proposed to revise the regulations at § 413.79(e)(1)(i) that discuss the methodology used to calculate a qualifying teaching hospital's cap adjustment for a new residency training program if residents training in the new program are rotating to more than one hospital during the 5-year window. We proposed to revise the regulations to specify that, in calculating the cap adjustment for each new program started within the

5-year window, we would look at the highest total number of FTE residents training in any program year during the fifth academic year of the first new program's existence at all participating hospitals to which these residents rotate and multiply that highest FTE resident count by the number of years in which residents are expected to complete the program, based on the minimum accredited length of the specific program. Furthermore, we proposed that, for each new program started within the 5-year window, we would take that product and multiply it by each hospital's ratio of the number of FTE residents in that new program training over the course of the 5-year period at each hospital to the total number FTE residents training in that new program at all participating hospitals over the course of the 5 years. We believed it was appropriate to propose to apportion the overall FTE cap among the hospitals participating in training residents in the new program based on the percentage of FTE residents each hospital trained over the course of the entire 5-year period, rather than the percentage of FTE residents each hospital trained only during the fifth academic year, because the trend of training over the entire 5 years may reflect more completely the patterns in the training in years subsequent to the fifth academic year. Otherwise, a hospital's FTE cap adjustment, which is permanent, may reflect too heavily the share of training time solely in the fifth academic year, which may or may not be beneficial to the hospital. We noted that a hospital's cap adjustment could differ, depending on whether we look only at the fifth academic year of the first new program or look at every available year (up to 5 years) for which training occurred to calculate each hospital's share of the aggregate cap for a specific program.

In addition, we proposed to revise the existing regulation text at § 413.79(e)(1)(i) to include the phrase "the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program." This proposed language is consistent with our past, current, and proposed policy. We also noted that § 413.79(e)(1) applies in instances where the residents in the new program train only at one hospital; § 413.79(e)(1)(i) applies when residents in the new program train at more than one hospital, regardless of whether each of those hospitals are hospitals that qualify for a permanent cap adjustment or existing teaching hospitals with previously established caps. The example below illustrates the methodology we proposed to use to calculate a qualifying teaching hospital's cap if we changed the cap-building period from 3 years to 5 years. In this example, as explained above, we proposed that we would calculate the cap based on what is occurring at the qualifying teaching hospital(s) during the fifth academic year of the qualifying teaching hospital's first new program (or the fifth academic year of the rural teaching hospital's new residency training program). The provider community has requested that the cap-building period be increased from 3 years to 5 years. Therefore, we proposed that we would only look at the training that is occurring during the fifth academic year of the first new program to calculate the aggregate cap adjustment. However, we proposed that we would look at the FTE residents training at the hospital(s) during all 5 years to determine how we would distribute the aggregate cap adjustment among the participating hospitals. We included the following example in the proposed rule:

Example: Hospital A is a hospital that becomes a new teaching hospital by training residents in a new family medicine program in academic year 1. Within its 5-year window, it also begins a new surgery program in academic year 4 of the first new program, the family medicine program. The family medicine program is accredited for 15 positions, 5 positions per year (the minimum accredited length of a family medicine program is 3 years). The surgery program is accredited for 20 positions, 4 positions per year (the minimum accredited length of a surgery program is 5 years). Residents in both the family medicine program and the surgery program also rotate to Hospital B. Hospital B is an existing teaching hospital (nonrural) with a cap that is already established; therefore, it will not receive any cap adjustments for training FTE residents in the new family medicine program or the new surgery program. However, because both of these programs are approved programs and FTE residents are training at Hospital B for part of the time, Hospital B can receive payment for the FTE residents training in the family medicine program and the surgery program at its hospital if it has room under its caps.

First, we would determine the cap adjustment that Hospital A will receive for training FTE residents in the family medicine program. The following table includes the allowable FTE resident counts in the family medicine program at both Hospital A and Hospital B during the 5-year window. These numbers are FTE resident counts because they reflect the share of training time spent at Hospital A and Hospital B, and also assume for this example that we have excluded some nonallowable time, such as the time residents spend training in didactic activities in a medical school lecture hall.

Hospital A

Year 1	Year 2	Year 3	Year 4	Year 5
0.75 PGY 1 0.00 PGY 2 0.00 PGY 3	2.60 PGY 1 2.80 PGY 2 0.00 PGY 3	4.00 PGY 1 3.40 PGY 2 2.40 PGY 3	4.10 PGY 1 3.40 PGY 2 2.80 PGY 3	4.20 PGY 1 3.70 PGY 2 2.80 PGY 3
Total 0.75	Total 5.40	Total 9.80	Total 10.30	Total 10.70

Hospital A's 5 year total = 36.95.

Hospital B

Year 1	Year 2	Year 3	Year 4	Year 5
3.75 PGY 1 0.00 PGY 2 0.00 PGY 3	2.20 PGY 1 2.00 PGY 2 0.00 PGY 3	0.90 PGY 1 1.50 PGY 2 2.40 PGY 3	0.80 PGY 1 1.50 PGY 2 2.00 PGY 3	0.60 PGY 1 1.20 PGY 2 2.00 PGY 3
Total 3.75	Total 4.20	Total 4.80	Total 4.30	Total 3.80

Hospital B's 5 year total = 20.85.

Total Hospital A and Hospital B over 5 years = 36.95 + 20.85 = 57.80 FTEs.

To calculate the cap adjustment for Hospital A with respect to the family medicine program, we need to take the highest number of FTE residents training in any program year in this program (that is, FTE residents training at both Hospital A and Hospital B) in the fifth year of the first new program's existence (which is the family medicine program). If we add the PGY 1s, the PGY 2s, and the PGY 3s at both hospitals, in year 5, we see that we would use the total number of PGY 2s to calculate the FTE cap adjustment for the family medicine program, because the total number of PGY 2s at both hospitals is 4.90 FTEs (3.70 + 1.20), whereas the total number of PGY 1s and PGY 3s is only 4.80. We multiply 4.90 by the minimum accredited length of the family medicine

program to get the total possible cap adjustment for the family medicine program (4.90 x 3 = 14.70). The cap adjustment that Hospital A receives for the family medicine program will be some number less than 14.70 based on the ratio of the number of FTEs in the new program training over the course of the 5-year period at Hospital A to the total number FTE residents training at both hospitals over the course of the 5-year period.

To determine this ratio, note that Hospital A's total FTE residents in the new family medicine program over the course of 5 years is the numerator, 36.95. The total FTE residents at Hospitals A and B in the new family medicine program over the course of 5 years is the denominator, 57.80 (that is, 36.95 + 20.85). The ratio of training that occurred at Hospital A is 36.95/57.80 = 0.64. Therefore, Hospital A's cap for its share of the family medicine program is 0.64 x 14.70, or 9.41. (If Hospital B had been eligible to receive a cap adjustment, its ratio of the cap would have been 0.36, that is, (20.85/57.80), and its share would have been 5.30 (0.36 x 14.70). If we add 9.41 to 5.30, we get 14.71 (we note that 14.71 is "approximately" equal to 14.70, the total cap determined for the entire family medicine program, with a slight difference due to rounding). Thus, we have ensured that, in assigning a cap of 9.41 to Hospital A on behalf of its family medicine program, the total allowable and accredited number of slots has not been exceeded).

Now we will determine the cap adjustment that Hospital A will receive for training FTE residents in the new surgery program that began in year 4 of the first new program. The following tables include the allowable FTE resident counts in the surgery program at Hospital A and Hospital B, respectively, during the hospital's 5-year window.

Again, assume we have excluded nonallowable time, such as time residents spent training in didactic activities in a medical school lecture hall.

Hospital A

Year 1	Year 2	Year 3	Year 4	Year 5
0.00 PGY 1	0.00 PGY 1	0.00 PGY 1	4.10 PGY 1	4.20 PGY 1
0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	2.70 PGY 2
0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3
0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4
0.00 PGY 5	0.00 PGY 5	0.00 PGY 5	0.00 PGY 5	0.00 PGY 5
Total 0.00	Total 0.00	Total 0.00	Total 4.10	Total 6.90

Hospital A's 5 year total = 11.00.

Hospital B

Year 1	Year 2	Year 3	Year 4	Year 5
0.00 PGY 1	0.00 PGY 1	0.00 PGY 1	1.70 PGY 1	0.60 PGY 1
0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	1.50 PGY 2
0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3
0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4
0.00 PGY 5	0.00 PGY 5	0.00 PGY 5	0.00 PGY 5	0.00 PGY 5
Total 0.00	Total 0.00	Total 0.00	Total 1.70	Total 2.10

Hospital B's 5 year total = 3.80.

Total Hospital A and Hospital B over 5 years = 11.00 + 3.80 = 14.80 FTEs.

To calculate the cap adjustment for Hospital A with respect to the surgery program, we need to take the highest number of FTE residents training in this program (that is, FTE residents training at both Hospital A and Hospital B) in the fifth year of the

first new program's existence (which is the family medicine program). Because the surgery program only started in Year 4 of the family medicine program, there are only PGY 1s and PGY 2s training at both Hospitals A and B in year 5; thus, we consider the surgery PGY 1s and PGY 2s in year 5 of the family medicine program. If we add the PGY 1s and the PGY 2s at both hospitals in year 5, we see that we would use the total number of PGY 1s to calculate the FTE cap adjustment for the surgery program, because the total number of PGY 1s is 4.80 FTEs (4.20 + 0.60), whereas the total number of PGY 2s is only 4.20. However, because the regulations do not permit a hospital to count more FTE residents in each program year than what the program is approved for (in this example, 4 FTE residents for each program year), we must multiply 4.0 by the minimum accredited length of the surgery program to get the total possible cap adjustment for the surgery program (4.0 x 5 = 20). That is, because the surgery program is only accredited for 20 positions, the overall FTE resident cap associated with the surgery program that is to be apportioned between Hospital A and Hospital B is limited to a maximum of 20. The cap adjustment that Hospital A receives for the surgery program will be some number less than 20 and is based on the ratio of the number of FTE residents in the new program training over the course of the 2-year period at Hospital A to the total number FTEs training at both hospitals over the course of the 2-year period.

To determine this ratio, note that Hospital A's total FTE residents in the new surgery program over the course of 2 years is the numerator, 11.00. The total number of FTE residents at Hospitals A and B in the new surgery program over the course of 5 years is the denominator, 14.80 (that is, 11.00 + 3.80). The ratio of training that occurred

at Hospital A is 11.00/14.80 = 0.74. Hospital A's cap for its share of the surgery program is 0.74 x 20 = 14.80. (If Hospital B had been eligible to receive a cap adjustment, its share of the cap would have been 5.20 ((3.80/14.80) x 20) = 5.20. Thus, we have ensured that, in assigning a cap of 14.80 to Hospital A on behalf of its surgery program, the total allowable and accredited number of slots has not been exceeded).

Adding together the cap adjustment Hospital A receives for the new family medicine program and the cap adjustment it receives for the new surgery program, Hospital A's total permanent cap is 24.21 (9.41 + 14.80 = 24.21).

In summary, we proposed to revise the regulations at § 413.79(e)(1) for the purposes of direct GME and, by reference, § 412.105(f)(1)(vii) for purposes of IME to state that if a hospital begins training residents in a new program for the first time on or after October 1, 2012, that hospital's caps may be adjusted based on the product of the highest number of FTE residents training in any program year during the fifth academic year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The cap would be applied beginning with the sixth academic year of the first new program. We also proposed conforming changes throughout paragraph (e)(1) of § 413.79 to correspond with the proposed change to increase the length of the cap-building period from 3 to 5 years. In addition, we proposed to change the regulation text at § 413.79(e)(1)(i) to reflect a methodology to calculate a qualifying teaching hospital's cap adjustment if the residents in the new training program are training at more than one hospital. We proposed that these changes

would be effective for a hospital that begins training residents for the first time on or after October 1, 2012. Lastly, we proposed to make a clarification to the existing regulation text at § 413.79(e)(1)(i) to insert the missing phrase "and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program." This change is consistent with our past, current, and proposed policy.

Comment: Commenters supported extending the cap-building period for a new teaching hospital from 3 years to 5 years. Commenters stated that the proposal provided an accurate characterization of challenges that a hospital may face with trying to establish a cap within a 3 year period. Commenters stated that extending the cap-building period from 3 years to 5 years would permit new teaching hospitals to meet accreditation requirements and grow programs in order to help address the country's physician shortage and provide greater flexibility in the timeline for starting new programs. Another commenter stated that the extension from 3 to 5 years is generally an improvement and provides teaching hospitals with time to reach a steady number of FTE residents and allows the hospital to find residents that may be a better fit for a specific residency training program. The commenters stated they believe that 5 years is likely a sufficient period of time because many new programs will fill their higher PGY levels by accepting transfer residents from other programs rather than just filling up only the PGY1 level.

Several commenters supported extending the cap-building period from 3 to 5 years because creating a new teaching hospital involves collaboration among several

different participants, for example medical schools and nonteaching hospitals, and also requires interactions with regulatory bodies and accrediting agencies. The commenters stated that, in addition to a 3-year window being a challenge due to the number and variety of participants involved in establishing a new teaching hospital, 3 years is based on "…an unreasonable and aggressive expectation that an organization can establish its desired complement of training programs nearly simultaneously in such a period while ensuring a high-quality educational experience for residents and fellows and a seamless transition from a nonteaching to a teaching service care model for Medicare beneficiaries." The commenters stated it is not appropriate to limit hospitals' access to GME payments based on factors that the hospitals cannot control, such as ACGME and National Resident Matching Program requirements and timelines. Another commenter stated that a cap-building period of 5 years will permit four community hospitals that are considering building GME programs in Northeast Georgia to grow their programs more fully and with greater flexibility. One commenter stated that extending the cap-building period to 5 years will aid it in its collaboration with a school of medicine to support their efforts of training residents in areas across Indiana where no residency training programs previously existed. Another commenter stated the proposed change from 3 years to 5 years will promote the establishment of needed residency programs by establishing caps that reflect the number of FTE residents that a hospital will be able to train once the programs have matured and will give new teaching hospitals more time to make the necessary initial investment of resources. The commenter stated that expanding residency training programs will help address the physician shortage in Arizona that is

expected to grow as a result of an aging population and increased insurance coverage under the Affordable Care Act. One commenter stated that it supported a 5-year window because it will aid in developing new emergency medicine residencies, extending emergency medical residencies from 3 years to 4 years, and meeting the needs of other specialty residency training programs that want to expand their programs to the maximum number of accredited positions. Another commenter supported the expansion from a 3-year window to a 5-year window and encouraged CMS to revisit this policy in several years to confirm that 5 years is an adequate amount of time for the cap-building process.

One commenter stated it understood that, due to accreditation rules, it is very difficult for a new teaching hospital to start several residency training programs within the current 3-year window. The commenter stated that it understood that if a new teaching hospital tries to start a second program during its 3-year window, it is almost impossible to start that second program before the third year of the hospital's 3-year window. The commenter noted that it understood the ACGME has a reasonable expectation that new teaching hospitals need to gain experience training residents and have a strong educational infrastructure in place before they start to train residents in specialty residency training programs. The commenter stated that if a new teaching hospital is only really provided with one year to start a second residency training program, the hospital is forced to be aggressive in filling a full cohort of first-year residents, which may be neither in the hospital's nor the residents' best interest. The commenter stated that extending the cap-building period from 3 years to 5 years will

allow teaching hospitals to build residency training programs "…that will best serve the patients in their community and provide a strong educational infrastructure for their residents."

Response: We appreciate the commenters' support of our proposal to expand the cap-building period from 3 years to 5 years. Therefore, we are finalizing our proposal to provide qualifying teaching hospitals with a 5-year window to grow their cap. The 5-year window will begin once the qualifying teaching hospital first starts training residents in its first new program and the cap will apply beginning with the sixth program year of the first new program. In response to the commenters who stated that a 5-year window is a sufficient period of time for building a hospital's cap because new programs may accept transfer residents from other programs rather than filling only PGY1 slots, we remind hospitals that filling a program with transfer residents from other hospitals' existing residency training programs may jeopardize the program's status as "new." As we explained in the August 27, 2009 **Federal Register** (74 FR 43908), one of the factors CMS considers in determining whether a residency training program can be considered a new program for Medicare GME payment purposes is whether residents entering a program are new residents or residents transferring from an existing program(s).

Comment: Although commenters supported extending the cap-building period from 3 years to 5 years, many did not support making the policy effective for new teaching hospitals that first begin to train residents in their first new program on or after October 1, 2012. Commenters requested that the extension of the cap-building period from 3 to 5 years apply to new teaching hospitals that are currently within their 3-year

window, new teaching hospitals that started training residents for the first time in a new program on or after July 1, 2010, or at the very least apply effective July 1, 2012. Commenters stated that new teaching hospitals that are currently within the 3-year window are facing the same challenges that CMS described in the proposed rule and deserve to benefit from a 5-year window. Commenters stated that CMS would be able to apply the 5-year window without any additional administrative burden on its part. One commenter requested that, because a new teaching hospital that begins training residents July 2010 would begin the third year of its cap-building period July 1, 2012 and would not have its caps set until July 1, 2013, CMS amend its proposed regulation text to apply the 5-year window to a hospital that first begins training residents in a new program for the first time on or after July 1, 2010. The commenter stated that, if CMS does not agree to apply the 5-year window to hospitals that are still within their 3-year window on October 1, 2012, CMS at least apply the 5-year window to new teaching hospitals that had not been training residents as of the publication of the proposed rule, that is, effective July 1, 2012. The commenter stated that this application would be prospective and would result in an even smaller cost than applying the 5-year window to all hospitals that are still within their 3-year window for establishing a cap. One commenter stated that making the 5-year window effective for hospitals that are still within their 3-year window as of October 1, 2012, would allow it to continue to develop its fellowships in geriatrics and palliative care and expand its internal medicine program, and that without the possibility of this additional payment, it may not be able to support these programs which would increase the community's access to primary care and support the future physician

workforce. Another commenter stated that it is just about to start the third year of its new residency program and there is nothing precluding CMS from applying the 5-year window to hospitals that are currently growing their caps. The commenter stated that, given the likely upcoming physician shortage, there is a public health benefit to applying the 5-year window as broadly as possible.

Another commenter stated that the proposal to expand the cap-building period is long overdue especially due to the fact that in the last decade residency training has been expanded to address physician shortage and complement new medical schools. The commenter stated that two of its member hospitals have recently or currently are establishing new programs and will be negatively affected by the 3-year window. Therefore, the commenter requested the 5-year window be applied to all hospitals currently growing their caps as of October 1, 2012.

One commenter requested that CMS provide for an exception for hospitals that may have had a cap based on very few residency rotations but want to be able to train more residents because of a new medical school or an expansion of an existing medical school. The commenter stated that it has been a leader in Wisconsin in developing a report that addresses the potential physician shortage and in establishing a task force to address the need to train new physicians. The commenter stated that one of its State's medical schools may be able to expand into at least one new area in the State and that hospitals that want to grow their residency training programs as a result of this expansion should be provided with special consideration and an exemption from their caps.

Another commenter stated that it is beginning a family medicine and internal medicine program and if it were to have a 5-year window it would be able to expand the number of primary care residents that it trains. The commenter requested that the 5-year window apply retroactively to any hospital that has not yet established a cap.

Response: We disagree with the commenters who suggested applying the 5-year window to hospitals that are still within their 3-year window effective October 1, 2012, or to hospitals that begin training in July 2012. We believe it is appropriate that the policies included in this final rule will be effective with the start date of the next fiscal year, in this case, October 1, 2012. Therefore, we are finalizing the policy to extend the cap-building period from 3 years to 5 years, effective for hospitals that first begin to train residents in their first new program on or after October 1, 2012.

Comment: Some commenters supported CMS' proposed methodology for calculating a new teaching hospital's cap adjustment if residents in the new program are training at more than one hospital (proposed § 413.79(e)(1)(i)). However, some commenters also expressed concern regarding the proposed methodology to consider all 5 years of the cap-building period for purposes of determining a participating hospital's cap adjustment. Commenters stated that considering all 5 years prevents nonteaching hospitals from training residents in the new program if it wants to establish its own programs in the future. The commenters stated that, under the proposed methodology, a new teaching hospital could "lose" cap slots if it rotated residents in a new program at any time during the 5-year window to another hospital, even if by the last year of the 5-year window, it would be able to offer all of the rotations at its facility. Commenters

stated that if a methodology for allocating cap slots among participating hospitals is adopted, it should only consider the training that is occurring during the fifth year after training starts.

One commenter stated that it is in the process of developing residency training programs and is seeking a Trauma designation. The commenter stated that until it receives its Trauma designation, it plans to send its Emergency Medicine residents to other facilities for the program's Trauma rotation. The commenter stated that due to these outside rotations, its cap will be reduced and it will not be able to receive a cap adjustment for those FTE residents it would have the capacity to train later on.

Commenters stated that while they believe the proposed calculation of the total cap is appropriate, the proposed apportionment of FTE residents among participating hospitals may result in inappropriate cap determinations if the programs were in existence for less than their minimum accredited length by the fifth year of the cap-building period. One commenter stated "…the result of utilizing a limited data set and extrapolating those resident counts to represent the anticipated resident rotation activity for the entire program may result in an apportionment of resident FTEs that is misaligned and varies markedly from the actual experience of the training program." Commenters stated that while existing teaching hospitals may participate in Medicare GME affiliation agreements to temporarily adjust their caps, new teaching hospitals are not permitted to temporarily lend some of their cap through an affiliation agreement and, therefore, it is not feasible for a new teaching hospital to use a Medicare GME affiliation agreement to alleviate the effects of an inappropriate cap determination. Commenters therefore

requested that if the new program has been in existence for less than its minimum accredited length by the fifth year of the cap building period, participating hospitals should be permitted to collaborate and submit an attestation certifying a preferred way of dividing the cap slots. The commenters stated that the total cap adjustment should be calculated as proposed; however the individual cap determinations should be adjusted as follows:

- For any program that has operated for a period of time less than the number of years equal to the minimum accredited program length as of Year 5 (the cap adjustment year), if consensus is reached among all of the hospitals participating in the development of the new program that the apportionment as determined by the CMS formula does not appropriately reflect the anticipated deployment of residents across the full program and accordingly advantages or disadvantages one or more of the new teaching hospitals, the hospitals may collectively recommend, certify, and submit to CMS an alternative apportionment for the resident FTE counts that are associated with that particular program and that will be assigned to the hospitals.

- For any program that has operated for a period of time equal to or greater than the minimum accredited program length by Year 5, the hospitals will not have an opportunity to recommend an alternative apportionment of resident FTEs for cap adjustment purposes.

Several commenters recommended changing the regulation text at 42 CFR 413.79(e)(1)(i) by replacing the phrase “an entire program year (or years)” with

"portions of a program year (or years)" because it more accurately describes the proposed methodology for determining an individual hospital's cap adjustment.

Response: We appreciate the commenters' support of the methodology we proposed to use to calculate a qualifying teaching hospital's total cap adjustment for a new program. We disagree with commenters who stated that it is inappropriate to consider all 5 years of the cap-building period in determining a specific qualifying teaching hospital's cap adjustment for a new program. There may be some merit to the commenters' suggestions that it may take several years until a program is fully operational so by the end of the 5-year window a hospital may be able to have all the rotations occur at its facility. However, we believe that considering all 5 years of the cap-building period in calculating a qualifying teaching hospital's cap adjustment is appropriate, as it provides a more complete picture of the actual rotations that will be part of the approved residency training program as opposed to just taking into account what is happening in the new program during the final year of the cap building period, which may not accurately reflect the hospitals' plans for dividing rotations among participating hospitals which may fluctuate from year to year. We do not believe it would be appropriate to allow participating hospitals to submit alternative methodologies for dividing the total cap adjustment if they do not agree with the cap calculations that have been determined by CMS. The policy used to apportion a total cap adjustment among participating hospitals must be a single national policy. Permitting hospitals to develop and apply their own methodologies may lead to disparate treatment among qualifying teaching hospitals. Furthermore, requiring Medicare contractors to apply specific

individual policies for determining a hospital's cap adjustment, as opposed to applying one national policy, would prove to be administratively difficult and could significantly delay the determination of a hospital's cap.

After considering the public comments we received on the proposed methodology to be used in determining individual cap adjustments for qualifying teaching hospitals that participate in training residents in a new program, we are finalizing our methodology as proposed. That is, in order to determine a qualifying teaching hospital's cap adjustment for a new program(s), we will take the sum of the products of three factors (limited to the number of accredited slots for each program): (1) the highest total number of FTE residents trained in any program year, during the fifth year of the first new program's existence at all of the hospitals to which the residents in that program rotate; (2) the number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program; and (3) the ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

Because we are finalizing the methodology as proposed, we refer readers to the examples provided in the proposed rule and also included earlier in this preamble for further guidance. We agree with the commenters who suggested that we replace the phrase "an entire program year (or years)" at 42 CFR 413.79(e)(1)(i) with the phrase "portions of a program year (or years)" and, therefore, are amending this regulation text to include this change. We also are amending the regulation text at

42 CFR 413.79(e)(1)(i) to more clearly describe that an individual hospital's cap adjustment for a new program that rotates residents to more than one hospital is based on the product of three factors, which are described earlier in this paragraph. Furthermore, in this final rule, we are making minor revisions to the regulation text at 42 CFR 413.79(e)(2) through (e)(4) for purposes of maintaining consistency throughout 42 CFR 413.79(e).

Comment: Several commenters referred to a statement reiterated in the proposed rule (77 FR 27977) that a new teaching hospital can only receive a cap adjustment for training residents in a truly "new" program and to the August 27, 2009 final rule (74 FR 43908) in which CMS discussed the requirements that a residency training program must meet in order to be considered a new program. The commenters requested that CMS clarify the definition of a new residency training program so that hospitals can use the 5-year window for building their caps. Commenters stated that because of CMS' "ambiguous criteria" used to define a new program, hospitals hoping to start brand new programs have not been able to get a clear opinion from CMS or legal counsel as to whether a program is, in fact, new. Commenters stated that this lack of clarity leads to financial risks for a hospital and does not provide any incentives for hospitals to participate in residency training. Commenters stated that hospitals are concerned that if they hire a program director with significant experience to meet ACGME requirements, their program will not be considered new. Commenters requested that CMS develop a bright line policy regarding the definition of a new program and suggested that CMS consider a program to be new if all PGY 1 residents are new and 90 percent of residents

in later PGY years are new. Commenters requested CMS clarify that prior experience and status of the program director and teaching physicians are not relevant in determining whether a program is considered new.

Several commenters referred to CMS' existing policy that when a nonteaching hospital starts training residents in a new program, it enters a cap-building period and receives a PRA. Commenters stated that such a policy hinders the development of GME training at small hospitals in rural and underserved areas because the result of a resident rotation of short duration is a low PRA and small cap which will prevent the hospitals from establishing their own viable residency training programs later on. Commenters stated that assigning a cap and PRA to a nonteaching hospital that does not have a rotation of long duration does not permit these small nonteaching hospitals to determine whether residency training would be a viable option for them. Commenters requested that CMS consider one or more of the following proposals:

- A teaching hospital should be allowed to rotate residents for a period equal to or less than 3 months (or a maximum percentage of training time) per resident per year without triggering the cap or PRA in a nonteaching hospital.
- A new teaching hospital should be allowed to rotate residents in high-need specialties (for example, primary care, general surgery) without triggering a cap or PRA in a nonteaching hospital.
- Small rural hospitals and hospitals located in remote or underserved areas should be allowed to rotate residents to non-teaching hospitals without triggering caps or PRAs in those institutions.

One commenter offered a fourth recommendation to be used if CMS continues with its current policy of assigning a PRA and cap to nonteaching hospitals that train residents in a new program for a rotation of short duration. The commenter stated that if a hospital has not had residents rotating to its site for a reasonable period of time (the commenter suggested 3 or 5 years), the hospital's cap should expire and the hospital should be considered a nonteaching hospital.

Response: We do not consider these comments to be within the scope of the provisions of the FY 2013 IPPS/LTCH PPS proposed rule. In terms of the comment regarding the definition of a new residency training program, we did not propose to redefine the requirements that a program must meet in order to be considered a new program. The discussion cited was part of the background discussion of existing policies. These public comments may be considered for future rulemaking. In terms of the commenters' concerns regarding nonteaching hospitals that receive a cap adjustment and PRA for participating in training residents in a new program even if the rotation to the nonteaching hospital is of short duration, perhaps these concerns could be potential topics for future rulemaking because they have ramifications that go beyond the establishment of a cap for a new program, for example, for establishing the PRA of a "new" teaching hospital training residents in an existing program. Some commenters seemed to suggest that if an existing teaching hospital sends residents to a nonteaching hospital for a rotation of very short duration, the existing teaching hospital should be able to count the residency training time at the nonteaching hospital. We remind readers that a hospital cannot count the residency training time that is occurring at another hospital. Therefore,

it would not be possible for one hospital to count rotations occurring at other hospitals even if the rotations are of a short duration.

Comment: One commenter asked "when CMS refers to the accredited length for the 'type' of program, is CMS referring to a specific program with a specific accreditation time period, or the average accredited time for a type of specialty, such as primary care?" The commenter recommended "…that the minimum length of time for each training program is based on the accreditation for a specific program, rather than on the average training time for a general type of program." Another commenter requested that CMS clarify the following language included in the proposed rule (77 FR 27979): "However, because both of these programs are approved programs and FTE residents are training at Hospital B for part of the time, Hospital B can count the FTE residents training in the family medicine program and the surgery program at its facility if it has room under its caps to do so." The commenters stated they believed hospitals should count FTE residents regardless of whether the hospital has room under its caps. The commenters requested CMS "…clarify whether or not a hospital should report all allowable resident FTEs when a hospital does not have room under its caps…"

Response: When we refer to the accredited length of a "type" of program in the proposed rule and in this final rule, we are referring to the minimum accredited length for a specific specialty program, that is, the number of years of residency training that a resident must complete in order to be board certified in that specialty. For example the minimum accredited length for family medicine is 3 years and the minimum accredited length for surgery is 5 years.

In response to the commenter's request that CMS clarify whether a hospital should report all allowable FTE residents when a hospital does not have room under its caps, if an existing teaching hospital with an already established cap participates in training residents in a new program, unless it is a rural hospital, it cannot receive a permanent cap adjustment for training residents in the new program. If the new program is an approved program and the existing teaching hospital is training below its caps, the existing teaching hospital can count and receive payment for the residents training in the new program at its facility up to its caps. The commenter is correct that if the existing teaching hospital is training residents in an approved program(s) it should report those FTE residents on its cost report regardless of whether or not it is training over its caps. However, the existing teaching hospital would only be able to receive Medicare payment for training residents in the new program up to its cap limit.

Comment: One commenter requested that CMS provide new teaching hospitals with additional flexibility to grow GME programs and provide additional investments in GME that will be required to grow and improve the geriatrics workforce. One commenter also requested that CMS provide GME funding for second year pharmacy residency programs. One commenter expressed concern that the policy of assigning a cap and PRA after a short rotation to a formerly nonteaching hospital may be a policy that is applied to teaching hospital centers, which it believed would have a negative effect on the creation of new teaching health centers.

Response: We consider these public comments to be outside the scope of the proposed rule and, therefore, we are not addressing them in this final rule.

In summary, we are finalizing our proposal to increase the cap-building period from 3 years to 5 years. We also are finalizing the proposed methodology used to calculate a cap adjustment for an individual hospital if a new program rotates residents to more than one hospital (or hospitals). The methodology is based on the sum of the products of the following three factors: (1) the highest total number of FTE residents trained in any program year, during the fifth year of the first new program's existence at all of the hospitals to which the residents in that program rotate; (2) the number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program; and (3) the ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period. In addition, we are making minor revisions to the regulation text at 42 CFR 413.79(e)(2) through (e)(4) for purposes of maintaining consistency throughout 42 CFR 413.79(e).

3. Policies and Clarification Related to 5-Year Period Following Implementation of Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes under Section 5503 of the Affordable Care Act

As previously discussed, in an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes. Some hospitals have trained a number of allopathic and osteopathic residents in excess of their FTE resident caps, while other hospitals are training a number

of allopathic and osteopathic residents at some level below their FTE resident caps. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for reductions in the statutory FTE resident caps for direct GME payment purposes under Medicare for certain hospitals that are training allopathic and osteopathic residents at a level below their FTE resident caps, and to authorize a "redistribution" to certain hospitals of the estimated number of FTE resident slots resulting from the reductions. Section 5503 of the Affordable Care Act also amended section 1886(d)(5)(B)(v) of the Act to require application of the provisions of section 1886(h)(8) of the Act "in the same manner" to the FTE resident caps for IME payment purposes.

Section 1886(h)(8)(A)(i) of the Act provides that, effective for portions of cost reporting periods occurring on or after July 1, 2011, a hospital's FTE resident cap will be reduced by 65 percent of the difference between the hospital's "otherwise applicable resident limit" and its "reference resident level," if its "reference resident level" is less than its "otherwise applicable resident limit" (as defined at section 1886(h)(8)(H) of the Act). (We refer readers to the November 24, 2010 final rule with comment period (75 FR 72155 through 72161) for a discussion of these terms.) Section 1886(h)(8)(A)(ii) of the Act and the November 24, 2010 final rule with comment period (75 FR 72147) describe which hospitals are exempt from a cap reduction under section 5503 of the Affordable Care Act, including rural hospitals with fewer than 250 acute care inpatient beds.

Under section 1886(h)(8)(B) of the Act, the Secretary is authorized to increase the FTE resident caps for certain categories of hospitals for portions of cost reporting periods

occurring on or after July 1, 2011, in the aggregate, by a number that does not exceed the estimated overall reduction in FTE resident caps for all hospitals under section 1886(h)(8)(A) of the Act. In determining which hospitals will receive an increase in their FTE resident caps, sections 1886(h)(8)(C) through 1886(h)(8)(E) of the Act direct us to do all of the following:

- Take into account the demonstrated likelihood of the hospital filling the additional positions within the first three cost reporting periods beginning on or after July 1, 2011.
- Take into account whether the hospital has an accredited rural training track program.
- Distribute 70 percent of the resident slots to hospitals located in States with resident-to-population ratios in the lowest quartile.
- Distribute 30 percent of the resident slots to hospitals located in a State, a territory of the United States, or the District of Columbia that are among the top 10 States, territories, or the District in terms of the ratio of the total population living in an area designated as a health professional shortage area (HPSA), as of March 23, 2010, to the total population, and/or to hospitals located in rural areas.

A comprehensive description of the rules implementing the cap slot redistribution under section 1886(h)(8) of the Act can be found in the November 24, 2010 final rule with comment period (75 FR 72168). Section 1886(h)(8)(B)(ii) of the Act, as added by section 5503(a)(4) of the Affordable Care Act, specifies that a hospital that receives an increase in its cap shall ensure, during the 5-year period beginning on the date of such

increase (July 1, 2011), that certain requirements, referred to as the primary care average and the 75-percent threshold, are met in order to retain those slots. Otherwise, section 1886(h)(8)(B)(iii)(I) of the Act authorizes the Secretary to reduce the FTE resident caps of the hospital by the same number of FTE residents by which the hospital's FTE resident caps were increased if the hospital fails to meet either requirement; and section 1886(h)(8)(B)(iii)(II) of the Act authorizes the Secretary to redistribute those positions.

Specifically, section 1886(h)(8)(B)(ii) of the Act states, ". . . a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that—

(I) The number of full-time equivalent primary care residents, as defined in paragraph (5)(H) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of fulltime equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to the date of enactment of this paragraph; and

(II) Not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period."

In a case where the Secretary determines that a hospital did not meet the requirements in a cost reporting year during the 5-year time period, section 1886(h)(8)(B)(iii) of the Act states that ". . . the Secretary shall—

(I) Reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and

(II) Provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph."

In the November 24, 2010 final rule with comment period (75 FR 72195 through 72203), we stated that the "5-year period beginning on the date of such increase" is July 1, 2011 through June 30, 2016, and we provided a detailed discussion of what the two requirements under sections 1886(h)(8)(B)(ii)(I) and 1886(h)(8)(B)(ii)(II) of the Act entail. In that final rule, we noted that section 1886(h)(8)(B)(ii) of the Act allows the Secretary to "determine whether a hospital has met the requirements . . . during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period," and section 1886(h)(8)(B)(iii) of the Act instructs the Secretary to "reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased . . . ." We also explained that we believe the Secretary has the discretion to consider a hospital's performance over more than one year or to review each year during the 5 years independently in determining whether or not a hospital is in compliance with the primary care average and the 75-percent threshold, as required (75 FR 72196 and 72197 and 72200 and 72201). We emphasized that it is within CMS' and the Medicare contractors' authority to adjust a hospital's IME and direct GME payments as early as it is feasible within a cost report's submission and review cycle, and that we need not wait until final settlement to do so. We further stated in the November 24, 2010 final rule with comment period

implementing section 5503 that "We also understand that we should consider that hospitals might not immediately fill all the slots they receive, particularly because they are only required to demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011" (75 FR 72197). However, we gave an example that indicated that, of the section 5503 FTE slots that the hospital does begin to use, 75 percent of those slots must be in primary care or general surgery.

Since we awarded the section 5503 slots pursuant to section 1886(h)(8) of the Act, and prior to issuance of the proposed rule, we have received questions from hospitals asking if and how CMS would enforce the primary care average and the 75-percent threshold requirements under sections 1886(h)(8)(B)(ii)(I) and 1886(h)(8)(B)(ii)(II) of the Act if a hospital does not use any of its section 5503 slots until year 4 or year 5 of the 5-year period, or if a hospital does not use any of the section 5503 slots until after expiration of the 5-year period. We have informed hospitals that the 75-percent threshold requirement applies once the hospital starts using any of the section 5503 slots, and the 3-year primary care average requirement applies immediately on July 1, 2011, regardless of whether or not the hospital begins to use its additional section 5503 slots in year 1 of the 5-year period. This is because the 3-year primary care average test applies to the hospital's pre-section 5503 resident complement as well, and not exclusively to the additional FTE residents associated with slots awarded under section 5503.

In determining which hospitals applying for slots under section 5503 will receive slots, section 1886(h)(8)(C)(i) of the Act specifies that the Secretary shall take into account the demonstrated likelihood of the hospital filling the slots within the first three

cost reporting periods beginning on or after July 1, 2011. Hospitals included evidence supporting the demonstrated likelihood stipulation in their applications and we took that into consideration in awarding slots under section 5503. We believe that it is inappropriate and in direct conflict with a base consideration in the awarding of slots under section 5503 for hospitals to refrain from using their section 5503 slots until after the initial 3 years after the slots have been awarded in an attempt to circumvent the primary care average or the 75-percent threshold requirements, or both.

As stated in the November 14, 2010 final rule, CMS reserves the right to assess as many times as necessary in the 5-year period whether a hospital is meeting the required criteria. The agency also may remove the slots awarded to a hospital at any point during the 5-year period (75 FR 72196 and 72197 and 72200 and 72201). Because a statutorily directed criterion for consideration in awarding slots under section 5503 included the requirement that hospitals applying for slots demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011, and we relied on that information in awarding slots, we stated in the proposed rule that we believe it is reasonable to expect that hospitals that received slots under section 5503 should begin to use their slots within the first three 12-month cost reporting periods beginning on or after July 1, 2011, of the 5-year period in order to give full effect to the requirements under section 1886(h)(8)(B)(ii) of the Act. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27982), we proposed that a hospital must fill *at least half* of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes, or lose its section 5503 slots: (A) in its first 12-month cost

reporting period of the 5-year period; and/or (B) in its second 12-month cost reporting period of the 5-year period; and/or (C) in its third 12-month cost reporting period of the 5-year period. For example, Hospital A and Hospital B both have June 30 fiscal year ends (FYEs), and they received 10 slots under section 5503. In its FYE June 30, 2012, Hospital A filled 8 slots. In its FYE June 30, 2013, Hospital A filled 0 slots. In its FYE June 30, 2014, Hospital A filled 5 slots. However, Hospital B, in its FYEs June 30, 2012, 2013, and 2014, only filled 3 slots respectively in each of the 3 years. Hospital A would have complied with our proposed requirement, because it filled at least half of its section 5503 slots in either its first, and/or second, and/or its third 12-month cost reporting period during the 5-year period. Hospital B would not have complied with our proposed requirement because in neither its first, second, nor third 12-month cost reporting period had it filled at least 5 (half of 10) slots.

We proposed to interpret that a hospital's failure to use slots awarded under section 5503 in a timely manner to also be a failure to meet the 75-percent threshold. We believe that we have the authority to interpret section 1886(h)(8)(B)(ii) of the Act in such a manner and to propose this requirement because section 1886(h)(8)(B)(ii) of the Act allows the Secretary to " . . . determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period." We reiterated that the 75-percent threshold applies in the instance where a hospital uses *less than half, or any amount,* of its slots prior to its third 12-month cost reporting period during the 5-year period (75 FR 72197). In other words, the 75-percent threshold applies

throughout the 5-year period, as long as the hospital is using some amount of its section 5503 slots in the respective cost reporting period. If a hospital is using some of its section 5503 slots in a cost reporting period, the 75-percent threshold would be enforced; if a hospital is not using any of its section 5503 slots in a cost reporting period, the 75-percent threshold would not be enforced. However, as stated earlier, we proposed that a hospital must use its section 5503 slots no later than the hospital's third 12-month cost reporting period (and that at least half of its section 5503 slots must be used in either the first, or second, or third 12-month cost reporting period).

We noted in the proposed rule that we did not specify that a hospital must use at least half of its section 5503 slots in its third 12-month cost reporting period of the 5-year period in the November 24, 2010 final rule with comment period because the possibility that a hospital might not begin to use its section 5503 slots for several years only came to our attention after July 1, 2011, in response to questions raised by hospitals. Furthermore, given the demand for these slots (we ran out of slots during the redistribution process and were unable to award any slots to hospitals in qualifying, but lower ranking, States), and that the slots were slated to be distributed in States where there was an acute need for additional residents (that is, as sections 1886(h)(8)(D) and 1886(h)(8)(E) of the Act specify, to States with resident-to-population ratios in the lowest quartile, and to States that are among the top 10 in terms of the HPSA population to total population ratios), we did not expect that hospitals that received section 5503 slots would not be able to make almost immediate use of the slots. Consequently, in the proposed rule, we stated that given the presumed huge need for these slots in the States where

Congress directed that they be awarded, we believe it is appropriate to use our authority to reasonably ensure that those slots awarded are used in compliance with section 5503 (hence, the proposals in the proposed rule), and, if not, are able to be redistributed to other hospitals in need of slots as Congress intended.

Section 1886(h)(8)(B)(iii) of the Act states that if the Secretary determines that a hospital does not meet either the primary care average or the 75-percent threshold, "the Secretary shall (I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and (II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph." Accordingly, we indicated in the proposed rule that we were exercising the broad authority that the Secretary is given to determine whether the requirements at section 1886(h)(8)(B)(ii) of the Act are met by proposing that if a hospital fails to fill *at least <u>half</u>* of its section 5503 slots, IME and direct GME respectively, in its first 12-month cost reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period, this would mean failure to meet the 75-percent threshold. In the case of such failure, we indicated that CMS would instruct the Medicare contractor after audit to permanently remove <u>all</u> of the hospital's section 5503 slots from the earliest cost reporting period that is subject to reopening and in which it would be determined that the hospital did not meet the requirements (in accordance with existing § 413.79(n)(2)(iii), which was proposed to be redesignated as § 413.79(n)(2)(iv) in the proposed rule), even if the hospital had used at least half of its section 5503 slots in its fourth or subsequent

cost reporting year of the 5-year period. Thus, as part of the Medicare contractors' reviews of the hospitals that received section 5503 slots, we proposed that the Medicare contractors would determine whether a hospital filled at least half of its section 5503 slots in its first 12-month cost reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period. We stated in the proposed rule that we believe it is appropriate to remove the slots from a hospital that has not filled at least half of its slots in any 12-month cost reporting year prior to and including the third 12-month cost reporting period so that these slots may be redistributed to other hospitals that may have greater success in filling the slots and that are located in States that are described in sections 1886(h)(8)(D) and 1886(h)(8)(E) of the Act.

We noted in the proposed rule that, as explained in the November 24, 2010 final rule with comment period (75 FR 72197), the start and end of each year of the 5-year period depend on the fiscal year begin date of each hospital's cost reporting periods. Hospitals with fiscal year begin dates of July 1 will have five 12-month cost reporting periods starting on July 1, 2011, and ending on June 30, 2016, while hospitals with fiscal year begin dates of other than July 1 will have a partial cost reporting period that includes July 1, 2011, four 12-month cost reporting periods, and another partial cost reporting period that includes June 30, 2016 (75 FR 72197). We proposed that, for example, if Hospital A has a June 30 fiscal year end, its third 12-month cost reporting period of the 5-year period would be July 1, 2013, to June 30, 2014, and Hospital A must fill *at least* ***half*** of its section 5503 slots, IME and direct GME respectively, in its first 12-month cost

reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period. If Hospital B has a September 30 fiscal year end, its cost reporting periods occurring during July 1, 2011 through June 30, 2016 are as follows:

Year 1—July 1, 2011—September 30, 2011

Year 2—October 1, 2011—September 30, 2012

Year 3—October 1, 2012—September 30, 2013

Year 4—October 1, 2013—September 30, 2014

Year 5--October 1, 2014—September 30, 2015

Year 6—October 1, 2015—June 30, 2016

Hospital B's third 12-month cost reporting period would be October 1, 2013, to September 30, 2014, and Hospital B must fill *at least* <u>*half*</u> of its section 5503 slots, IME and direct GME, respectively, in its first 12-month cost reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period. As explained in the November 24, 2010 final rule with comment period (75 FR 72197), if hospitals have other than a June 30 fiscal year end, for their cost reports that include July 1, 2011 and June 30, 2016 respectively, we consider whether the hospital meets the primary care average and the 75-percent threshold requirements based on an annualized FTE count. Also, if during the period of July 1, 2011 through June 30, 2016, hospitals, for whatever reason, actually have less than 12-month cost reports, we would consider on a case-by-case basis which cost reports we would evaluate for purposes of meeting the proposed requirement of filling at least

half of the section 5503 slots in its first, second, and/or third cost reporting period. As under existing policy, if the hospital does begin to fill its section 5503 slots but fails to meet the 75-percent threshold, the Medicare contractor would also remove the section 5503 slots, effective with the earliest year that the 75-percent threshold is not met.

Lastly, considering again that hospitals that received section 5503 slots had to demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011, we proposed to require that hospitals that received section 5503 slots must fill *all* of the slots they received in their final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016 (IME and direct GME respectively), or lose *all* of their section 5503 slots after June 30, 2016. As stated above and in the proposed rule, we consider it to be appropriate to remove the slots from a hospital that has not filled at least half of its slots in any 12-month cost reporting period prior to and including the third 12-month cost reporting period, so that these slots may be redistributed to other hospitals that otherwise qualified to receive slots, but did not receive them because the available slots were granted to higher ranking hospitals. We also stated that we were interested in commenters' recommendations regarding alternative approaches to encouraging compliance with the 3-year primary care average requirement and the 75-percent threshold.

In summary, we proposed that a hospital must fill *at least <u>half</u>* of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes or lose its section 5503 slots: (A) in its first 12-month cost reporting period of the 5-year period; and/or (B) in its second 12-month cost reporting period of the 5-year period;

and/or (C) in its third 12-month cost reporting period of the 5-year period. We proposed to enforce the 75-percent threshold test once the hospital begins to use its section 5503 slots, which we proposed must be no later than the hospital's third 12-month cost reporting period (and that at least half of its section 5503 slots must be used in either the first, or second, or third 12-month cost reporting period). In addition, we proposed that a hospital does not meet the 75-percent threshold if it fails to fill *at least half* of its section 5503 slots, IME and direct GME, respectively, in one or a combination of the first three 12-month cost reporting period of the 5-year period, and upon that basis, CMS would instruct the Medicare contractor, after audit, to permanently remove all of the hospital's section 5503 slots from the earliest cost reporting period that is subject to reopening and in which it would be determined that the hospital did not meet the requirements (in accordance with existing § 413.79(n)(2)(iii), which was proposed to be redesignated as § 413.79(n)(2)(iv) in the proposed rule), even if the hospital had used at least half of its section 5503 slots in its fourth or subsequent cost reporting year of the 5-year period. Thus, as part of the Medicare contractors' reviews of the hospitals that received section 5503 slots, we proposed that the Medicare contractors would determine whether a hospital filled at least half of its section 5503 slots in its first 12-month cost reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period. Lastly, we proposed to require that a hospital that received section 5503 slots must fill *all* of the slots it received in their final cost reporting period beginning during the timeframe of July 1, 2011

through June 30, 2016 (IME and direct GME respectively), or lose *all* of its section 5503 slots after June 30, 2016.

We proposed that these requirements would be effective for a hospital's third 12-month cost reporting period occurring during the 5-year period of July 1, 2011 through June 30, 2016. For example, for hospitals with a June 30 fiscal year end, this would be July 1, 2013 through June 30, 2014. For hospitals with a September 30 fiscal year end, this would be October 1, 2013 through September 30, 2014. For hospitals with a December 31 fiscal year end, this would be January 1, 2014 through December 31, 2014. We proposed to make appropriate changes to the regulations text at § 413.79(n)(2) to incorporate our proposals. The IME regulations regarding section 5503 slots that are at existing § 412.105(f)(1)(iv)(C)(*2*) reference the direct GME regulations text at § 413.79(n) and would not require amendments.

Comment: Many commenters opposed CMS' proposal to require hospitals to use at least half of their section 5503 slots in either the first, second, or third 12-month cost reporting period of the 5-year period, and to use all of their slots by the fifth year. One commenter stated that the proposal "over-reaches" and the penalty for failure to meet the timeline for filling the section 5503 slots is "too harsh," unjustly penalizing hospitals. Commenters explained how, given the date when CMS announced the section 5503 awards (August 2011, which they believed was already too late to recruit resident for the July 1, 2011 academic year), and the complexity and length of the process for receiving accreditation and hiring staff for a new program, a 3-year timeframe for filling at least half of the slots is impossible for hospitals to meet. Some commenters gave examples of

a hospital that is using its section 5503 to start a new program, but because of time constraints in accrediting and growing the program, by the 5th year, the hospital would still only have less than 75 percent of the slots filled. They stated that, under CMS' proposal, this hospital would lose all 10 of its section 5503 slots.

Some commenters expressed concern about the proposed timeline for filling slots as it relates to longer residencies such as general surgery, a 5-year program. These commenters requested that CMS revise the proposal to require that 80 percent, rather than 100 percent, of the slots are filled by the fifth year. Other commenters recommended that CMS remove the requirement that half the slots be filled by the third year, and instead either require that half the slots be filled by the fifth year, or that hospitals prove that they *began* to start or expand programs before the end of the fifth year, and that they received accreditation for the full number of slots they were awarded.

Another commenter suggested that, if the hospitals can provide appropriate documentation from the National Residency Match Program (NRMP) or other appropriate match programs that, based on their recruitment numbers, they have recruited for all the slots allocated, then that hospital should be considered as meeting the 5-year requirement. Alternatively, one commenter recommended that if CMS insists on an "interim check" of the progress of slot-filling, instead of using years 1, 2, and 3 of the 5-year evaluation period, CMS should use years 2, 3, and 4. The commenter argued that leaving out the first year "seems fair and appropriate," considering that the public would not have known about CMS' clarification until well into the first year and well after the point in time during which residents for the following academic year are selected.

Other commenters suggested that any hospital that received an increase for a new program should demonstrate that the program is starting within the first three cost reporting periods, as outlined in the final regulations published in the November 24, 2010 final rule with comment period (75 FR 72168). The same commenters also stated that any hospital that received an increase for a new program should submit to CMS a 5-year plan on how it plans to fill its slots. The commenters stated that this should be done in a similar manner as for hospitals that participated in the New York Demonstration, the Utah Demonstration, or a Voluntary Residency Reduction Program (VRRP) (as outlined in the final regulations published in the November 24, 2010 final rule with comment period (75 FR 72168)). Commenters argued that, because of the tremendous investment required to start a new program, it is highly unlikely that a hospital would abandon that effort "both for financial and reputational reasons."

Two commenters stated that the ACGME accreditation process for new programs is more complex than for expansion of existing programs. The commenters asked that CMS acknowledge the effort and time required to start a new program, and CMS "should continue to make a distinction between expansions of existing programs and the establishment of new programs in the requirements for the use of the redistributed GME slots." The commenters noted that CMS made this distinction between starting new programs and expanding existing programs under Demonstrated Likelihood Criterion 1 in the November 24, 2010 final rule with comment period (75 FR 72168), where CMS added the option of submitting "documentation demonstrating that it has made a commitment to start a new program. One example of such a commitment would be for

the hospital to provide the minutes from the meeting at which the hospital's GME committee gave approval for the hospital to proceed with the process of applying to the accrediting agency for approval to start a new program. We are not adding a similar option under Demonstrated Likelihood Criterion 2 because we understand that the process for requesting approval to expand an existing program is not as time-consuming and labor-intensive as the process for requesting approval for a brand new program."

Commenters asked that if CMS does finalize a penalty for hospitals that fail to use all of their slots, CMS only remove the slots that the hospital did *not* fill by year 5, and if any removal of slots occurs, it should only be prospective (that is, starting with the year *after* failure to meet the 75-percent test). Commenters argued that it is "draconian" for CMS to remove all or any of a hospital's awarded slots, if, for example, in the fifth year, the hospital has not filled a fraction of the slots.

One commenter argued that there is no statutory requirement to use "all" the awarded section 5503 slots. The commenter stated that the only statutory requirements are to make certain that the hospital trains primary care residents at or above its primary care average and, also, that 75 percent of the positions attributable to the additional slots are in primary care or general surgery training. The commenter asserted that this statutory requirement does not suggest a need for use of all slots or any particular need to analyze the use of slots, if any, for any slots not used for primary care or general surgery. The commenter argued that Congress did not place any other requirements on the use of the slots and clearly is allowing for 25 percent of the slots used to be for nonprimary care training. The commenter gave an example where if the primary care average is 12.2 and

the hospital was awarded 10 section 5503 slots, the commenter believes that, in year 5, to determine compliance with the statutory 75-percent requirement and primary care average, the only analysis should be whether the hospital, in year 5, is training at least 12.2 residents in primary care and also at least an additional 7.5 FTEs in primary care or general surgery. The commenter believed that it should not matter what, if anything, the hospital might be doing with the other 2.5 FTEs of the 10 awarded section 5503 slots. The commenter added that it would be difficult to determine use of all awarded slots without knowing precisely what figure in year 5 will be compared to what figure from another year or years.

Commenters also requested that CMS permit hospitals to choose to start the 5-year evaluation period *either* to be July 1, 2011, or July 1, 2012. Commenters stated that although section 5503 is effective July 1, 2011, the section 5503 awards were not announced until after the start of the July 1, 2011 academic year, and therefore, unless a hospital had already recruited residents to positions during the 2010 match program, there is no way for any hospital to actually have used any of the section 5503 awarded positions for the period of July 1, 2011 through June 30, 2012.

Response: We have considered all the public comments we received and we are convinced that, with respect to starting a brand new program, it is possible that even if a hospital began in earnest the process of seeking accreditation for and starting a new program right after the section 5503 slots were awarded in August 2011, half of the slots may not be filled by the third 12-month cost reporting period of the 5-year evaluation period. Nevertheless, we emphasize that our proposal that hospitals must fill at least half

of their slots in years 1, 2, or 3 was based on the *statutory* directive that, in distributing the slots, CMS should take into account the demonstrated likelihood of the hospital filling the additional slots within the *first three cost reporting periods beginning on or after* July 1, 2011. Arguably, our proposal was *less* restrictive than this directive, in that hospitals would have to fill only *half* of their slots, and not all of the slots, and do so in either the first, second, or third *12-month cost reporting period* of the 5-year evaluation period. However, in this final rule, based on consideration of the public comments we received, we are finalizing a policy that differs from what we proposed.

As we explain further below, we will be modifying the hospital cost report to require hospitals to report the number of FTE residents that they have added because of their section 5503 slots. The hospitals must specify on the cost report, of the additional FTEs added because of section 5503, the number that are in a new program(s), if any, and the new program specialty(ies), and the number that are expansions to an existing program(s), if any, and the expanded program's or programs' specialty(ies). This information will assist the Medicare contractor in determining how many slots are being used and the purpose for which they are being used, at least for cost reports that have not yet been filed in the 5-year evaluation period. We received many comments convincing us of the complexity and devotion of time and resources associated with starting a new program, but commenters did not do the same regarding the process for expanding existing programs. In fact, after noting that the ACGME process for starting a new program is more complex than for expanding an existing program, two commenters also pointed out that, consequently, CMS has already distinguished between new programs

and program expansions with regard to the type of documentation required in the section 5503 application process (that is, the documentation requirements for applications seeking slots to start a new program were somewhat less stringent than the documentation requirements for expanding existing programs (75 FR 72168)). Those commenters asked that CMS continue to distinguish between new programs and program expansions, presumably by being less stringent with regard to the requirements imposed when slots must be filled for new programs. These comments highlighting the differences in the level of difficulty between starting a new program and expanding an existing program, and the general lack of comments voicing concern over our proposals with regard to expanding existing programs, confirm our belief that it is much easier for a hospital to expand an existing program than to start a new one. Therefore, in this final rule, we are continuing to distinguish between new programs and expansions of existing programs, and with regard to expansions of existing programs, we believe that a hospital should be able to achieve its expansions fully by its fourth 12-month cost reporting period. With regard to establishing new programs, we understand that a new program may not yet be fully grown by its final (full or partial) cost report. As we explain further below, we are finalizing a policy wherein the Medicare contractor would remove from the final cost report the section 5503 slots that are unused in a hospital's final (full or partial) cost report in the 5-year evaluation period. We are concerned that hospitals may seek to suddenly expand existing primary care or general surgery programs in the final (full or partial) cost report as a means of holding on to their section 5503 slots, only to reverse those expansions after June 30, 2016, and use the section 5503 slots for some

other purpose inconsistent with the policy goals of section 5503. We believe it is reasonable and fair to choose the fourth 12-month cost report as the year in which a hospital must have achieved its full program expansion(s) because this is one year *more* than the statutory requirement at section 1886(h)(8)(C)(i) of the Act that the Secretary shall take into account the demonstrated likelihood that a hospital would fill the slots within the first 3 cost reporting periods beginning on or after July 1, 2011. We hope that this final policy encourages hospitals to achieve the full expansion by their fourth 12-month cost report, and to maintain that full expansion in the final cost report. We believe that, in this manner, the hospital would be demonstrating at least 2 years of commitment to the expanded program(s), and as a result, the hospital may be less likely to reverse the expansion after June 30, 2016.

Accordingly, we are finalizing a policy wherein if a hospital uses any section 5503 slots for program expansions, the Medicare contractor will review those slots used for program expansions and, in determining the number of applicable unused slots to remove, compare the number of FTEs associated with program expansion in the fourth 12-month cost reporting period to that in the final cost report (full or partial). If the final cost report indicates a number of FTEs associated with program expansion that is more than the number of FTEs associated with program expansion in the fourth 12-month cost reporting period, the Medicare contractor would ignore the additional expansion in the final cost report in calculating the applicable unused slots because, as noted above, we believe the full expansion should have been achieved in the fourth 12-month cost reporting period. Effective for portions of cost reports on or after July 1, 2016, we would

remove those additional expanded FTEs (thereby reducing the section 5503 award) that are over and above the FTEs associated with program expansion in the fourth 12-month cost reporting period. If the number of FTEs associated with program expansion in the final cost report is equal to or less than the number of FTEs associated with program expansion in the fourth 12-month cost reporting period, the hospital's section 5503 award would be reduced by removing any FTE slots that are unused in the final (full or partial) cost report, effective for portions of cost reports on or after July 1, 2016.

For example, assume Hospital X was awarded 20 slots under section 5503. In its fourth 12-month cost reporting period, it has added 16 FTEs, 10 of which are associated with a new family medicine program, and 6 are associated with an expanded surgery program. In its final cost report, Hospital X has expanded its internal medicine program by 3 FTEs, and it continues to train the 6 surgery residents and the 10 family medicine residents added in its fourth cost reporting period. One slot of the 20 section 5503 slots remains unused in the final cost report. Because we believe all program expansions should have occurred no later than the fourth 12-month cost reporting period, effective July 1, 2016, the Medicare contractor would remove the three (internal medicine) FTE slots. In addition, effective July 1, 2016, the Medicare contractor would remove the one unused FTE slot. Therefore, effective July 1, 2016, Hospital X's section 5503 cap would be 16, not 20.

Alternatively, Hospital Y was awarded 20 slots under section 5503. In its fourth 12-month cost reporting period, it has added 16 FTEs, 10 of which are associated with a new family medicine program, and 6 are associated with an expanded surgery program.

In its final cost report, Hospital Y continues to train the 6 surgery residents and add 1 family medicine resident, so Hospital Y is training 11 family medicine residents. Hospital Y has maintained the same level of program expansions in its final cost report as in its fourth 12-month cost report (that is, 6 surgery residents). Three slots of the 20 section 5503 slots are unused in the final cost report. Therefore, the Medicare contractor would only remove the 3 FTE unused slots effective for portions of cost reporting periods on or after July 1, 2016. Hospital Y's section 5503 cap would be 17, not 20, effective for portions of cost reporting periods on or after July 1, 2016.

We are revising the proposed regulations text to conform to the final policy regarding reduction of the section 5503 cap awards effective for portions of cost reports on or after July 1, 2016, due to unused slots. Specifically, we are revising the regulations text at § 413.79(n)(2)(ii) to state that if a hospital received a section 5503 cap award, and does not use all of the award in its final (12-month or partial) cost report of the 5-year period beginning July 1, 2011, and ending June 30, 2016, the Medicare contractor will remove the applicable unused slots, and the hospital's section 5503 award will be reduced for portions of cost reporting periods on or after July 1, 2016. The number of applicable unused slots is equal to the difference between the number of slots awarded and the number of slots used. In determining the applicable slots used, the following amounts are added, as relevant:

(1) If a hospital uses the section 5503 slots to expand an existing program(s), the used slots are equal to the lesser of the number of slots used for an expansion(s) in the fourth 12-month cost report or the final cost report.

(2) If a hospital uses the section 5503 slots to start a new program(s), the used slots are equal to the number of slots used for a new program(s) in the final cost report.

(3) The portion, if any, of the section 5503 slots used for cap relief, subject to the 75 percent test and the 3-year primary care average requirement.

Because we are directing the contractors to only remove the applicable unused slots awarded under section 5503, effective for portions of cost reporting periods on or after July 1, 2016, it is important to define what we mean by "used" versus "unused" slots. As one commenter argued in great detail, there is no statutory requirement to use "all" the awarded section 5503 slots. The only statutory requirements are to make certain that the hospital trains primary care residents at or above its primary care average and, also, that 75 percent of the positions attributable to the additional slots are in primary care or general surgery training. The commenter asserted that it should not matter what, if anything, the hospital might be doing with the other 25 percent of its section 5503 slots. The commenter argued that Congress did not place any other requirements on the use of the slots and clearly is allowing for 25 percent of the slots used to be for non-primary care training.

We believe that the intent of section 5503 was to provide Medicare-funded slots to hospitals in States that had documented shortages of physicians, in primary care or otherwise, and, therefore, the slots are intended to pay for *additional* FTE residents that the hospitals in those States were previously *not* training. That is, the section 5503 slots were not intended to cover existing residency positions (that is, cap relief), but to be used to create new residency positions either through starting new programs or expanding

existing programs. In fact, hospitals were precluded from applying for section 5503 slots for cap relief, and no place was provided on the section 5503 application form to even apply for cap relief (75 FR 72171, 72173 and 72174). Furthermore, in light of the 75-percent requirement, the intent of section 5503 is that a sizeable majority of the additional resident slots are to be filled with new primary care or general surgery residents. Arguably, it is acceptable if 25 percent of the remaining 5503 slots are used for additional nonprimary care programs, considering that the States that were awarded the slots have shortages of *multiple kinds* of physicians, not just primary care and general surgery. Nevertheless, it appears that, based on the language in the November 24, 2010 final rule with comment period implementing section 5503 (75 FR 72198), hospitals may use 25 percent of their section 5503 slots for cap relief.

While we believe that it is not desirable to use any amount of section 5503 slots for cap relief, we are not instructing the contractor to automatically disallow the portion of slots used for cap relief if the 3-year primary care average and the 75-percent tests are met. However, it is important for hospitals to understand that application of any amount of section 5503 slots toward cap relief constitutes a definite "use" of those section 5503 slots; therefore, section 5503 slots utilized for cap relief count with respect to the determination of whether 75 percent of a hospital's section 5503 slots are being used for training additional primary care or general surgery residents, and whether the total primary care FTE count equals at least the 3-year primary care average number. We emphasize that we are not instituting a new policy in this final rule with regard to using slots for cap relief. As stated above, it appears that, based on language in the

November 24, 2010 final rule with comment period implementing section 5503, using 25 percent of the slots for cap relief is permissible (75 FR 72198). This existing policy would apply to cost reports that hospitals have already filed after July 1, 2011 (the effective date of section 5503), and certainly applies to cost reports that have not yet been filed. For example, assume Hospital A has a cap of 100 FTEs, and is training 110 residents. Hospital A has a fiscal year end of December 31 and was awarded a total of 20 slots under section 5503. On July 1, 2011, Hospital A did add one more primary care resident, which equates to .5 FTE on the December 31, 2011 cost report. Also, on its December 31, 2011 cost report (Form CMS-2552-10, line 8.01 of Worksheet E, Part A, and line 4.01 of Worksheet E-4), Hospital A reported "10" section 5503 slots as its cap increase (that is, half of the 20 section 5503 slots applicable to July 1, 2011 through December 31, 2011), and it reported 110.5 unweighted FTEs as its current year allowable allopathic and osteopathic FTE count (Form CMS-2552-10, line 10 on Worksheet E, Part A and line 6 Worksheet E-4). In effect, Hospital A "used" all of its section 5503 slots, which meant that the 9.5 FTEs by which Hospital A previously exceeded its cap of 100 are now covered by 10 of the section 5503 slots, generating payment on the December 31, 2011 cost report for an additional 9.5 preexisting FTEs (for purposes of simplicity, we have disregarded the effects of the rolling average calculation). However, Hospital A has only added 0.5 of an additional slot in primary care, while 9.5 of the other section 5503 slots are used for cap relief. In this example, the 75-percent test is not met. Thus, in accordance with the regulations at § 413.79(n)(2)(iv), all 20 of Hospital A's section 5503 slots would be removed.

Consider the difference in reporting with Hospital B. Hospital B also has a cap of 100 FTEs and is training 110 residents. Hospital B has a fiscal year end of December 31 and was awarded a total of 20 slots under section 5503. On July 1, 2011, Hospital B did add one more primary care resident, which equates to .5 FTE on the December 31, 2011 cost report. On its December 31, 2011 cost report (CMS Form 2552-10, line 8.01 of Worksheet E, Part A, and line 4.01 of Worksheet E-4), Hospital B reported "0.66" section 5503 slots as its cap increase. By reporting 0.66 FTEs, the hospital would be reporting 0.5 of its section 5503 cap associated with the 0.5 additional primary care FTE, plus 25 percent more for cap relief (that is, 0.5 is 75 percent of 0.66, and 0.16 is 25 percent of 0.66). Hospital B's adjusted cap for FYE 12/31/11 is 100 + 0.66 = 100.66. Hospital B reported 110.5 unweighted FTEs as its current year allowable allopathic and osteopathic FTE count (CMS Form 2552-10, line 10 on Worksheet E, Part A and line 6 on Worksheet E-4). Hospital B would be paid for 100.66 FTEs on its December 31, 2011 cost report (disregarding the rolling average). Hospital B has permissibly "used" 75 percent of its section 5503 slots for an additional primary care resident and 25 percent for other purposes, such as cap relief.

These examples demonstrate how cap relief constitutes "use" of section 5503 slots, and also show that in the 5-year evaluation period, a hospital should <u>not automatically</u> report (that is, use) <u>all</u> of its section 5503 cap increase (on Form CMS-2552-10, line 8.01 of Worksheet E, Part A, and on line 4.01 of Worksheet E-4), but should only report (that is, use) a portion that at least is equal to the additional primary care/general surgery FTEs added, with no more than an additional 25 percent allowed to

be reported for other purposes. (We plan to update the cost report instructions to reflect this directive.) We reiterate that a hospital is responsible for meeting the 75-percent test based on whatever amount of section 5503 cap increase it reports on its cost report (Form CMS-2552-10, line 8.01 of Worksheet E, Part A, and line 4.01 of Worksheet E-4) during each year of the 5-year evaluation period. If use of slots for cap relief results in the hospital using less than 75 percent of the slots in a year for primary care and/or general surgery residents, the hospital risks losing all of section 5503 slots from the earliest cost reporting period that is reopenable in which it would be determined that the hospital did not meet the requirements in accordance with § 413.79(n)(2)(iv). For example, in year 5 (that is the final cost report), a hospital that was awarded 10 slots is training 6 new primary care/general surgery residents in a new program. That means in order to meet the 75-percent test in year 5, the most that can be used for cap relief or non-primary care is 2 FTEs (2 is 25 percent of 8), and an amount of 8 may be reported on Form CMS-2552-10, line 8.01 of Worksheet E, Part A, and on line 4.01 of Worksheet E-4, and the remaining 2 FTEs would be removed by the contractor effective for portions of cost reporting periods on or after July 1, 2016. If this hospital had reported all 10 of its section 5503 slots on line 8.01 of Worksheet E, Part A, and on line 4.01 of Worksheet E-4 in year 5, while actually only adding 6 primary care/general surgery residents in the new program, this hospital would fail the 75 percent test. Under the regulations at § 413.79(n)(2)(iv), this hospital would lose all 10 of its section 5503 cap slots, from the earliest cost reporting period that is reopenable in which it would be determined that the hospital did not meet the requirements.

In order for the Medicare contractors to determine whether a hospital is complying with the 75-percent test and the 3-year primary care average requirement, hospitals would have to provide their contractors with information as part of the cost report (possibly on Worksheet S-2, Part I of the CMS Form 2552-10), the following for IME and direct GME separately:

(1) The baseline FTE count, which is used for determining whether FTEs are added in cost reports in the 5-year evaluation period. The baseline FTE count is the total unweighted allopathic and osteopathic FTE count from the hospital's 12-month cost report that immediately precedes the cost report that includes July 1, 2011. (That is, the baseline cost report for June 30 providers would be July 1, 2010 through June 30, 2011; for December 31 providers, this would be January 1, 2010 through December 31, 2010; for September 30 providers, this would be October 1, 2009 through September 30, 2010). (On the CMS Form 2552-96, the baseline FTE count is on line 3.08 of Worksheet E, Part A, and on line 3.05 of Worksheet E-3, Part IV. On the CMS Form 2552-10, the baseline FTE count is on line 10 of Worksheet E, Part, and on line 6 of Worksheet E-4).

(2) The number of additional FTEs above the baseline FTE count that were added in the current cost reporting period, because of the section 5503 award. (These FTEs are part of the current year FTE count, and would be included on CMS Form 2552-10, line 10 of Worksheet E, Part A, and line 6 of Worksheet E-4).

(3) Of the additional FTEs in item 2, specify each new program specialty, if any, and the number of FTE residents for each new program.

(4) Of the additional FTEs in item 2, specify each expanded program specialty, if any, and the number of FTE residents for each program expansion.

(5) The amount of the section 5503 award that is being used for cap relief, if any.

(6) The current year's total unweighted primary care FTE count (excluding obstetrics and gynecology). (The 3-year primary care average from the 3 most recent cost reports ending prior to March 23, 2010, must already be reported on Worksheet S-2, Part I, line 61).

In order to determine compliance with the 75-percent test and the 3-year primary care average, the Medicare contractor would first determine the number of "used" slots. That is, the Medicare contractor would compare the amount on the hospital's section 5503 award letter to the section 5503 cap line on the Medicare cost report (line 8.01 of Worksheet E, Part A, and line 4.01 of Worksheet E-4). Then, the Medicare contractor would determine if the hospital reported the full amount of its section 5503 cap increase on the section 5503 cap line of the cost report, or a partial cap increase. The amount of the section 5503 cap increase that is reported on the section 5503 cap line (line 8.01 of Worksheet E, Part A, and line 4.01 of Worksheet E-4) is the amount of the "used" slots, and it influences the additional number of FTE residents that would be paid for in the current cost report. Therefore, while the sum of items 2 and 5 above should equal the cap increase amount reported on the section 5503 cap line, 75 percent of that cap increase amount reported on the section 5503 cap line must be used for additional primary care or general surgery FTEs added to the baseline number of FTEs.

If no residents were added on the current year line 10 or line 6 (item 2 above), but the hospital reported some or all of its section 5503 cap increase on line 8.01 of Worksheet E, Part A or line 4.01 of Worksheet E-4, the section 5503 cap increase is being used for cap relief. The 75-percent test would not be met, and all of the section 5503 cap slots would be removed in accordance with § 413.79(n)(2)(iv). If no section 5503 cap increase is reported on the section 5503 cap line (line 8.01 of Worksheet E, Part A or line 4.01 of Worksheet E-4), the contractor would still determine if the primary care average requirement is met in the current year. Failure to comply with either the 75 percent or 3-year primary care average test means permanent removal of all section 5503 slots from the earliest applicable cost reporting period under the regulations at § 413.79(n)(2)(iv).

With regard to the Medicare contractor's review of a hospital's final (full or partial) cost report, if the Medicare contractor determines that the hospital complied with the 75-percent test and the 3-year primary care average requirement, the Medicare contractor would assess the number of applicable unused slots, in accordance with the revised regulations text at § 413.79(n)(2)(ii). Any amount of "unused" section 5503 award, that is, the portion above 25 percent of the total award that is not being used for nonprimary care "growth" or for cap relief, would be removed permanently by the contractor for portions of cost reporting periods on or after July 1, 2016. For example, in year 5 (that is, the final cost report), a hospital that was awarded 10 slots is training 6 new primary care/general surgery residents in a new program. That means the most that can be used for cap relief or nonprimary care is 2 FTEs (2 is 25 percent of 8), and an amount

of 8 may be reported on line 8.01 of Worksheet E, Part A, and on line 4.01 of Worksheet E-4, and the remaining 2 FTEs would be removed for portions of cost reporting periods on or after July 1, 2016 by the contractor. (That is, effective for portions of cost reporting periods on or after July 1, 2016, the hospital's section 5503 award would be permanently reduced by 2 FTEs). If this hospital had reported all 10 of its section 5503 slots on line 8.01 of Worksheet E, Part A, and on line 4.01 of Worksheet E-4 in year 5, while actually only adding 6 primary care/general surgery residents in the new program, this hospital would fail the 75 percent test. Under the regulations at § 413.79(n)(2)(iv), this hospital would lose all 10 of its section 5503 cap slots, effective with the earliest cost reporting period that is reopenable in which it would be determined that the hospital did not meet the requirements.

With regard to the commenters who stated that any hospital that received an increase for a new program should submit to CMS a 5-year plan on how it plans to fill its slots, we believe that is superfluous. Hospitals that received section 5503 slots were already required to demonstrate in their initial application a commitment to fill the slots within the first three cost reporting periods of receiving the slots. Therefore, it would not be helpful to require hospitals to submit additional plans for CMS to review. We also do not see the need to allow hospitals to choose the start of their 5-year evaluation period to be either July 1, 2011 or July 1, 2012. If the 5-year evaluation period begins July 1, 2012, that would extend the 5-year period beyond June 30, 2016, and we stated in the November 24, 2010 final rule with comment period that the 5-year probationary period ends on June 30, 2016 (75 FR 72200). Because we believe we have modified and

significantly relaxed our requirements for hospitals with regard to the timeframe for filling section 5503 slots, we do not believe it is necessary to further prolong the 5-year evaluation period beyond June 30, 2016.

Comment: One commenter did not understand CMS' use of "and/or" to describe the requirement that a hospital must fill at least half of its slots in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period of the 5-year period, and/or in its third 12-month cost reporting period of the 5-year period. The commenter believed it would be clearer to state that a hospital must fill "at least half of its section 5503 slots in at least one of the following timeframes . . . its second 12-month cost reporting period of the 5-year period, or its third 12-month cost reporting period of the 5–year period; or its fourth 12-month cost reporting period of the 5-year period." Another commenter asked that CMS clarify its language regarding use of all the slots in the fifth year, noting that the proposed preamble states that hospitals would be required to "fill all of the slots they received *in* their final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016" (emphasis added by the commenter), while the proposed regulations at 42 CFR 413.79(n)(2)(ii) state that the hospital "must fill all of the slots it received *by* its final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016" (emphasis added by the commenter). The commenter asked that CMS not measure a hospital's compliance with a rate of usage of section 5503 slots based on a single year, noting that a hospital might fill all of its slots in the fourth year, but for reasons beyond its control, may lose one of the residents in the fifth year, putting the hospital at risk to lose all of its

slots. Yet another commenter noted that CMS has not indicated how it would measure compliance with the requirement that "all" awarded slots be filled in the fifth year of the evaluation period. The commenter suggested that CMS establish a baseline and indicate whether it is a single year FTE count or an average FTE count of more than one year.

Response: We regret the confusion we caused by using "and/or" to describe the requirement that a hospital must fill at least half of its slots in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period of the 5-year period, and/or in its third 12-month cost reporting period of the 5-year period. In any case, because we are not finalizing that proposal, this language is irrelevant and will not be included in the final regulations text. Regarding the language in the proposed preamble that states that hospitals would be required to "fill all of the slots they received *in* their final cost reporting period" (emphasis added by the commenter), while the proposed regulations at 42 CFR 413.79(n)(2)(ii) state that the hospital "must fill all of the slots it received *by* its final cost reporting period" (emphasis added by the commenter), we believe that "in" and "by" may be used interchangeably. The point is that Medicare counts and pays for FTEs, not resident positions, as reported on the Medicare cost report. We have stated what we mean by the 5-year evaluation period, and described that depending on a hospital's fiscal year end, some hospitals will have five 12-month cost reporting periods (if they have a June 30 FYE), while other hospitals would have first a partial cost report, then four 12-month cost reports, and then finally a partial cost report, so as not to go beyond June 30, 2016, which is 5 years from the effective date of July 1, 2011 (75 FR 72197 and 77 FR 27983). We also have stated

that, for hospitals with other than a June 30 FYE, in order to measure compliance with the 75-percent test and the 3-year primary care average requirement, an annualized FTE count in the first and final partial cost reports would be employed (75 FR 72197). Thus, the annualized FTE count and the annualized FTE resident cap increase *in that final full or partial cost reporting period* will be used to determine compliance with the tests and to determine the amount of slots that are "unused." Finally, as we stated in response to the previous comment, in this final rule, unlike in the proposed rule, we are not requiring that "all" awarded slots be filled in the fifth year. Rather, we have revised the regulation text at §413.79(n)(2)(ii) to describe when slots would be removed, in the event that not "all" of them are filled (that is, used) by the fifth year. Furthermore, in the previous response, we also have defined a base year, or baseline number of FTEs, for the purpose of determining "growth" of additional FTE slots added in accordance with section 5503. However, we are not necessarily measuring a hospital's compliance with a rate of usage of section 5503 slots based on a single year or an average of years. As stated in the November 24, 2010 final rule (75 FR 72200 and 72201), CMS could consider an average of a hospital's performance over more than 1 year, rather than only always reviewing each year during the 5 years independently. Regardless of when the Medicare contractor audits a hospital to determine if it is meeting the criteria within the 5-year period, a hospital should not view this policy as an encouragement to have an "off" year where the requirements need not be met.

Comment: One commenter asked how CMS would determine if a hospital filled half of its section 5503 slots. For example, if a hospital was awarded 10 slots, would

CMS or a MAC seek to confirm that the hospital is training 3.75 FTEs above its primary care average, because 3.75 is 75 percent of 5, which is half of the 10 awarded slots? The commenter believed such an approach makes sense, "as it provides for a clear, straightforward comparison of primary care/general surgery training in a particular year to the known, established 3-year primary care average." The commenter stated that because up to 25 percent of the awarded slots can, at any time, be used for any type of non-primary care residency training, it would be very difficult to demonstrate use of all 5 slots (that is, half the awarded 10), when 1.25 FTEs could be used for any purpose and there would be no clear reference point to determine that nonprimary care training is also increased by a specific amount (given that there is no nonprimary care historical reference—or not one that has been clearly identified for this purpose).

Response: The commenter's question was asked in the context of the proposed policy, which proposed to require hospitals to fill at least half of their section 5503 slots in at least one of the first three 12-month cost reporting periods of the 5-year evaluation period. In this final rule, we are finalizing a policy wherein, regardless of whether a hospital is starting new programs, expanding programs, or doing a combination of both, the Medicare contractor will remove the portion of the section 5503 award that is unused in the final cost report. (However, as explained earlier, in the case of slots used to expand an existing program, if the number of slots associated with a program expansion in the final cost report is greater than the number of slots associated with a program expansion in the fourth 12-month cost report, the Medicare contractor would remove those additional expanded FTEs that are over the FTEs associated with program expansion in

the fourth 12-month cost reporting period.) We agree that, of the applicable section 5503 cap increase reported on a hospital's cost report in the 5-year evaluation period, 25 percent of the cap increase amount may be used for any purpose. We also have defined a base year, or baseline number of FTEs, for the purpose of determining "growth" of additional FTE slots added in accordance with section 5503. The baseline for determining whether FTEs are added in each cost report in the 5-year evaluation period is the total unweighted allopathic and osteopathic FTE count from the hospital's 12-month cost report that immediately precedes the cost report that includes July 1, 2011 (that is, the baseline cost report for June 30 providers would be July 1, 2010 through June 30, 2011; for December 31 providers, this would be January 1, 2010 through December 31, 2010; for September 30 providers, this would be October 1, 2009 through September 30, 2010). (On the CMS Form 2552-96, the baseline number is the number on line 3.08 of Worksheet E, Part A, and on line 3.05 of Worksheet E-3, Part IV. On the CMS Form 2552-10, the baseline number is the number on line 10 of Worksheet E, Part, and on line 6 of Worksheet E-4). We believe this base year provides a clear reference point for determining whether both primary care/general surgery or nonprimary care training has increased during the 5-year evaluation period.

Comment: A few commenters supported the proposal to require hospitals to use at least half of their section 5503 slots in either the first, second, or third 12-month cost reporting period of the 5-year period, and to use all of their slots by the fifth year, stating that the proposed standards appear reasonable and consistent with statutory intent. One commenter stated that the proposals "drive earlier implementation of new positions and

strengthen requirements that institutions fulfill the obligation of the statute regarding primary care and general surgery positions." With regard to the proposed requirement that Medicare contractors determine whether a hospital filled at least half of its section 5503 slots in any of the first three cost reporting periods, the commenter asked that CMS add to this a requirement consistent with Evaluation Criterion 3 of the section 5503 application form, which was targeted to primary care programs with a "demonstrated focus" on residents who pursue careers in primary care. Hospitals that received points under Evaluation Criterion Three had to "demonstrate" that residents graduating from their programs actually do practice in primary care, and do not enroll in nonprimary care subspecialty programs or work as something other than a primary care practitioner. CMS stated that a threshold of greater than 50 percent of graduates would be acceptable as a basis to demonstrate that a program produces physicians who pursue careers in primary care. The commenter stated that, given that Medicare contractors will be able to identify which positions are filled with primary care positions after the third year, CMS should utilize the 50-percent threshold and require Medicare contractors to identify the number of graduates who remain in primary care practice in the fifth year after medical school (2 years after primary care residency completion), and remove slots from institutions that do not graduate over 50 percent who remain in primary care. The commenter believed that this can be accomplished by counting those residents who are not in residency or fellowship training in their fifth year, in relation to those who are continuing training.

One commenter that supported the proposal is a hospital that consistently trains residents in excess of its caps and that is not located in a State with a resident-to-

population ratio in the lowest quartile or in an area designated as a health professional shortage area (HPSA), and therefore was not eligible to receive slots from redistribution under section 5503. The commenter stated that if hospitals are not using the caps they received, the slots should become available to hospitals that will use them. The commenter asserted that there is no guarantee that physicians trained in rural, low resident to population ratio areas or HPSAs will stay in those areas. Therefore, the commenter encouraged CMS to develop a methodology with appropriate criteria to redistribute slots not used under section 5503 to those hospitals that have consistently trained residents over their cap.

Response: We appreciate the commenters' support for our proposals. However, we have considered the comments in their totality and are persuaded by those comments that opposed our proposed policies, and, therefore, we are modifying our proposed policy in this final rule accordingly. Moreover, we do not believe it would be appropriate to adopt the commenter's suggestion of removing slots from hospitals that do not graduate over 50 percent of residents who train in primary care. We also note that distribution of slots under section 5503 was statutorily directed to only certain States.

Comment: One commenter noted that, as part of the Medicare contractors' reviews of the hospitals that received section 5503 slots, CMS proposed that the Medicare contractors would determine whether a hospital filled at least half of its section 5503 slots in its first 12-month period, its second 12-month period, and/or its third 12-month period. The commenter stated that, for any new requirements finalized in the final rule, CMS should provide specific desk review and/or audit steps for the contractors to

follow. With regard to the hospitals, the commenter noted that there is no reporting requirement or mechanism for a hospital to report the manner in which it fills its section 5503 FTE cap slots, making it difficult for a Medicare contractor to determine whether such a hospital is meeting its requirements. On the Medicare cost report, a hospital reports its FTE residents in total, with no distinction as to whether the FTE residents were added as a result of the addition of the section 5503 FTE cap slots. The commenter recommended that CMS require hospitals that received Section 5503 slots to report how they filled the slots as a separate data submission. Because these hospitals received the benefit of additional FTE cap slots, the commenter believed it is not unreasonable to require them to report how they meet the requirements accompanying this benefit. If the hospital is required to report section 5503 information to the Medicare contractor, the commenter stated that it is possible that the review could be part of the desk review process. However, if the hospital is not required to submit information specific to its section 5503 requirements, the commenter believed that the contractor might have to review this information on audit.

Response: We will provide additional instructions for the Medicare contractors to follow in the desk review and audit process. As stated in response to the comments above, we also are modifying the cost report for hospitals to provide specific information regarding how they are using the section 5503 slots. As with other provisions, hospitals are required to supply information and documentation to the Medicare contractor upon request.

Comment: One commenter noticed that CMS reiterated in the proposed rule (77 FR 27982) the policy finalized in the November 24, 2010 final rule with comment period (75 FR 72196 and 72197, and 72200 and 72201), that CMS has the right to audit at any time during the 5-year period and remove reallocated slots. The commenter expressed concern that this policy "undercuts" the procedures for assuring that slots are filled. The commenter argued that if CMS audits and removes slots in Year 1, 2, or 4, and the hospital had not yet filled half or all of the slots, but would meet the requirement in Year 3 or Year 5, CMS "has subverted its own rule." The commenter pointed out that CMS already has the authority to investigate civil or criminal fraud or abuse; therefore, the commenter recommended that CMS clarify the circumstances under which it could conduct such audits and "not subject providers to undefined second-guessing."

Response: Although this comment was made in the context of the proposal which we have revised significantly in this final rule, this comment prompts us to provide more clarification for those who may be unclear about the rules that are applicable during the 5-year evaluation period between July 1, 2011 and June 30, 2016. The commenter argued that, if CMS audits and removes slots in Year 1, 2, or 4, and the hospital had not yet filled half or all of the slots, but would meet the requirement in Year 3 or Year 5, CMS "has subverted its own rule." It appears that the commenter is saying that by auditing and perhaps removing slots for failing to meet the 75 percent test or the 3-year primary care average requirement in years prior to Year 3 or Year 5, CMS is not even giving a hospital a chance to meet CMS' proposed rules. However, section 1886(h)(8)(B)(ii) of the Act states that a hospital that receives section 5503 slots "shall

ensure, *during the 5-year period beginning on the date of such increase*" (emphasis added) that it meets those two requirements. Therefore, whether or not a hospital meets CMS' proposed (or even modified final) rules regarding by when and how many of the awarded slots must be filled is irrelevant if, at any point during the 5-year evaluation period, the hospital fails to meet the 75 percent test or the 3-year primary care average requirement. As we stated in response to a previous comment, regardless of when the Medicare contractor audits a hospital to determine if it is meeting the criteria every year within the 5-year period, a hospital should not view this policy as an encouragement to have an "off" year where the requirements need not be met. Thus, a contractor could remove all of the slots awarded to the hospital in any year of the 5-year evaluation period because either the 75 percent test or the 3-year primary care average was not met, even if the hospital *does* fill half of its section 5503 slots by its third 12-month cost report, or fills all of its slots by its final cost reporting period (based on the proposed policy). Therefore, we disagree with the commenter that we are "subverting" our own rules by reserving the right to have the Medicare contractors assess as many times as necessary during the 5-year period that the hospital is meeting the statutory criteria.

Comment: One commenter asked that CMS clarify whether the analysis of whether a hospital meets the primary care average and the 75 percent test will be conducted separately for IME and direct GME respectively.

Response: The primary care average and the 75-percent test are conducted separately with respect to IME and direct GME, and many hospitals received different award amounts for IME and direct GME.

In summary, we are finalizing a policy under section 5503 and we are revising the regulations text at §413.79(n)(2)(ii) to state that if a hospital received a section 5503 cap award, and does not use all of the award in its final (12-month or partial) cost report of the 5-year period beginning July 1, 2011 and ending June 30, 2016, the Medicare contractor will remove the applicable unused slots, and the hospital's section 5503 award will be reduced for portions of cost reporting periods on or after July 1, 2016. The number of applicable unused slots is equal to the difference between the number of slots awarded and the number of slots used. In determining the applicable slots used, the following amounts are added, as relevant:

(1) If a hospital uses the section 5503 slots to expand an existing program(s), the used slots are equal to the lesser of the number of slots used for an expansion(s) in the fourth 12-month cost report or the final cost report.

(2) If a hospital uses the section 5503 slots to start a new program(s), the used slots are equal to the number of slots used for a new program(s) in the final cost report.

(3) The portion, if any, of the section 5503 slots used for cap relief, subject to the 75 percent test and the 3-year primary care average requirement.

We also clarify that cap relief constitutes "use" of section 5503 slots, and we instruct that, in the 5-year evaluation period, a hospital should not automatically report (that is, use) all of its section 5503 cap increase (on Form CMS-1-2552-10, line 8.01 of Worksheet E, Part A, and on line 4.01 of Worksheet E-4), but should only report (that is, use) a portion that at least is equal to the additional primary care/general surgery FTEs added, with no more than an additional 25 percent allowed to be reported for other

purposes. We reiterate that a hospital is responsible for meeting the 75-percent test based on whatever amount of section 5503 cap increase it reports on its cost report (on Form CMS-2552-10, line 8.01 of Worksheet E, Part A, and line 4.01 of Worksheet E-4) during each year of the 5-year evaluation period. We also reiterate that the 3-year primary care average requirement applies immediately on July 1, 2011, regardless of when a hospital begins to use its additional section 5503 slots in the 5-year period. This is because the 3-year primary care average test applies to the hospital's pre-section 5503 resident complement as well, and not exclusively to the additional FTE residents associated with slots awarded under section 5503.

4. Preservation of Resident Cap Positions from Closed Hospitals (Section 5506 of the Affordable Care Act)

a. Background

Under existing regulations at § 413.79(h) for direct GME and § 412.105(f)(1)(ix) for IME, a hospital that is training FTE residents at or in excess of its FTE resident caps and takes in residents displaced by the closure of another teaching hospital may receive a temporary increase to its FTE residents caps so that it may receive direct GME and IME payment associated with those displaced FTE residents. However, those temporary FTE resident caps are associated with those specific displaced FTE residents, and the temporary caps expire as those displaced residents complete their training program. Thus, in the past, if a teaching hospital closed, its direct GME and IME FTE resident cap slots would be "lost," because those cap slots are associated with a specific hospital's Medicare provider agreement, which would be retired upon the hospital's closure.

Section 5506 of the Affordable Care Act addressed that situation by amending section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the total number of FTE resident cap slots distributed shall be equal to the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively. Under existing regulations at § 489.52 and § 413.79(h), "closure of a hospital" means the hospital terminates its Medicare provider agreement. As finalized in the November 24, 2010 final rule with comment period (75 FR 72213), we also specified that the FTE resident cap slots of the hospital that closed no longer exist as part of any other hospital's permanent FTE resident cap.

Section 1886(h)(4)(H)(vi)(II) of the Act, as added by section 5506(a) of the Affordable Care Act, specifies that the Secretary shall distribute the FTE cap increases in the following priority order, "with preference given within each category to hospitals that are members of the same affiliated group" (as defined by the Secretary) as the closed hospital:

- First, to hospitals located in the same core-based statistical area (CBSA) as, or in a CBSA contiguous to, the hospital that closed.
- Second, to hospitals located in the same State as the closed hospital.
- Third, to hospitals located in the same region of the country as the hospital that closed.

- Fourth, only if the slots are not able to be fully distributed under the third priority group, to qualifying hospitals in accordance with the criteria established under section 5503 ("Distribution of Additional Residency Positions") of the Affordable Care Act.

For a detailed discussion on these ranking categories, we refer readers to the November 24, 2010 final rule with comment period (75 FR 72214 and 72215). In the November 24, 2010 final rule with comment period (75 FR 72212 through 72240), we also finalized the following Ranking Criteria:

□ Ranking Criterion One. *The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program(s) exactly as it had been operated by the hospital that closed (that is, same residents, possibly the same program director, and possibly the same (or many of the same) teaching staff).*

□ Ranking Criterion Two. *The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital received slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed was with*

a hospital that itself has closed or is closing, preference would be given to an applying hospital that was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital received slots from the closed hospital under the terms of that affiliation agreement.

□ Ranking Criterion Three. *The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).*

□ Ranking Criterion Four. *The applying hospital does not fit into Ranking Criteria One, Two, or Three, and will use additional slots to establish a new or expand an existing geriatrics residency program.*

□ Ranking Criterion Five*: Applying hospital does not meet Ranking Criterion One, Two, or Three, is located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.*

□ Ranking Criterion Six*: Applying hospital does not meet Ranking Criterion One, Two, or Three, is not located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.*

□ Ranking Criterion Seven*: Applying hospital seeks the slots for purposes that do not fit into any of the above ranking criteria.*

In determining which hospitals should receive the slots associated with the closed hospital, in addition to considering the ranking categories and criteria listed above, section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a) of the Affordable Care Act, states that the Secretary may only award slots to an applying hospital "if the Secretary determines that the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years." "Within 3 years" means within the 3 academic years immediately following the application deadline to receive slots after a particular hospital closes (75 FR 72224). For example, where the application deadline is April 1, 2011, the immediately following academic year is July 1, 2011; therefore, hospitals must demonstrate the likelihood of filling their slots by June 30, 2014.

Finally, section 5506(d) of the Affordable Care Act specifies that "the Secretary shall give consideration to the effect of the amendments made by this section on any temporary adjustment to a hospital's FTE cap under § 413.79(h) . . . (as in effect on the date of enactment of this Act) in order to ensure that there is no duplication of FTE slots . . . ." In distributing slots permanently under section 5506, we need to be cognizant of the number of FTE residents for whom a temporary FTE cap adjustment was provided under existing regulations at § 413.79(h), and when those residents will complete their training, at which point the temporary slot associated with those displaced residents would be available for permanent redistribution.

b. Change in Amount of Time Provided for Submitting Applications under Section 5506 of the Affordable Care Act

In the August 3, 2010 proposed rule (75 FR 46422), we proposed to establish an application process for hospitals to apply to CMS to receive an increase in FTE caps based on slots from closed hospitals. Section 5506 of the Affordable Care Act did not specify an application deadline for hospitals to request an increase to their caps when a hospital closes. With respect to the first application process, which applied to all teaching hospital closures between March 23, 2008, and August 3, 2010, we established an application deadline of April 1, 2011. For future teaching hospital closures, we finalized a policy whereby we would inform the public through an appropriate medium that increases to hospitals' FTE resident caps are available for distribution due to the closure of a teaching hospital, and the application deadline would be 4 months following the issuance of that notice to the public (75 FR 72215).

Prior to issuance of the FY 2013 IPPS/LTCH PPS proposed rule, some representatives of the provider community had commented that providing hospitals with 4 months following the announcement of a teaching hospital closure to apply for slots under section 5506 is longer than necessary. They asserted that such a long application period unnecessarily delays CMS' review of applications and the resulting distribution of resident cap slots from closed hospitals to the applicants. The provider representatives suggested that perhaps a 2-month application window is sufficient and is more practical.

As we discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27985), we have considered the suggestion of the provider representatives, and after our initial experience in implementing section 5506 of the Affordable Care Act, we agree that 4 months may be more time than is needed for hospitals to properly prepare and submit

section 5506 applications to CMS. Accordingly, we proposed to set the application deadline for future section 5506 applications to be 60 days following CMS' public notice of a hospital's closure and the availability of resident cap slots increases. We stated that we believe that reducing the application submission timeframe from 4 months to 60 days will shorten the entire process for awarding FTE resident cap slots from closed hospitals considerably.

Comment: Many commenters supported CMS' proposal for a 60-day application period as a reasonable timeframe and commended CMS' efforts to expedite the process of awarding section 5506 FTE resident cap slots. One commenter did not support the shortened application period because the commenter believed it may lead to less thoughtful decision-making and it could have a disproportionately adverse effect on smaller hospitals with fewer resources at their disposal when applying for additional FTE resident cap slots.

Another commenter supported the 60-day application period but suggested that CMS use the IPPS final rule as a medium to issue the public notice of a hospital's closure The commenter believed that CMS' issuance of the public notice as part of the IPPS final rule instead of issuing a separate public notice would ease an applicant hospital's administrative burden in that the hospital would have advance knowledge of the forthcoming public notice and could plan accordingly.

Response: We appreciate the commenters' support for our proposal, and at the same time, we also understand the commenter's concerns regarding a shortened application period. As noted above, we initially implemented a 4 month application

period because we believed that 4 months provided adequate time for hospitals to gather the appropriate documentation and prepare a section 5506 application (75 FR 72215). In light of the public comments received on our proposed policy to reduce the length of the application period to 60 days, and our understanding of the efforts required to prepare a section 5506 application, we believe an appropriate compromise is to provide for a 90-day application period for future section 5506 applications. Therefore, we are finalizing a section 5506 application deadline of 90 days following CMS' public notice of a hospital's closure and the availability of resident cap slots increases.

With respect to the comment suggesting that we include public notice of hospital closures in the IPPS final rule, we believe this could unnecessarily delay the section 5506 award process. We prefer to have the flexibility to issue public notices of hospital closures at other times during the year and not limit the notices to the IPPS final rule, and we believe it is in hospitals' best interests to maintain such flexibility.

In summary, after consideration of the public comments we received, we are finalizing a section 5506 application period of 90 days following CMS' public notice of a hospital's closure and the availability of resident cap slots increases.

c. Change to the Ranking Criteria under Section 5506

In the November 24, 2010 final rule with comment period (75 FR 72223), we finalized the Ranking Criteria within each of the three first statutory priority categories (that is, same or contiguous CBSAs, same State, and same region) to be used to rank applications. For each application, we assigned slots based on Ranking Criteria, with Ranking Criterion One being the highest ranking and Ranking Criterion Seven being the

lowest. For a complete list of the Ranking Criteria, we refer readers to section IV.I.4.a. of this preamble, which discusses the background for preservation of resident cap positions from closed hospitals under section 5506 of the Affordable Care Act. For a detailed discussion of the ranking categories, we refer readers to the November 24, 2010 final rule with comment period (75 FR 72212 through 72240).

After reviewing applications from the first section 5506 application process (those applications that were due to CMS on April 1, 2011), we observed that the overwhelming majority of applications fell under Ranking Criterion Seven, that is, the applying hospital seeks the slots for purposes that do not fit into any of Ranking Criterion One through Ranking Criterion Six. These applications included applications from hospitals that applied for FTE cap slots for both primary care and/or general surgery and for nonprimary care specialties as well as applications for general cap relief. (A request for slots only for primary care and/or general surgery programs would qualify under either Ranking Criterion Five or Ranking Criterion Six). The sheer number of applications we received under Ranking Criterion Seven indicated a need to further prioritize among the applicants that would previously have qualified under Ranking Criterion Seven. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27985), we proposed to replace current Ranking Criterion Seven with the two separate proposed Ranking Criteria listed below. We noted that we were not proposing to make any changes to Ranking Criteria One through Six. We proposed the following two criteria to replace existing Ranking Criterion Seven:

- *Proposed Ranking Criterion Seven:* The program does not meet Ranking Criterion One through Six, and the slots for which the hospital is applying are for a primary care or a general surgery program, but the hospital is also applying for slots under Ranking Criterion Eight.

- *Proposed Ranking Criterion Eight:* Applying hospital seeks the slots for purposes that do not fit into any of the above ranking criteria.

The proposal to modify Ranking Criterion Seven is consistent with current Medicare policy goals to increase residency training in primary care and general surgery, because we proposed to give a higher ranking to those applications from hospitals applying for primary care and general surgery FTE cap slots, as well as nonprimary care programs. Under the current Ranking Criteria, when a hospital applies for additional FTE cap slots for primary care and/or general surgery as well as nonprimary care programs, we do not distinguish between the primary care/general surgery and nonprimary care applications. Therefore, because the hospital would be applying for nonprimary program(s), all the hospital's applications would fall under proposed Ranking Criterion Seven. Under our proposal, although the hospital's application that requests FTE cap slots for primary care/general surgery would qualify for proposed Ranking Criterion Seven, the application for nonprimary care/general surgery would be classified as proposed Ranking Criterion Eight.

Following is an example of how Ranking Criteria Seven and Eight would be assigned:

Hospital A applies for slots from closed Hospital B. Hospital A is seeking to expand its internal medicine and dermatology programs. Under the current ranking system, both of Hospital A's applications would receive consideration under Ranking Criterion Seven. That is, the internal medicine application is ranked equally with the dermatology application even though internal medicine is a primary care specialty. Under the proposed change to the Ranking Criteria, Hospital A's internal medicine program would receive consideration under proposed Ranking Criterion Seven while the dermatology program would receive consideration under proposed Ranking Criterion Eight.

Comment: One commenter objected to CMS' policy of giving higher ranking to hospitals that apply for FTE cap slots for primary care or general surgery programs only than to hospitals that apply for FTE cap slots for primary care or general surgery as well as for other nonprimary care or nongeneral surgery programs. The commenter suggested that CMS rank all applications for primary care or general surgery programs equally, regardless of the existence or nonexistence of other nonprimary care or nongeneral surgery applications. Another commenter urged CMS not to advance the creation of primary care or general surgery programs at the expense of other essential yet nonprimary care or nongeneral surgery specialties such as psychiatry.

Response: We disagree with the first commenter. We do not believe that a hospital that applies for slots under section 5506 for the purpose of starting or expanding only programs in primary care and general surgery should be ranked equally with a hospital that applies for the purpose of starting or expanding primary care and/or general

surgery programs, and other nonprimary care programs as well. We continue to believe that our Ranking Criteria, which give a higher ranking to hospitals that apply only for primary care or general surgery programs, are consistent with the expressed goals of sections 5503 and 5506 of the Affordable Care Act, and are in keeping with the important policy objective of promoting the growth in the number of primary care and general surgery residents, and reducing the shortage of primary care physicians and general surgeons. Thus far, Congress has not identified other specialties for special treatment. However, we note that under Ranking Criteria One, Two, and Three, hospitals can use slots awarded under section 5506 for nonprimary care programs because these Ranking Criteria do not consider or specify a program type, and instead give priority to hospitals that continue to maintain the level and type of training that were occurring prior to the hospital closure.

After consideration of the public comments we received, we are finalizing our proposed changes to the Ranking Criteria with some modification. As proposed, we are replacing current Ranking Criterion Seven with the two separate Ranking Criteria listed below. We also are modifying our proposed language for Ranking Criterion Seven in order to highlight and clarify how Ranking Criterion Seven differs from Ranking Criterion Five and Ranking Criterion Six. A program may only qualify for Ranking Criterion Five or Six if the applying hospital will use all of its additional slots to establish or expand primary care or general surgery programs. Therefore, a hospital that submits several applications that include requests for additional FTE slots for purposes other than solely to establish or expand primary care or general surgery programs may not apply

under Ranking Criterion Five or Six for additional FTE slots for its primary care or general surgery programs. Rather, a hospital that is applying both for the purpose of establishing or expanding primary care or general surgery programs, and for the purpose of establishing or expanding nonprimary care or nongeneral surgery programs and/or for cap relief must submit an application requesting additional FTE slots under Ranking Criterion Seven for its primary care or general surgery programs. The hospital's requests for additional FTE slots to establish or expand a nonprimary care or nongeneral surgery program and/or for additional FTE slots for cap relief would properly be made under Ranking Criterion Eight. In summary, we are finalizing Ranking Criterion Seven as follows:

- *Ranking Criterion Seven:* The applying hospital will use additional slots to establish or expand a primary care or general surgery program, but the program does not meet Ranking Criterion Five or Six because the hospital is also separately applying under Ranking Criterion Eight for slots to establish or expand a nonprimary care or non-general surgery program and/or for cap relief.

In light of the modifications we are making in this final rule to the proposed Ranking Criterion Seven, we also believe it is appropriate to modify the language of proposed Ranking Criterion Eight to specify the types of applications that would properly be made under this Ranking Criterion. In the proposed rule, we proposed to replace the existing Ranking Criterion Seven with a new Ranking Criteria Seven, and create a new Ranking Criterion Eight for situations where an "applying hospital seeks the slots for

purposes that do not fit into any of the above ranking criteria." We are modifying this proposed language and finalizing Ranking Criterion Eight as follows:

- *Ranking Criterion Eight:* The applying hospital will use the additional slots to establish or expand a nonprimary care or nongeneral surgery program or for cap relief.

We note that we did not propose, nor are we making, any changes to Ranking Criteria One through Six.

d. Effective Dates of Slots Awarded under Section 5506

As stated previously, section 5506(d) of the Affordable Care Act instructs the Secretary, in pertinent part, ". . . to ensure that there is no duplication of FTE slots . . . ." Accordingly, in distributing slots permanently under section 5506, we need to be cognizant of the number of FTE residents for whom a temporary FTE cap adjustment was provided under existing regulations at § 413.79(h), when those residents will complete their training, and at which point the temporary slots associated with those displaced residents would be available for permanent redistribution. With that in mind, in the first distribution of section 5506 cap slots from hospitals that closed between March 23, 2008, and August 3, 2010, we used the following several effective dates based on the ranking criterion under which a hospital applied:

- Date of hospital closure. This effective date could have applied to Ranking Criterion Two. It also could have applied to Ranking Criteria One and Three if there were no temporary cap adjustments given for any displaced FTE residents.

- Cost reporting period following date of hospital closure. This effective date could have been used for awarding slots to hospitals that were training displaced FTE residents and qualified for Ranking Criterion One or Ranking Criterion Three because they were taking over an entire program or part of a program from a closed hospital and had received a temporary cap adjustment to train those displaced residents under 42 CFR 413.79(h).

- July 1 effective date. This effective date, which could have been retroactive, could have been used for awarding slots to hospitals that qualified under Ranking Criteria

Four through Seven where there were temporary cap adjustments made for displaced FTE residents that completed training in a program on a specific June 30.

- Date of award announcement (January 30, 2012). This effective date could have applied to hospitals that qualified under Ranking Criteria Four through Seven either where there were no temporary cap increases under 42 CFR 413.79(h), or where there were temporary cap increases but those slots associated with the temporary cap increases were already accounted for. That is, displaced FTE residents graduated prior to a specific July 1, and, therefore, the cap slots associated with these FTE residents had already been permanently assigned that specific July 1, but the closed hospital still had remaining cap slots available for permanent assignment.

We stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27986) that, based on comments we have received from hospitals that were involved in the initial phase of section 5506 implementation (hospitals that applied for cap slots from hospitals that closed between March 23, 2008 and August 3, 2010), we believe we need to clarify certain existing policies and propose a change to the effective dates associated with several ranking criteria.

First, we clarified in the proposed rule the effective date of slots awarded under section 5506 with respect to Ranking Criterion Two. Ranking Criterion Two applies to hospitals that participated in a Medicare GME affiliation agreement with the closed hospital (but not one that was entered into more than 5 years prior to the hospital's closure), received slots from the closed hospital as part of the affiliation agreement, and will use any additional awarded slots to continue to train at least the same number of FTE

resident slots it trained as part of the affiliation agreement. For hospitals that qualify for additional slots under Ranking Criterion Two, we award the 5506 slots effective on a permanent basis with the date of the hospital's closure. However, for hospitals that qualify under Ranking Criteria One and Three and are already receiving temporary cap adjustments for displaced FTE residents under 42 CFR 413.79(h), we award the 5506 slots effective on a permanent basis with the cost reporting period following the date of the hospital's closure. Because these hospitals are already receiving temporary cap adjustments for their portion of their cost reporting period following the closure, for administrative ease, slots became permanent due to the section 5506 award effective with the cost reporting period following the date of the hospital's closure. However, this policy, applicable to hospitals that qualify under Ranking Criterion One or Three, is not appropriate for hospitals that qualify under Ranking Criterion Two and that participated in a Medicare GME affiliation agreement with the closed hospital and received cap slots from the closed hospital as part of that affiliation agreement. This policy is not appropriate because, in this case, there were no displaced FTE residents from the Medicare GME affiliation agreement and, therefore, the hospital did not receive a temporary cap adjustment. For example, if Hospital A received slots from Hospital B as part of an affiliation agreement so that FTE residents could train at Hospital A and Hospital B closes, Hospital A lost the cap adjustment it received from Hospital B as part of the affiliation agreement as of the date of the hospital's closure, and a temporary cap adjustment under 42 CFR 413.79(h) is not available to Hospital A. In this case, no FTE residents are displaced.

In the proposed rule and in this final rule, we are clarifying that, for hospitals qualifying under Ranking Criterion Two that are awarded cap slots from the closed hospital, the award is effective with the date of the hospital's closure. This effective date allows a hospital applying under Ranking Criterion Two to receive funding for training the additional FTE residents it was training as part of the Medicare GME affiliation agreement with the closed hospital immediately after the closure, without having to wait until the following cost reporting period to receive that cap adjustment. We note that, under existing regulations at 42 CFR 413.79(d), additional FTEs that a hospital receives under the terms of a Medicare GME affiliation agreement are subject to the 3-year rolling average. Therefore, hospitals that receive permanent assignment of FTE resident cap slots under Ranking Criterion Two do not receive an exemption from the rolling average. With regard to the IME intern and resident-to-bed (IRB) ratio, the existing regulations at 42 CFR 412.105(a)(1)(i) indicate that the numerator of the prior year IRB ratio may be adjusted to reflect FTEs added under a Medicare GME affiliation agreement. The affiliation agreement would terminate when the hospital closes. Thus, on the cost report of the hospital that receives slots under Ranking Criterion Two, the prior year numerator of the IRB ratio would only be adjusted to reflect the portion of the affiliated FTEs that the hospital received prior to the other hospital's closure and the termination of the affiliation agreement.

As we did in the proposed rule, we also are clarifying that when there are no temporary cap adjustments for displaced FTE residents from hospitals that closed, and an applying hospital qualifies under Ranking Criterion One or Ranking Criterion Three, the

FTE resident cap slots are awarded effective with the date of the hospital's closure. This was indicated in the November 24, 2010 final rule with comment period (75 FR 72225), but we understand, based on comments received after the initial phase of section 5506 slot awards, that this policy was not clearly understood. These slots are also immediately included in applying the rolling average and IRB ratio cap.

We proposed to change the effective date of an award of additional FTE caps for hospitals that qualify under Ranking Criterion Four through proposed Ranking Criterion Eight where temporary caps were given for displaced FTE residents (we refer readers to section IV.I.4.b. of this preamble for a discussion of proposed Ranking Criteria Seven and Eight). As a general matter, hospitals that apply under Ranking Criterion Four through proposed Ranking Criterion Eight are applying either to establish or expand a program or to seek cap relief. In the proposed rule, we stated that we do not believe that, when a hospital receives additional cap slots to establish or expand a residency training program, we need to award the cap slots retroactively to a previous July 1 effective date. Rather, the awarded cap slots are to be used on a prospective basis to allow hospitals to expand current programs or establish new ones. We understand that if a hospital is applying for cap relief under proposed Ranking Criterion Eight (previously Ranking Criterion Seven), the hospital would want its cap slots awarded retroactively to the date of the hospital's closure or the July 1 after a specific displaced resident has graduated if that date is prior to the date of the award announcement. However, we stated in the proposed rule that we do not believe such a policy is consistent with the spirit of the BBA caps. Furthermore, the purpose of section 5506 is for hospitals to receive slots from the

closed hospital to facilitate the continuity of the closed hospital's programs and to promote stability in the number of physicians in a community.

The proposed Ranking Criterion Eight of section 5506 does not serve to encourage the continuity of the closed hospital's programs; it merely provides Medicare funding for a certain amount of slots in excess of the BBA caps. Accordingly, we indicated in the proposed rule that we believe that hospitals applying for cap relief under proposed Ranking Criterion Eight should only receive their permanent cap slots effective on a prospective basis. Therefore, while under the initial section 5506 application process, it was possible for an applying hospital that qualified under Ranking Criteria Four through Seven to receive slots retroactive to the July 1 after a specific displaced FTE resident's graduation date, we proposed that, for hospitals that qualify under Ranking Criteria Four through Eight for cap slots from a closed hospital even where there were temporary caps given for displaced FTE residents, the applying hospitals would receive the permanent FTE cap slots effective no earlier than the date of the award announcement. That is, if an applying hospital that qualified under Ranking Criterion Four through proposed Ranking Criterion Eight receives cap slots associated with a displaced FTE resident and that resident graduated prior to the date of the award announcement, the earliest the applying hospital could receive the permanent cap adjustment would be the date of the award announcement. If a hospital qualified under Ranking Criterion Four through proposed Ranking Criterion Eight, and the only available cap slots are temporarily being used to train displaced FTE residents that are expected to graduate after the date of the award, the applying hospital will receive the permanent

slots effective the July 1 after those displaced FTE residents complete their training. For example, if a hospital closed January 1, 2012, and the section 5506 slot awards were announced May 1, 2013, but residents displaced from the closed hospital did not complete their training until June 30, 2013, the applying hospital will receive section 5506 slots for those displaced residents effective July 1, 2013, following the completion of training of those displaced residents. We did not propose to change the effective date of section 5506 awards for applying hospitals that qualify under Ranking Criterion Four through proposed Ranking Criterion Eight where there were no temporary caps given for displaced residents; as described in the November 24, 2010 final rule with comment period (75 FR 72227), those applying hospitals will continue to receive their section 5506 cap slots effective with the date of the award announcement.

In the proposed rule, we discussed another option to consider for the effective date of Ranking Criteria Four through proposed Ranking Criterion Seven, which are Ranking Criteria associated with either starting a program or expanding a program, would be to award the slots in accordance with when the hospital actually needs the slots, as asserted in the hospital's section 5506 application. (The proposed effective date for proposed Ranking Criterion Eight would still be no earlier than the date of the award announcement.) For example, assume a hospital applies under Ranking Criterion Five to expand an internal medicine program by nine positions. As described in its section 5506 application, the hospital plans that expansion to occur beginning on July 1, 2012, and at that time, the hospital would add three residents, on July 1, 2013, the hospital would add another three residents, and on July 1, 2014, the hospital would add the last three internal

medicine residents. Therefore, the effective date of three slots could be July 1, 2012, the effective date of three additional slots would be July 1, 2013, and the effective date of the last three slots would be July 1, 2014. We stated that we were interested in receiving public comments on this policy alternative. We still proposed that the effective date for proposed Ranking Criterion Eight would be no earlier than date of the award.

Comment: A number of commenters addressed our clarifications and proposals of the effective dates for all of the Ranking Criteria. Commenters agreed that cap slots received under Ranking Criterion Two should be effective with the date of the hospital closure. One commenter stated that because the receiving hospital had already been using the cap slots from the closed hospital as part of a Medicare GME affiliation agreement, there is no reason the slots should be awarded any later than the date of the hospital closure. The commenter added that it supported making slots received under Ranking Criterion Two effective with the date of the hospital closure because there are no temporary cap adjustments and exemptions from the rolling average applied to these cap slots.

Other commenters believed cap slots from closed hospitals should be awarded on an "as-needed" basis. They stated that, therefore, it is appropriate that the cap slots received under Ranking Criterion Two be awarded when the hospital closes because the receiving hospital would need the additional cap slots as of the date of the hospital's closure.

Response: We agree with the commenters that cap slots received under Ranking Criterion Two should be effective with the date of the hospital closure because the

receiving hospital had already been using the cap slots from the closed hospital as part of a Medicare GME affiliation agreement, and there are no temporary cap adjustments and exemptions from the rolling average applied to these cap slots. Therefore, we are finalizing our clarification that, if a hospital is awarded cap slots under Ranking Criterion Two, those cap slots are effective with the date of the hospital closure.

Comment: Some commenters specifically addressed our clarifications and proposals for the effective dates of Ranking Criteria Four through proposed Eight. One commenter did "not believe that it is appropriate for CMS to institute a 'one size fits all' policy to determine the effective dates for all awards," and that the awards should be "driven by the reasons for which the slots are being awarded." The commenter believed that making all awards for program establishment or expansion under Ranking Criteria Four through Eight prospectively *could* be appropriate if it was done in a manner consistent with a reasonable policy regarding the application of the temporary cap adjustments that hospitals have received for taking in displaced residents and it is done in a manner that does not "over manage" the distribution of the slots by doling them out on a slot by slot basis. Another commenter encouraged CMS to award section 5506 slots under all ranking criteria prospectively.

Other commenters recommended that the effective date for section 5506 direct GME and IME positions be the date when the slots are needed by the awardee hospital. The commenters believed that assigning effective dates based on this principle would avoid confusion and some of the problems hospitals encountered under CMS' current system for assigning effective dates. Commenters suggested that, for hospitals that begin

new programs (that is, apply for slots under Ranking Criterion Four, Five, or Six), section 5506 slots should become effective on the date the hospital's new program begins. The commenters recommended that, for administrative simplicity, the effective date should be the same for all awarded positions (that is, all slots become effective the date the new program begins). For a hospital that starts and is awarded slots for a new program that happens to begin in the time period between the date it submits an application to CMS and the date CMS announces the slot award, the commenters recommended that the effective date be retroactive to the date the hospital actually started the new program. (The commenters noted that this issue is relevant particularly given the large time lags between section 5506 slot application deadlines and award announcements.)

Response: We agree with the commenters that the effective dates of the various Ranking Criteria should be driven by the reasons for which they are awarded, and by when they are needed. However, while we do not want to over-complicate or "over-manage" the awarding of the slots, as one commenter cautioned against, we do believe that a certain amount of discretion and control should be maintained in the timing of the effective dates. Some commenters stated that section 5506 slots should become effective on the date the hospital's new program begins, and that for administrative simplicity, the effective date should be the same for all awarded positions (that is, all slots become effective the date the new program begins). However, these commenters did not address the fact that Ranking Criteria Four through the new Eight are also for expansions of existing programs. (The new Ranking Criterion Eight could be used for hospitals applying for slots to start or expand nonprimary care programs, and/or for cap relief.)

The timing of program expansions, which may not always require separate approval from the accrediting body if the hospital is training below its accredited number of positions, may be more challenging to pinpoint. Nevertheless, we believe that slots awarded under Ranking Criteria Four through Seven (and Eight if the slots are for starting or expanding a nonprimary care program) should be effective only with the date that they are actually needed, or, if applicable, only delayed sufficiently until displaced residents have graduated, freeing up those slots for use under Ranking Criteria Four through Eight.

Accordingly, consistent with some commenters' suggestion and our assessment that slots awarded under Ranking Criteria Four through Seven (and Ranking Criterion Eight if the slots are for starting or expanding a nonprimary care program) should be effective only when they are actually needed, we are finalizing a policy as follows:

For hospitals awarded slots under these Ranking Criteria, in the hospital's award letter, CMS will specify the program for which slots are being awarded, whether those slots are for a new program, or for an expansion of a program, the number of FTE slots awarded for that program, and the Ranking Criterion under which those slots are awarded. The award letter will not specify an effective date, although it may indicate that the slots can be used *no earlier* than a certain date in the instance where displaced residents need to graduate in order to free up slots. Rather, the slots would be "pending" with the Medicare contractor, and the hospital would have to contact its Medicare contractor and submit documentation proving that it needs a certain number of its slots awarded under Ranking Criteria Four through Seven (or Ranking Criterion Eight, as applicable, for nonprimary care programs) as of a certain date, because the hospital has

filled that number of positions in the National Resident Match Program (Match) (or other applicable recruitment process) as of that date, over the number of positions that it had trained in that program in the prior academic year.

For example, for a subsequent section 5506 application process, a hospital's award letter would state that it is awarded four slots to expand a pediatrics program under Ranking Criterion Six. The hospital would not be able to report a cap increase of any of the four FTEs on the section 5506 line of its Medicare cost report unless it receives permission from its Medicare contractor to do so. Assume that in March 2014, the awardee hospital documents to the Medicare contractor that in the March 2014 Match, it actually filled (not just placed) two more positions than it had trained in that program for the academic year beginning July 1, 2013. In this manner, because two additional slots are actually filled as compared to the preceding July 1, the hospital shows the Medicare contractor that effective July 1, 2014, it indeed will need two of the section 5506 FTEs that it was awarded under Ranking Criterion Six. The Medicare contractor could then release two of the four slots awarded for the purpose of expanding a pediatrics program effective July 1, 2014, and the hospital could report two FTEs (or some prorated amount if the hospital's FYE is other than June 30) on the section 5506 line of its Medicare cost report that includes July 1, 2014. The hospital shall not report the full cap increase of four on the section 5506 line of the cost report until it similarly proves that it has actually filled the remaining two positions. The documentation process would be the same if a hospital is awarded slots for starting a new program under Ranking Criteria Four through Seven (or Ranking Criterion Eight, as applicable, for nonprimary care programs). That

is, the hospital would have to prove that it actually has filled slots in the Match (or applicable process) associated with the new program for the upcoming academic year before the Medicare contractor would release the appropriate number of slots for that academic year.

Comment: Regarding cap slots received under section 5506 for cap relief (previously Ranking Criterion Seven, now Ranking Criterion Eight in this final rule), commenters stated that those cap slots should be awarded effective with the date of the hospital closure. Commenters stated that following the principle that cap slots should be assigned to receiving hospitals on an "as-needed" basis, if a hospital applied for cap relief, it would need those cap slots at the time of the hospital closure. One commenter disagreed with the proposal to assign cap slots for cap relief at the earliest with the date of the award announcement. The commenter stated that any teaching hospital that applied for cap relief should be awarded cap slots at the earliest point they are available. The commenter stated that "there is no justifiable policy reason to withhold a cap increase if the closed hospital's slots are available to be awarded and the hospital receiving the award, with all due respect to CMS, never claimed in its application that it was going to do anything different on a prospective basis (for example, expand a program) to justify its need for the slots." The commenter stated it did not understand CMS' statement that retroactive application of cap slots received for cap relief is not consistent with the caps. The commenter stated that the intent of section 5506 is to redistribute a closed teaching hospital's cap to other teaching hospitals, many of them in the same community, and that these teaching hospitals' caps are what prevent them from

receiving additional Medicare funding to support their operations as academic centers. The commenter stated that for CMS to delay awarding cap slots that they were instructed to award without a policy justification, would be "extremely unfortunate." The commenter requested that CMS withdraw its proposal related to the awarding of slots for cap relief and that the effective date for these cap slots be the date they become available.

Response: We disagree with the commenter who stated there is no justifiable policy reason that cap slots awarded for cap relief cannot be applied retroactively. When a teaching hospital closes, this occurrence may cause a disruption and loss of a GME infrastructure and a source of physicians to a community that can be a daunting task to rebuild and replace. The purpose of section 5506 is to attempt to preempt such disruption and loss by encouraging other hospitals in the area to continue the training programs of the closed hospital, not merely to use the section 5506 slots for an applicant hospital's own financial benefit to cover its unfunded slots. Consistent with the purpose of section 5506, we developed Ranking Criteria to give preference to those hospitals that take over a closed hospital's entire program or part of a program, and to hospitals that participated in a Medicare GME affiliation agreement with the closed hospital. These hospitals have had a direct relationship with the closed hospital and are helping to maintain the residency training program(s) of that closed hospital, thereby also minimizing the disruption and loss to the community at large. Therefore, because we do not believe that there is a justifiable policy reason to award slots for cap relief retroactively, we are finalizing a policy that cap slots received under Ranking Criterion Eight, specifically for cap relief, are effective the later of the date of the award announcement, or a July 1 *after*

displaced FTE residents complete their training if the cap slots awarded were associated with temporary adjustments made for displaced FTE residents.

Comment: One commenter stated that if, for purposes of the Medicare cost report, hospitals that receive cap slots under Ranking Criterion Two are treated differently from hospitals that receive cap slots under other Ranking Criteria, Medicare contractors must be notified of any such distinction. The commenter stated that the distinction would affect application of the 3-year rolling average and the IRB ratio cap. The commenter also stated that Medicare cost report instructions should be revised to reflect the difference between Ranking Criterion Two and other Ranking Criteria.

Response: In this final rule, as we explained in response to comments above, because we are no longer employing a policy where temporary cap increases would be replaced by permanent cap increases on the cost report, and the 3-year rolling average and the IRB ratio cap exemption would no longer be suspended as a consequence of receipt of permanent slots, we believe the cost reporting effect of receipt of section 5506 slots is the same, regardless of the Ranking Criteria under which the slots are awarded. That is, on the applicable cost report that an FTE cap increase is effective, whether retroactive or prospective, the hospital will be able to count more residents under the increased FTE resident cap in that cost report. Consequently, more FTE residents would be drawn into the rolling average for IME and direct GME, and more FTE residents would be subject to the IRB ratio cap for IME purposes. Therefore, we do not believe there is any distinction regarding the effect of reporting section 5506 slots about which we need to notify Medicare contractors or hospitals. However, we note that, as is the

case with the first two rounds of section 5506 slot awards, a hospital may receive a number of slots with various effective dates. Therefore, it is important that a hospital not report its full section 5506 cap increase on the section 5506 cap increase line (Form CMS-2552-10, Worksheet E, Part A, line 8.02 for IME, and Worksheet E-4, line 4.02 for direct GME) on its cost report all at once, but, rather, only report the portions of the section 5506 awards as they become effective.

In summary, we are finalizing our clarification that section 5506 slots awarded under Ranking Criterion Two are effective the date of the hospital closure. In response to public comments, we are finalizing a policy that the effective date for Ranking Criteria Four through Seven is the later of when a hospital can demonstrate to the Medicare contractor that the slots associated with a new program or expanded program are actually filled and, therefore, are needed as of a particular date (usually July 1, possibly retroactive), or the July 1 *after* displaced residents complete their training. Regarding Ranking Criterion 8, if slots are for starting or expanding a nonprimary care program, the effective date is the same as that for Ranking Criteria Four through Seven. If the slots are for cap relief, the effective date is the date of the CMS award announcement, or the July 1 *after* displaced residents complete their training, whichever date is later.

Thus far, we have discussed our proposed clarifications regarding when various effective dates have been used (that is, the date of closure, or the cost reporting period following the date of the closure, or a July 1 date), and our proposal to change the effective date of Ranking Criteria Four through proposed (now finalized) Ranking Criterion Eight when temporary cap adjustments for displaced residents were given (to be

no earlier than the date of the award announcement). However, due to concerns expressed by recipients of slots under the first round of section 5506, particularly regarding the interaction with the rolling average as the retroactive section 5506 slots become effective, in the proposed rule, we solicited public comments on alternative approaches to implementing section 5506. While bearing in mind that section 5506(d) of the Affordable Care Act instructs the Secretary ". . . to ensure that there is no duplication of FTE slots . . .," we stated that we would be interested in public comments regarding whether to either make the effective dates prospective for all section 5506 slots awarded under all ranking criteria, or, in certain instances such as when slots are awarded under Ranking Criteria One or Three, make the effective dates of the section 5506 slots seamless with the expiration of applicable temporary cap adjustments under § 413.79(h). We also solicited public comments on whether the regulatory temporary cap adjustment for residents displaced from closed hospitals under § 413.79(h) is still necessary and appropriate, now that there is a provision in the statute that addresses permanent reassignment of slots from closed teaching hospitals. Alternatively, we stated that we would be interested in comments regarding whether the regulatory temporary cap adjustment for displaced residents under § 413.79(h) should be preserved, but the exemption from the rolling average for those displaced FTE residents should be eliminated. We indicated that these options should be considered by commenters not only in the context of section 5506 slots that have already been assigned, but also in the context of future teaching hospital closures, and how previously awarded section 5506

slots that have not as yet been filled might interact with eligibility for temporary cap adjustments for additional displaced residents in the future.

Comment: Commenters supported the concept of making the effective dates of the section 5506 awards under Ranking Criteria One and Three seamless with the expiration of applicable temporary cap adjustments (that is, at the time when a displaced resident graduates). The commenters stated that this would allow the temporary cap adjustment and the exemption from the rolling average and IRB ratio cap to apply for the duration of time that the displaced residents are in training.

Response: We appreciate the commenters' support. To accommodate seamless awards under Ranking Criteria One and Three, we are modifying the CMS Application Form (formerly, the Evaluation Form) to instruct a hospital applying under Ranking Criteria One and Three to list the names and graduation dates of specific displaced residents whom the hospital believes it has seamlessly replaced or will be seamlessly replacing with new PGY1 residents upon graduation of the displaced residents. Similarly, in the award letters, we will specify whether slots are being awarded under Ranking Criterion One or Three, the amount of FTEs awarded, and the names and graduation dates of specific displaced residents of whom we believe the hospital has proven that it has or will be seamlessly replacing. The effective date of these slots will be the day after the applicable graduation date(s).

Comment: One commenter requested clarification on the "seamless" requirement for Ranking Criterion One and Ranking Criterion Three. The commenter stated that under Ranking Criterion One and Ranking Criterion Three, a hospital applying for

additional cap slots must demonstrate that it will continue to train FTE residents in the same program as the closed hospital without any lapse in training. The commenter stated, for example, that if a hospital applied to take over part of a closed hospital's program under Ranking Criterion Three, which means it is also training some of the FTE residents that were displaced from that closed hospital's program, the applying hospital must be able to demonstrate that once those displaced FTE residents graduate on June 30, it will immediately fill those positions with new FTE residents the next day on July 1. The commenter stated that if a teaching hospital closes even just a couple of months after the start of the academic year (July 1), it is very difficult for a hospital applying under Ranking Criterion One or Ranking Criterion Three to fill a slot vacated by a displaced FTE resident(s) who is graduating June 30 of that academic year by July 1 of the following academic year. The commenter stated that recruitment for most residency training programs is organized in accordance with the National Resident Matching Program schedule. This schedule generally requires that the Match quotas for specialty programs must be submitted by January 31 and that the Match quotas for subspecialty programs be submitted even earlier than the January deadline for specialty programs. Therefore, if a hospital took in a displaced FTE resident who was scheduled to graduate the upcoming June 30, it would likely be impossible for the hospital to fill that slot vacated by the displaced FTE resident immediately with the following July 1. The commenter stated it understands CMS' goal of requiring hospitals that apply under Ranking Criterion One or Ranking Criterion Three to seamlessly fill slots vacated by displaced FTE residents. However, the commenter requested that CMS clarify its policy

to state that for those hospitals that apply under Ranking Criterion One and Ranking Criterion Three, in situations where FTE residents will graduate the next June 30, the applying hospital is required to demonstrate that it will fill the slots vacated by the displaced FTE residents by July 1 of the second academic year following the hospital closure.

Response: We acknowledge that the timeline used by the National Resident Match Program or other resident match services can make it difficult, if not impossible, to seamlessly fill the slots of a displaced resident graduating on June 30 in the instance where a teaching hospital closes (or its programs close) after the date (for example, January 31) that positions must be placed in the Match for the upcoming academic year beginning July 1. However, we are not convinced that the same challenge exists even in instances where a hospital closes, or the programs close, at any point after "just a couple of months" following the start of an academic year, as the commenter asserted. With regard to allopathic and osteopathic programs, because the deadline for submitting the Match quota is approximately the end of January, we believe December 31 of the same academic year is a reasonable date to use for the purpose of determining the feasibility of seamlessly replacing displaced residents who are scheduled to graduate on the upcoming June 30. Therefore, we are stating in this final rule that, in the instance where a teaching hospital closed after December 31 of an academic year, in order for a hospital to qualify under Ranking Criterion One or Ranking Criterion Three for cap slots associated with displaced FTE residents that will graduate June 30 of the academic year in which the applying hospital took in the displaced FTE residents, the applying hospital must be able

to demonstrate that it will fill slots vacated by displaced FTE residents by July 1 of the second academic year following the hospital closure. For example, if a hospital closes January 1, 2013, an applying hospital must be able to demonstrate that it will fill any positions vacated by displaced FTE residents who will graduate June 30, 2013, by July 1, 2014. However, in the instance where a teaching hospital closed before December 31 of an academic year, in order for a hospital to qualify under Ranking Criterion One or Ranking Criterion Three for cap slots associated with displaced FTE residents that will graduate June 30 of the academic year in which the applying hospital took in the displaced FTE residents, the applying hospital must be able to demonstrate that it will "seamlessly" fill slots vacated by displaced FTE residents by July 1; that is, the day immediately after the June 30 that the displaced FTE residents graduate.

Comment: Commenters stated that even though section 5506 exists to permanently redistribute slots from a closed teaching hospital, the temporary cap adjustments for displaced residents in the regulations at § 413.79(h) must continue to exist. The commenters argued that the temporary cap adjustment for displaced residents policy in regulations at § 413.79(h) and section 5506 are two provisions that serve different purposes and should be viewed independently; section 5506 should not be viewed as a replacement for the temporary cap adjustment. The commenters stated that the temporary cap adjustment addresses an immediate crisis situation, protecting displaced residents and providing immediate payment to hospitals taking in the displaced residents, while section 5506 is intended to address a long-term situation, and the entire process can easily take up to 2 years to complete. Commenters pointed out that a hospital

that takes in displaced residents and applies for section 5506 slots has no guarantee that it will be awarded permanent slots under the section 5506 program, and "given this lack of certainty, the mere possibility of being awarded section 5506 slots is simply not enough of an incentive for the hospital to take on displaced residents." One commenter stated that CMS should exercise "extreme caution before assuming that section 5506 can be or should be viewed as a replacement for the temporary cap adjustment policy in any meaningful way."

Commenters also asserted that if the temporary cap adjustment was removed from the regulations, the pool of potential hospitals willing to absorb the displaced residents would likely shrink. The commenters stated that, for a variety of practical and personal reasons, displaced residents are not always able to (and some may not desire to) continue their residency training in the same geographic location as the closed hospital, and hospitals that are not located in the same state as the closed hospital would not be in a position to receive slots permanently under section 5506. One commenter noted that significant financial barriers still exist for many hospitals despite Medicare's payment policies, because the temporary cap adjustment policy only accounts for the Medicare share of teaching hospital costs, and not others, such as Medicaid, which generally does not have a policy like Medicare's to address displaced residents.

Commenters also opposed the concept raised in the proposed rule of maintaining the temporary cap adjustment but of eliminating the exemption from the 3-year rolling average. Commenters argued that teaching hospitals should not have to face a short-term loss of funding due to the immediate application of the 3-year rolling average (and IRB

ratio cap) when taking in displaced residents. One commenter added that, although CMS did not directly ask for comments on the exemption from the IRB ratio cap, this exemption is also an important piece of the temporary cap adjustment policy and should be preserved.

Response: After considering the public comments received, we agree that the temporary cap adjustment policy in the regulations at § 413.79(h) and the permanent cap adjustments provided by section 5506 serve both different and necessary roles. We particularly agree that elimination of the temporary cap adjustment may influence the willingness of hospitals in states or geographic areas outside the state or geographic vicinity of the closed hospital to take in displaced residents. Therefore, we are not making any changes to the regulations at § 413.79(h), and are preserving the attending exemptions from the 3-year rolling average and the IRB ratio cap for the duration of a displaced resident's training in the program from which he/she was displaced

In summary, we are finalizing the policy that the effective dates of the section 5506 slots awarded under Ranking Criteria One and Three are seamless with the expiration of applicable temporary cap adjustments (that is, at the time when a displaced resident graduates). To accommodate seamless awards under Ranking Criteria One and Three, we are modifying the CMS Application Form (formerly, the Evaluation Form) to instruct a hospital applying under Ranking Criteria One and Three to list the names and graduation dates of specific displaced residents whom the hospital believes it has seamlessly replaced or will be seamlessly replacing with new PGY1 residents upon graduation of the displaced residents. We also are stating in this final rule that in the

instance where a teaching hospital closed after December 31 of an academic year, in order for a hospital to qualify under Ranking Criterion One or Ranking Criterion Three for cap slots associated with displaced FTE residents that will graduate June 30 of the academic year in which the applying hospital took in the displaced FTE residents, the applying hospital must be able to demonstrate that it will fill slots vacated by displaced FTE residents by July 1 of the second academic year following the hospital closure. Lastly, in this final rule, we are not making any changes to the regulations at § 413.79(h), and we are preserving the attending exemptions from the 3-year rolling average and the IRB ratio cap for the duration of a displaced resident's training in the program from which he/she was displaced.

Following is a chart of the Ranking Criteria and the effective dates we are finalizing:

Ranking Criterion	Effective Date
One: *The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program (s) exactly as it had been operated by the hospital that closed (that is, same residents, possibly the same program director, and possibly the same (or many of the same) teaching staff).*	The day after the graduation date(s) of actual displaced resident(s).
Two: *The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the*	Date of the hospital closure.

Ranking Criterion	Effective Date
applying hospital received slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, preference would be given to an applying hospital that was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital received slots from the closed hospital under the terms of that affiliation agreement.	
Three: *The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).*	The day after the graduation date(s) of actual displaced resident(s).

Ranking Criterion	Effective Date
Four: *The program does not meet Ranking Criteria 1,2, or 3, and the applying hospital will use additional slots to establish a new or expand an existing geriatrics residency program.* Five: *The program does not meet Ranking Criteria 1 through 4, the applying hospital is located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.* Six: *The program does not meet Ranking Criteria 1 through 5, and the applying hospital is not located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.* Seven: *The applying hospital will use additional slots to establish or expand a primary care or general surgery program, but the program does not meet Ranking Criterion 5 or 6 because the hospital is also separately applying under Ranking Criterion 8 for slots to establish or expand a nonprimary care or non-general surgery program and/or for cap relief.*	The later of when hospital can demonstrate to the Medicare contractor that the slots associated with a new program or program expansion are actually filled, and therefore, are needed as of a particular date (usually July 1, possibly retroactive), or the July 1 *after* displaced residents complete their training.
Eight: *The program does not meet Ranking Criteria 1 through 7, and the applying hospital will use additional slots to establish or expand a nonprimary care or a non-general surgery program or for cap relief.*	If slots are for starting or expanding a nonprimary care program, the effective date is same as that for Ranking Criteria Four through Seven. If slots are for cap relief, the effective date is the effective date of CMS' award announcement, or the July 1 *after* displaced residents complete their training, whichever is later.

e. Clarification of Relationship Between Ranking Criteria One, Two, and Three

In the November 24, 2010 final rule with comment period, as part of the response to a comment we received requesting that the order of Ranking Criterion One (regarding an applicant hospital that assumes an entire program from a closed hospital) and Ranking Criterion Two (regarding an applicant hospital that received slots under the terms of a Medicare GME affiliation agreement from a closed hospital) be switched, we stated: "Furthermore, the commenter need not be concerned that hospitals that would fit into Ranking Criterion Two would be at a disadvantage and deprived of their fair share of slots to hospitals that would fit under Ranking Criterion One. In fact, Ranking Criteria One and Two are *not* competing with each other, and hospitals fitting into each category would get their 'fair' share of slots. For example, assume a hospital with an FTE resident cap of 100 closes. Hospital A assumes the entire programs in which 80 FTE residents were training when the hospital closed. Hospital B had been receiving 20 FTE slots from the closed hospital under the terms of a Medicare GME affiliation agreement. Hospital A applies for 80 slots under Ranking Criterion One and, all other things being equal, is awarded 80 slots. Hospital A could apply for more than 80 slots, *but it could only receive consideration under Ranking Criterion One for a maximum of 80 slots*. Therefore, 20 slots would remain for Hospital B to apply for and receive under Ranking Criterion Two. Accordingly, we do not believe it is necessary to reorder Ranking Criteria One and Two" (75 FR 72218).

Prior to the issuance of the proposed rule, we had been made aware that it may *not* always be true that Ranking Criteria One, Two, and even Three are not competing

with each other. For example, in the case where the closed hospital was training residents in excess of its FTE resident caps, it is possible for hospitals to apply under Ranking Criteria One, Two, and/or Three for more slots than are available. However, under the policy expressed in the response quoted above from the November 24, 2010 final rule with comment period, because a hospital that takes over an entire program from the closed hospital is ranked under Ranking Criterion One, and a hospital that received slots from a Medicare GME affiliation agreement from the closed hospital is ranked under Ranking Criterion Two, all the slots could be assigned to the hospital under Ranking Criterion One, leaving no slots for hospitals ranked under Ranking Criterion Two or Three. (We note that in the first round of section 5506 awards associated with hospitals that closed between March 23, 2008, and August 3, 2010, this turned out *not* to be a concern because even in the case where a closed hospital was training residents in excess of its FTE caps at the time of closure, there were no applicants for the slots that simultaneously qualified under Ranking Criteria One, Two, and/or Three). For example, a hospital that closed has an FTE resident cap of 10, but when it closed, it was training 15 FTEs in an internal medicine program. Hospital A assumes at least 90 percent of the internal medicine program; that is, the "entire" program (a hospital that takes on 90 percent of the residents training in a particular program at the closed hospital within 5 years prior to the hospital's closure or at the time of the hospital's closure would be deemed to have assumed an "entire" program (75 FR 72218)). Ninety percent of the internal medicine program is 13.5 FTEs. Because Hospital A took over the "entire" internal medicine program, it applies for slots under Ranking Criterion One. Hospital B

applies under Ranking Criterion Three because it assumes the other 10 percent of the program, or 1.5 FTEs. However, because the closed hospital's FTE resident cap was limited to 10, it would seem that all 10 slots would be assigned to Hospital A under Ranking Criterion One, leaving no slots for Hospital B under Ranking Criterion Three. Conversely, if Ranking Criteria One and Three were ranked as equals, the 10 slots could be prorated so that both Hospital A and Hospital B each receive a "fair" share.

Another example might be one in which a closed hospital that was training residents in excess of its FTE resident cap of 10 "lent" 2 of those 10 cap slots to Hospital C under the terms of a Medicare GME affiliation agreement. Although under the terms of the Medicare GME affiliation agreement, the hospital's FTE resident cap was reduced from 10 to 8, the hospital actually trained 9 FTEs, and continued to do so until it closed. Hospital D then assumes the 9 FTEs, or the entirety of the program that remained at the closed hospital when it closed. Again, one policy approach would be to rank the ranking criteria in descending order, and assign all 10 slots to Hospital D since Hospital D qualifies under Ranking Criterion One. Alternatively, another policy approach would be to treat Ranking Criteria One and Two as equals, and then a prorata share of the 10 slots could be given each to Hospital C and Hospital D.

After consideration of these scenarios, we stated in the proposed rule that we believe that in the case where the closed hospital was training residents in excess of its FTE resident caps, prorating among hospitals that qualify under Ranking Criteria One, Two, and Three is not warranted. This is because we believe that a hospital that assumes an entire program from the closed hospital should be ranked highest, as it has taken the

boldest step to ensuring the continuity of the closed hospital's program. As we explained first in the August 3, 2010 proposed rule (75 FR 46423) and again in the November 24, 2010 final rule with comment period (75 FR 72218), "We note that we are proposing this ranking criterion regarding affiliated hospitals as second, after the first ranking criterion regarding applying hospitals that assume an entire program or programs from the closed hospital because, even though section 5506 of the Affordable Care Act directs the Secretary to give preference to members of the same affiliated group, we believe that a hospital that assumes the responsibility for an entire program or programs demonstrates a commitment to maintain the programs to an even greater degree than does a hospital that was affiliated with the hospital that closed and may only be maintaining a portion of the residency program or programs." Similarly, we believe that because section 5506 of the Affordable Care Act does give preference to members of the same affiliated group as the closed hospital, hospitals qualifying for Ranking Criterion Two should receive slots first before hospitals qualifying for slots under Ranking Criterion Three. While we would encourage a hospital to assume a part of a closed hospital's program if it does not have the capacity to assume the entire program, such a hospital would be ranked under Ranking Criterion Three, still receiving preference before all hospitals that did not necessarily have any relationship with the closed hospital and that qualify under Ranking Criteria Four and below. As we stated in the November 24, 2010 final rule with comment period (75 FR 72226), "we would still assign the slots to hospitals qualifying under Ranking Criteria One, Two, and Three in descending order." Therefore, in the instance where a closed hospital is training residents in excess of its FTE resident caps

when it closes, we are clarifying that we would not prorate a closed hospital's FTE resident caps among applicant hospitals that qualify under Ranking Criteria One, Two, and Three.

We did not receive any public comments on this clarification regarding the relationship between Ranking Criteria One, Two, and Three. Therefore, we are finalizing the clarification.

f. Modifications to the Section 5506 CMS Evaluation Form

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27989), we proposed to make numerous changes to the Section 5506 CMS Evaluation Form. Most of the changes were not substantive, but were intended to clarify the requirements on the form, and therefore, we did not list them each individually. In the proposed rule, we indicated that there were several proposed changes that were more substantive, and we enumerated those. First, we proposed to change the name of the CMS Evaluation Form to the CMS Application Form. We believe this is a more appropriate name, as it is the form used by hospitals to apply for slots under section 5506. Second, we identified several instances on the proposed CMS Application Form where we proposed to prompt the applicant to specify whether the application is for a particular program, or for general cap relief, or for slots associated with a Medicare GME affiliation agreement with the closed hospital (which we did not do on the preceding form). Third, we proposed to clarify the titles of the Demonstrated Likelihood Criteria (DLC). Specifically, the proposed title for Demonstrated Likelihood Criterion 1 is "Establishing a New Residency Program", the proposed title for Demonstrated Likelihood Criterion 2 is "Taking Over All or Part of an

Existing Residency Program from the Closed Hospital, or Expanding an Existing Residency Program," the proposed title for Demonstrated Likelihood Criterion 3 is "Receiving Slots for General Cap Relief," and the proposed title for Demonstrated Likelihood Criterion 4 is "Receiving Slots by Virtue of Medicare GME Affiliated Group Agreement with Closed Hospital." Fourth, we proposed to add a category under Demonstrated Likelihood Criterion 2 stating that if the hospital currently has unfilled positions in a residency program that have previously been approved by the ACGME, AOA, or the ABMS, and the hospital is now seeking to fill those positions, the hospital must attach documentation clearly showing its current number of approved positions, and its current number of filled positions (as proof of the unfilled positions). Fifth, we proposed to change the wording in Ranking Criteria Four, Five, and Six, respectively, from "The applying hospital does not meet Ranking Criteria 1, 2, or 3" to "The program does not meet Ranking Criterion 1, 2, or 3" because the latter is more accurate. That is, it is possible for a hospital to qualify under Ranking Criterion 1, 2, or 3 for a particular program, and also to apply for slots separately under Ranking Criterion 4, 5, or 6 for a different program. Sixth, we proposed to add a new Ranking Criterion 7: *The program does not meet Ranking Criteria 1 through 6, and the slots for which the hospital is applying are for a primary care or a general surgery program, but the hospital is also applying for slots under Ranking Criterion Eight.* We also proposed to renumber what had been the previous Ranking Criterion Seven to be the proposed Ranking Criterion Eight. Lastly, in the proposed rule, we included the proposed revised CMS Section 5506 Application Form:

Comment: One commenter supported the proposed changes to the CMS Evaluation Form and believed that its use will improve the application and review process for section 5506 awards.

Response: We appreciate the commenter's support, and we are finalizing our proposed changes with some modifications. In response to public comments on Ranking Criteria One and Three, we are making additional changes to the CMS Evaluation Form (finalized as the CMS Application Form) under Ranking Criteria One and Three where hospitals applying under those Ranking Criteria must list the names and graduation dates of specific displaced residents whom, upon their graduation, the hospital seamlessly replaces (or intends to seamlessly replace) with new residents.

Following is the finalized revised CMS Section 5506 Application Form:

CMS Application Form

As Part of the Application for the Increase in a Hospital's FTE Cap(s) under Section 5506 of the Affordable Care Act: Preservation of FTE Cap Slots from Teaching Hospitals that Close

Directions: Please fill out the information below for each residency program for which the applicant hospital intends to use the increase in its FTE cap(s). If the hospital is applying for general FTE cap relief (an increase in the hospital's FTE cap(s) in recognition of already training residents in excess of the hospital's cap(s)), that application must be submitted separately from an individual program request. If the hospital is applying for slots associated with a Medicare GME affiliation agreement with a hospital that closed, that application must also be submitted separately from an individual program request.

NAME OF HOSPITAL: _____

MEDICARE PROVIDER NUMBER (CCN):
_____

NAME OF MEDICARE CONTRACTOR:_____

CORE-BASED STATISTICAL AREA (CBSA in which the hospital is physically located--write the 5 digit code here): _____

COUNTY NAME (in which the hospital is physically located): _____

Complete the following, as applicable:

1. **Name Of Specialty Training Program:_____**
2. **General FTE Cap Relief:_____**
3. **Medicare GME Affiliated Group:_____**

(Check one): □ Allopathic Program □ Osteopathic Program

NUMBER OF FTE SLOTS REQUESTED FOR SPECIFIC PROGRAM (OR HOSPITAL OVERALL IF SEEKING GENERAL CAP RELIEF OR SLOTS ASSOCIATED WITH A MEDICARE GME AFFILIATED GROUP) AT YOUR HOSPITAL:

Direct GME:_____ IME: _____

<u>Section A: Demonstrated Likelihood Criteria (DLC) of Filling the FTE Slots</u>

The applicant hospital must provide documentation to demonstrate the likelihood of filling requested slots under section 5506 within the 3 academic years immediately following the application deadline to receive slots after a particular hospital closes. Please indicate the specific use for which you are requesting an increase in your hospital's FTE cap(s). If you are requesting an increase in the hospital's FTE cap(s) for a combination of DLC1, DLC2, or DLC3, you must complete a separate CMS Application Form for each DLC and specify the distinct criterion from the list below within each Form.

Demonstrated Likelihood Criterion 1: Establishing a New Residency Program

The hospital does not have sufficient room under its direct GME FTE cap or IME FTE cap, or both, and will establish a new residency program in the specialty. **(The hospital must check at least one of the following.)**

□ Application for approval of the new residency program has been submitted to the ACGME, AOA or the ABMS **(The hospital must attach a copy.)**

□ The hospital has submitted an institutional review document or program information form concerning the new program in an application for approval of the new program. **(The hospital must attach a copy.)**

□ The hospital has received written correspondence from the ACGME, AOA or ABMS acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). **(The hospital must attach a copy.)**

□ The hospital has other documentation demonstrating that it has made a commitment to start a new program **(The hospital must attach a copy.).**

Demonstrated Likelihood Criterion 2: Taking Over All or Part of an Existing Residency Program from the Closed Hospital, or Expanding an Existing Residency Program

The hospital does not have sufficient room under its direct GME FTE cap or IME FTE cap, or both, and a) has permanently taken over the closed hospital's entire residency program, or b) is permanently expanding its own previously established and approved residency program resulting from taking over *part* of a residency program from the closed hospital, or c) is permanently expanding its own existing residency program. **(The hospital must check at least one of the following.)**

Hospitals applying for slots under option a) which correlates to Ranking Criterion 1 or b) which correlates to Ranking Criterion 3 must list the names and graduation dates of specific displaced residents who, upon their graduation, have been or will be seamlessly replaced by new residents. This list may be added as an attachment to this application.

□ Application for approval to take over the closed hospital's residency program has been submitted to the ACGME, AOA, or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

□ Application for approval of an expansion of the number of approved positions in its residency program resulting from taking over *part* of a residency program from the closed hospital has been submitted to the ACGME, AOA or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

□ Application for approval of an expansion of the number of approved positions in its residency program has been submitted to the ACGME, AOA or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

□ The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME, AOA, or the ABMS, and is now seeking to fill those positions. (**The hospital must attach documentation clearly showing its current number of approved positions, and its current number of filled positions**).

□ The hospital has submitted an institutional review document or program information form concerning the program in an application for approval of an expansion to the program **(The hospital must attach a copy).**

Demonstrated Likelihood Criterion 3: Receiving Slots for General Cap Relief

□ The hospital does not have sufficient room under its direct GME FTE cap or IME cap, or both, and is seeking an increase in its FTE cap(s) for general cap relief for residents that it is already training.

Demonstrated Likelihood Criterion 4: Receiving Slots by Virtue of Medicare GME Affiliated Group Agreement with Closed Hospital

□ The hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital received slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, the applying hospital was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to

the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital received slots from the closed hospital under the terms of that affiliation agreement. **(Copies of EACH of the following must be attached.)**

- Copies of the recent Medicare GME affiliation agreement of which the applying hospital and the closed hospital were a member of before the hospital closed.

- Copies of the most recent accreditation letters for all of the hospital's training programs in which the hospital had a shared rotational arrangement (as defined at §413.75(b)) with the closed hospital.

Section B. Level Priority Category

(Place an "X" in the appropriate box that is applicable to the level priority category that describes the applicant hospital.)

€ First, to hospitals located in the same core-based statistical area (CBSA) as, or in a CBSA contiguous to, the hospital that closed.

€ Second, to hospitals located in the same State as the closed hospital.

€ Third, to hospitals located in the same region as the hospital that closed.

€ Fourth, if the slots have not yet been fully distributed, to qualifying hospitals in accordance with the criteria established under section 5503, "Distribution of Additional Residency Positions"

Section C. Ranking Criteria

(Place an "X" in the box for each criterion that is appropriate for the applicant hospital and for the program for which the increase in the FTE cap is requested.)

□ Ranking Criterion One. *The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program (s) exactly as it had been operated by the hospital that closed (that is, same residents, possibly the same program director, and possibly the same (or many of the same) teaching staff).*

□ Ranking Criterion Two. *The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital received slots*

from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, preference would be given to an applying hospital that was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital received slots from the closed hospital under the terms of that affiliation agreement.

□ Ranking Criterion Three. *The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).*

□ Ranking Criterion Four. *The program does not meet Ranking Criteria 1,2, or 3, and the applying hospital will use additional slots to establish a new or expand an existing geriatrics residency program.*

□ Ranking Criterion Five: *The program does not meet Ranking Criteria 1 through 4, the applying hospital is located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.*

□ Ranking Criterion Six: *The program does not meet Ranking Criteria 1 through 5, and the applying hospital is not located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.*

□ Ranking Criterion Seven: *The applying hospital will use additional slots to establish or expand a primary care or general surgery program, but the program does not meet Ranking Criterion 5 or 6 because the hospital is also separately applying under Ranking Criterion 8 for slots to establish or expand a nonprimary care or non-general surgery program and/or for cap relief.*

□ Ranking Criterion Eight: *The program does not meet Ranking Criteria 1 through 7, and the applying hospital will use additional slots to establish or expand a nonprimary care or a non-general surgery program or for cap relief.*

Application Process and CMS Central Office and Regional Office Mailing Addresses for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. The following information must be submitted on applications to receive an increase in FTE resident caps:

- The name and Medicare provider number, and Medicare contractor (to which the hospital submits its cost report) of the hospital.
- The total number of requested FTE resident slots for direct GME or IME, or both.
- A completed copy of the CMS Application Form for each residency program for which the hospital intends to use the requested increase in FTE residents.
- Source documentation to support the assertions made by the hospital on the CMS Application Form.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (If the CMS Form 2552-96 is applicable, include copies of Worksheets E, Part A, E-3, Part IV, and if a hospital received an increase to its FTE cap(s) under section 422 of the MMA, a copy of E-3, Part VI. If the CMS Form 2552-10 is applicable, include copies of Worksheets E, Part A, and E-4).
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

5. Notice of Closure of Teaching Hospitals and Opportunity to Apply for Available Slots

a. Background

Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency cap slots after a hospital that trained residents in an approved medical residency program(s) closes. Specifically, section 5506 amended the Act by adding a subsection (vi) to section 1886(h)(4)(H) and modifying the language at section 1886(d)(5)(B)(v) to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed "on or after a date that is 2 years before the date of enactment" (that is March 23, 2008). In the CY 2011 OPPS/ASC final rule with comment period issued on November 24, 2010 (75 FR 72212), we established regulations and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from a hospital that closed. The procedures we established apply both to teaching hospitals that closed after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that closed after August 3, 2010. For teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, we established an application deadline of April 1, 2011, for a hospital to request cap slots from a closed hospital(s). We also stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72215) that hospitals that close at any point after August 3, 2010, will fall into additional categories of applications, for which we would provide a separate notice with a future application deadline.

b. Notice of Closure of Teaching Hospitals

We have learned of the closure of several teaching hospitals that occurred after August 3, 2010. This notice serves to notify the public of the closure of teaching hospitals, and to initiate another round of the section 5506 application and selection process. (We note that the first round applied to closed teaching hospitals listed at 76 FR 13294 (March 11, 2011), with an application deadline of April l, 2011; and the second round applied to one closed teaching hospital as discussed at 76 FR 55917 (September 9, 2011), with an application deadline of December 1, 2011.) The following closed teaching hospitals are part of a new application process under section 5506:

Provider Number	**Provider Name**	**City and State**	**CBSA Code**	**Terminating Date**	**IME Cap (including +/- MMA Sec. 422[1] and ACA Sec. 5503[2] Adjustments)**	**Direct GME Cap (including +/- MMA Sec. 422[1] and ACA Sec. 5503[2] Adjustments)**
120010	Hawaii Medical Center East	Honolulu, HI	26180	January 5, 2012	**15.73**	**16.12**
140301	Oak Forest Hospital	Oak Forest, IL	16974	August 31, 2011	**0**	4.40 - section 422 decrease 2.37 = **2.03[3]**
360101	Huron Hospital	East Cleveland, OH	17460	October 3, 2011	**50.06**	50.85 +.17 section 422 increase - .10 section 422 reduction =**50.92[4]**

[1]Section 422 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, redistributed unused residency slots effective July 1, 2005.
[2]Section 5503 of the Affordable Care Act (ACA), Pub. L. 111-148, redistributed unused residency slots effective July 1, 2011.

[3]Oak Forest Hospital's 1996 direct GME FTE cap is 4.40. Under section 422 of the MMA, the hospital received a decrease of 2.37 to its direct GME FTE cap: 4.40 – 2.37 = 2.03.
[4]Huron Hospital's 1996 direct GME FTE cap is 50.85. Under section 422 of the MMA, the hospital received an increase of 0.17 to its direct GME FTE cap and a decrease of 0.10 to its direct GME FTE cap: 50.85 + 0.17 – 0.10 = 50.92.

c. Application Process for Available Resident Slots

Under section IV.I.4. of the preamble of this final rule, in response to comments, we are finalizing a policy that provides an application period of 90 days following notification to the public of a hospital closure. Therefore, hospitals wishing to apply for and receive slots from the above hospitals' FTE resident caps must submit applications directly to the CMS Central Office no later than October 29, 2012. Unlike in the first 2 rounds of section 5506, under this round, hospitals need not submit applications to their respective CMS Regional Office. The mailing address for the CMS Central Office is included on the application form. Applications must be received, not postmarked, by the October 29, 2012 deadline date.

In the CY 2011 OPPS/ASC final rule with comment period, we did not establish a deadline by when CMS would issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we will review all applications received by the October 29, 2012 deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dgme.html to download a copy of the application form (CMS Section 5506 Application Form) that hospitals are to use to apply for slots under section 5506. We also refer readers to this same Web site to access a copy of the CY 2011 OPPS/ASC final rule with comment period and a list of additional section 5506 guidelines for an explanation of the policy and procedures for applying for slots, and the

redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act. We note that in section IV.I.4. of the preamble of this final rule, we are finalizing additional policies regarding the section 5506 application process and an updated and revised CMS Section 5506 Application Form as well.

J. Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51697), we finalized our policy for reporting costs of qualified defined benefit pension plans for Medicare cost-finding purposes. Specifically, beginning with cost reporting periods on or after October 1, 2011, a provider's pension cost for cost-finding purposes equals the cash basis contribution deposits plus any carry forward contributions, subject to a limitation. Providers with current contributions and carry forward contributions in excess of the limit may request approval of excess contributions, which will be reviewed on a case-by-case basis. Some or all of the excess contributions will be approved, as applicable, if it is determined that all or a portion of the excess contribution(s) are reasonable and necessary. To the extent that approval is granted, that portion of the excess is allowable as current period pension costs. We refer readers to the FY 2012 IPPS/LTCH PPS final rule for full details on this policy.

In addition to finalizing this new policy in the FY 2012 IPPS/LTCH PPS final rule, we stated that we intended to make future amendments to conform existing regulations to this final policy (76 FR 51693). The existing regulations at 42 CFR 413.24 and 413.100 specify that pension costs of qualified defined benefit plans are reported on

an accrual basis of accounting method. Sections 413.24 and 413.100 provide that revenue is reported in the period in which it is earned, regardless of when it is collected and expenses are reported in the period in which they are incurred, regardless of when it is paid. For Medicare payment purposes, the costs are generally allowable in the year in which the costs are accrued and claimed, subject to specific exceptions. Furthermore, for accrued costs to be recognized for Medicare payment in the year of the accrual, the requirements must be met with respect to the liquidation of related liabilities. Therefore, to conform these two existing regulations to the final policy we adopted in the FY 2012 IPPS/LTCH PPS final rule with regard to pension costs for Medicare cost-finding purposes, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27991), we proposed to amend the general cost reporting rules under §§ 413.24 and 413.100 to note the exception for recognizing actual pension contributions funded during the cost reporting period on a cash basis. We also indicated that we plan to revise section 2305.2 of the Provider Reimbursement Manual to reflect this policy change.

We did not receive any public comments on our proposal. We are finalizing our proposed amendments to the general cost reporting rules under §§ 413.24 and 413.100, without modification, to note the exception for recognizing actual pension contributions funded during the cost reporting period on a cash basis.

K. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of Pub. L. 108-173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing "rural community hospitals" to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that--

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Pub. L. 108-173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota,

South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003).

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost report years beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and converted to CAH status. This left nine hospitals participating at that time. In 2008, we announced a solicitation for up to six additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These four additional hospitals began under the demonstration payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275). One hospital restructured to become a CAH, and one hospital closed.) In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left 7 of the originally participating hospitals (that

is, hospitals that were selected to participate in either 2004 or 2008), participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111-148) amended section 410A of Pub. L. 108-173, which established the rural community hospital demonstration program. Sections 3123 and 10313 of the Affordable Care Act changed the rural community hospital demonstration program in several ways. First, it required the Secretary to conduct the demonstration program for an additional 5-year period that begins on the date immediately following the last day of the initial 5-year period. Further, the Affordable Care Act requires, in the case of a rural community hospital that is participating in the demonstration program as of the last day of the initial 5-year period, the Secretary to provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation (section 410A(g)(4)(A) of Pub. L. 108-173, as added by section 3123(a) of the Affordable Care Act and further amended by section 10313 of such Act). In addition, the Affordable Care Act provides that, during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20 (section 410A(g)(2) of Pub. L. 108-173, as added by section 3123(a) and amended by section 10313 of the Affordable Care Act). Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States under section 410A(a)(2) of Pub. L. 108-173 for purposes of the initial 5-year period. The Affordable Care Act also allows not more than 30 rural community hospitals in such

States to participate in the demonstration program during the 5-year extension period (section 410A(g)(3) of Pub. L. 108-173, as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of such Act).

We published a solicitation for applications for additional participants in the rural community hospital demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density that are eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011. These hospitals were notified of this start date in the award letter that was sent to them dated February 24, 2011

Three of these 19 hospitals declined participation prior to the start of the cost report periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008 and that are still participating, the new selection led to a total of 23 hospitals in the demonstration as of April 2011.

In addition, section 410A(c)(2) of Pub. L. 108-173 required that, "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary

would have paid if the demonstration program under this section was not implemented." This requirement is commonly referred to as "budget neutrality." Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral in its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration program could be viable under the usual form of budget neutrality. Specifically, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration program is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these same hospitals.

In the past eight IPPS final regulations, spanning the period for which the demonstration program has been implemented, we have adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration

program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. As we discussed in the FYs 2005 through 2012 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, and 76 FR 51698, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner. In light of the statute's budget neutrality requirement, in the FY 2013 IPPS/LTCH proposed rule (77 FR 27991 through 27995) we proposed a methodology to calculate a budget neutrality adjustment factor to the FY 2013 national IPPS rate. In this final rule, we are adopting the proposed methodology for calculating the budget neutrality adjustment to the FY 2013 national IPPS rates and finalizing the budget neutrality adjustment factor to be made to the FY 2103 national IPPS rate.

In general terms, in each of these previous years, we used available cost reports for the participating hospitals to derive an estimate of the additional costs attributable for the demonstration. We used finalized, or settled, cost reports, as available, and "as submitted" cost reports for hospitals for which finalized cost reports were not available. Annual market basket percentage increase amounts provided by the CMS Office of the Actuary reflecting the growth in the prices of inputs for inpatient hospitals were applied to these cost amounts. An annual update factor provided by the CMS Office of the Actuary reflecting growth in the volume of inpatient operating services was also applied. For the budget neutrality calculations in the IPPS final rules for FYs 2005 through 2011, the annual volume adjustment applied was 2 percent; for the IPPS final rule for FY 2012,

it was 3 percent. For a detailed discussion of our budget neutrality offset calculations, we refer readers to the IPPS final rule applicable to the fiscal year involved.

In general, for FYs 2005 through 2009, we based the budget neutrality offset estimate on the estimated cost of the demonstration in an earlier given year. For these periods, we derived that estimated cost by subtracting the estimated amount that would otherwise be paid without the demonstration in an earlier given year from the estimated amount for the same year that would be paid under the demonstration under the reasonable cost-based methodology authorized by section 410A of Pub. L. 108-173. The reasonable cost-based methodology authorized by section 410A of Pub. L. 108-173, as amended, is hereafter referred to as the "reasonable cost methodology" (We ascertained the estimated amount that would be paid in an earlier given year under the reasonable cost methodology and the estimated amount that would otherwise be paid without the demonstration in an earlier given year from "as submitted" cost reports that were submitted by the hospitals prior to the inception of the demonstration.) We then updated the estimated cost described above to the current year by multiplying it by the market basket percentage increases applicable to the years involved and the applicable annual volume adjustments. For the FY 2010, RY2010 IPPS/LTCH PPS final rule, data from finalized cost reports reflecting the participating hospitals' experience under the demonstration were available. Specifically, the finalized cost reports for the first 2 years of the demonstration, that is, cost reports for cost reporting years beginning in FYs 2005 and 2006 (CYs 2004, 2005, and 2006) were available. These data showed that the actual costs of the demonstration for these years exceeded the amounts originally estimated in

the respective final rules for the budget neutrality adjustment. In the FY 2010 IPPS/LTCH PPS final rule, we included in the budget neutrality offset amount an amount in addition to the estimate of the demonstration costs in that fiscal year. This additional amount was based on the amount that the costs of the demonstration for FYs 2005 and 2006 exceeded the budget neutrality offset amounts finalized in the IPPS rules applicable for those years.

As in the FY 2010 IPPS/LTCH PPS final rule, we have continued to propose a methodology for calculating the budget neutrality offset amount to account for both the estimated demonstration costs in the upcoming fiscal year and an amount by which the actual demonstration costs corresponding to an earlier year (which would be determined once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. However, we note that because of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we have been unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in a given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007. (For only a small fraction of the hospitals that have participated in the demonstration from FY 2007 to FY 2010 have cost reports been finalized in any year, making the overall calculation of this component of the budget neutrality impossible at this time for any given year.)

2. Budget Neutrality Offset Amount for FY 2013

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27993 and 27994), we revisited the issue of which cost reports to propose to use for calculating the FY 2013 budget neutrality offset amount. Although we used finalized cost reports where available for the FYs 2010, 2011, and 2012 IPPS/LTCH PPS final rules, for FY 2013, we proposed to use the "as submitted" cost report for each hospital participating in the demonstration for the cost report period ending in CY 2010 in estimating the costs of the demonstration. In the proposed rule, we stated that we believe a way to streamline our methodology for calculating the budget neutrality offset amount would be to use cost reports all with the same status (that is, only "as submitted" cost reports as opposed to a mix of "as submitted" and "settled" cost reports) from the same time period for all hospitals participating in the demonstration (as opposed to cost reports of varying statuses from varying years for the various hospitals as has been done previously). Therefore, because "as submitted" cost reports ending in CY 2010 are the most recent complete set of cost reports for all demonstration hospitals, we proposed to use these cost reports for our budget neutrality offset estimate. Further, because "as submitted" cost reports ending in CY 2010 are recent available cost reports, we stated that we believe they would be an accurate predictor of the costs of the demonstration in FY 2013 because they give us a recent picture of the participating hospitals' costs.

In revisiting the issue of which datasets to propose to use in the budget neutrality offset amount calculation, we also revisited the methodology for calculating the budget neutrality offset amount. In the proposed rule, we proposed changes to that methodology

in an effort to further improve and refine it. We noted that the proposed methodology varied, in part, from that finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51698 through 51707). Specifically, in proposing refinements to the methodology, our objective was to simplify the calculation so that it included as few steps as possible. In addition, we proposed to incorporate different update factors (the market basket percentage increase and the applicable percentage increase, as applicable, to several years of data as opposed to solely using the market basket percentage increase) for the calculation of the budget neutrality offset amount. As explained in greater detail below, we stated that we believed this approach would maximize the precision of our calculation because it would more closely replicate payments made with and without the demonstration.

We noted that, although we were proposing changes to certain aspects of the budget neutrality offset amount calculation, several core components of the methodology would remain unchanged. For example, we were continuing to propose to include in the budget neutrality offset amount the estimate of the demonstration costs for the upcoming fiscal year and the amount by which the actual demonstration costs corresponding to an earlier year (which would be determined once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule).

The proposed methodology for calculating the estimated FY 2013 demonstration cost for the 23 currently participating hospitals was as follows:

Step 1: For each of the 23 participating hospitals, we proposed to identify the general reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services (as indicated on the "as submitted" cost report for the hospital's cost reporting period ending in CY 2010) in FY 2010. The general reasonable cost amount calculated under the reasonable cost methodology for any applicable year was thereafter referred to as the "reasonable cost amount."

Because section 410A of Pub. L. 108-173 stipulates swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we also proposed to include the cost of these services, as reported on the cost reports for the hospitals that provide swing-bed services, within the general total estimated FY 2010 reasonable cost amount for covered inpatient hospitals services under the demonstration. As indicated above, we proposed to use "as submitted" cost reports for the hospital's cost reporting period ending in CY 2010 for this calculation.

We proposed to sum the two above-referenced amounts to calculate the general total estimated FY 2010 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We proposed to multiply this sum (that is, the general total estimated FY 2010 reasonable cost amount for covered inpatient hospital services for all 23 hospitals) by the FYs 2011 through 2013 IPPS market basket percentage increases, which were formulated by the CMS Office of the Actuary. We also proposed to then multiply the product of the general total estimated FY 2010 reasonable cost amount for all 23 hospitals and the

market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for the years 2011 through 2013—the result would be the general total estimated FY 2013 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We proposed to apply the IPPS market basket percentage increases applicable for FYs 2011 through 2013 to the FY 2010 reasonable cost amount described above to model the estimated FY 2013 reasonable cost amount under the demonstration. We proposed to use the IPPS market basket percentage increases because we believe that these update factors appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved. The 3-percent annual volume adjustment was stipulated last year by the CMS Office of the Actuary and was proposed because it is intended to accurately reflect the tendency of hospitals' inpatient caseloads to increase. We acknowledged the possibility that inpatient caseloads for small hospitals may fluctuate, and proposed to incorporate into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the 23 hospitals, we proposed to identify the general estimated amount that would otherwise be paid in FY 2010 under applicable Medicare payment methodologies for covered inpatient hospital services (as indicated on the "as submitted" cost report for cost reporting periods ending in CY 2010) if the demonstration was not implemented. Similarly, as in Step 1, for the hospitals that provide swing-bed services, we proposed to identify the estimated amount that generally would otherwise be paid for these services (as indicated on the "as submitted" cost report for cost reporting

periods ending in CY 2010) and include it in the total FY 2010 general estimated amount that would otherwise be paid for covered inpatient hospital services without the demonstration. We proposed to sum these two amounts in order to calculate the estimated FY 2010 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration.

We proposed to multiply the above amount (that is, the estimated FY 2010 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration) by the FYs 2011 through 2013 IPPS applicable percentage increases and a 3 percent annual volume adjustment for FYs 2011 through 2013, the result would be the general total estimated FY 2013 costs that would be paid without the demonstration for covered inpatient hospital services for the 23 participating hospitals. In the proposed rule, we indicated that this methodology differs from Step 1, in which we proposed to apply the market basket percentage increases to the sum of the hospitals' general total FY 2010 estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments would constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates. Hospitals participating in the demonstration would be participating under the IPPS payment methodology if they were not in the demonstration. We note that such use of the applicable percentage increase would

represent a shift from formulations in previous years of the budget neutrality offset amount. In the FY 2013 proposed rule, as well as in this FY 2013 final rule, we are trying to increase the precision of the different projections for estimating the reasonable cost amounts and the estimated payments that would otherwise be paid without the demonstration.

Step 3: We proposed to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the 23 hospitals for covered inpatient hospital services for FY 2013 if the demonstration was not implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amount that generally would be paid under the demonstration to all 23 hospitals for covered inpatient hospital services for FY 2013). We proposed that the resulting difference would be the amount for which an adjustment to the national IPPS rates would be calculated. In the proposed rule, we indicated the resulting difference was $35, 077,708. For the FY 2013 IPPS/LTCH PPS proposed rule, this amount was the estimated amount for which an adjustment to the national IPPS rates was calculated. We further indicated this estimated amount was based on the specific assumptions indentified regarding the data sources that were used, that is, “as submitted” recently available cost reports.

We also noted that if updated data become available prior to the FY 2013 final rule, we propose to use them to the extent appropriate to estimate costs of the demonstration program in FY 2013. Therefore, we indicated that the estimated budget neutrality offset amount may change in the final rule.

Similar to previous years, we proposed that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FY 2007, 2008, 2009, or 2010) were available prior to the FY 2013 IPPS/LTCH PPS final rule, we would include in the budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. (The final settled costs of the demonstration for a year would be calculated by subtracting the total amount that would otherwise be paid under the applicable Medicare payment system without the demonstration for the year from the amount paid to those hospitals under the reasonable-cost methodology for such year.)

For this FY 2013 final rule, we are adopting without modification our proposal to use the "as submitted" cost report for each hospital participating in the demonstration for the cost report period ending in CY 2010 in estimating the costs of the demonstration in FY 2010. We are finalizing this proposal because we continue to believe this approach enables us to streamline our methodology for calculating the budget neutrality offset amount as explained in detail above. In addition, this set of cost reports remains the most recent set of complete cost reports that have been accepted by the MACs. Therefore, we believe they are an accurate predictor of costs of the demonstration in FY 2013 because they give us a recent picture of the participating hospitals' costs.

For this final rule, we also are adopting as final, without modification, Steps 1 and 2 of the proposed methodology as set forth above for the reasons explained above and in section IV.K. of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27994 and 27995).

We note that, with respect to Step 1 of the methodology, the IPPS market basket percentage increase that is applicable to FY 2013 (and identified by the CMS Office of the Actuary) appears in section IV.H. of this preamble. We note that, with respect to Step 2 of the methodology, the IPPS applicable percentage increase that is applicable to FY 2013 is set forth in section IV.H. of the preamble to this FY 2013 final rule.

With respect to Step 3, for the reasons set forth above and in section IV.K. of the preamble of the proposed rule (77 FR 27994 and 27995) and this final rule, we are finalizing our proposal, without modification, to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the 23 hospitals for covered inpatient hospital services for FY 2013 if the demonstration was not implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amount that generally would be paid under the demonstration to all 23 hospitals for covered inpatient hospital services for FY 2013). The resulting difference is the amount for which an adjustment to the national IPPS rates is calculated. For this final rule, the resulting difference for which an adjustment to the national IPPS rates is made is $34,288,129. This amount is based on the specific assumptions identified regarding the data sources that are used, that is, "as submitted" recently available cost reports. We note that we proposed that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FY 2007, 2008, 2009, or 2010) were available prior to the FY 2013 IPPS/LTCH PPS final rule, we would include in the budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget

neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. However, finalized cost reports for the hospitals participating in the demonstration are not yet available for these years at the time of development of this FY 2013 IPPS/LTCH PPS final rule. Therefore, we are not finalizing this component of the proposed methodology. We are expecting settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FYs 2007, 2008, 2009, and 2010) to be available prior to the FY 2014 IPPS/LTCH PPS proposed rule. Thus, we expect to be in a position to propose to include in the budget neutrality offset amount for FY 2014 any additional amounts by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule.

Comment: One commenter requested clarification regarding how hospitals participating in the Rural Community Hospital Demonstration will be impacted by the Hospital Readmissions Reduction Program.

Response: As described above, the applicable hospital is defined as a subsection (d) hospital or certain Maryland hospitals. Hospitals participating in the Rural Community Hospital Demonstration are subsection (d) hospitals and, thus, will be included in the Hospital Readmissions Reduction. Accordingly, we have calculated excess readmission ratios and readmissions payment adjustment factors for hospitals in the Demonstration If hospitals in the Demonstration are subject to a readmissions payment reduction, the reduction will be applied to their base operating DRG amount as

if they were paid under the IPPS. At cost report settlement, the readmissions payment amount reduced from the hospital's base operating DRG amount will be reduced from the payments received under the Demonstration

L. Hospital Routine Services Furnished under Arrangements

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), we included a provision that limits the circumstances under which a hospital may furnish services to Medicare beneficiaries "under arrangement." Under the revised policy, therapeutic and diagnostic services are the only services that may be furnished under arrangements outside of the hospital to Medicare beneficiaries. "Routine services" (that is, bed, board, and nursing and other related services) must be furnished by the hospital. Under this revised policy, routine services furnished to Medicare beneficiaries as inpatients in the hospital are considered services furnished by the hospital. If these services are furnished outside of the hospital, the services are considered to be furnished "under arrangement."

As we stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27995), we have become aware that a number of affected hospitals need additional time to restructure existing arrangements and establish necessary operational protocols to comply with the requirement that therapeutic and diagnostic services are the only services that may be furnished outside of the hospital to Medicare beneficiaries "under arrangement," and that "routine services" must be furnished by the hospital. While we still believe that our policy is consistent with the statutory language, we also believe that because a number of hospitals are actively pursuing compliance (often building construction or restructuring is

involved), it is appropriate to postpone the effective date of this requirement to give hospitals additional time to comply with the provision.

Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to change the implementation date of this requirement to be effective for cost reporting periods beginning on or after October 1, 2013. We stated that we expect that, during FY 2013, hospitals will complete the work needed to ensure compliance with the new requirement. Beginning with a hospital's FY 2014 cost reporting period, we expect that all hospitals would be in full compliance with the revised policy for services furnished under arrangement. We indicated that we would continue to work with affected hospitals to communicate the requirement established by this provision, and to provide continued guidance regarding compliance with the provision.

Comment: Several commenters submitted comments that were mostly similar to those received last year when we proposed this policy. All commenters believed that another one year delay in the effective date of the revised policy was insufficient and that the policy should be rescinded. The primary objections from all commenters were that the policy is not required by statute or regulations, the policy runs counter to efforts promoting efficiency in delivering health care, and the costs that will be incurred by certain providers to comply with the new policy are unnecessary and burdensome.

Response: We continue to believe that the proposed policy is correct and consistent with the statute. As explained in more detail in our response to comments in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51712), we believe that when section 1862(a)(14) of the Act and section 1861(b) of the Act are read in conjunction with each

other, it becomes clear that the language limits the services that may be furnished outside of the hospital under arrangement to only diagnostic and therapeutic services, consistent with our revised policy. It is only paragraph (3) of the definition of "inpatient hospital services" at section 1861(b) of the Act, referencing diagnostic or therapeutic items or services, that includes the language, "furnished by the hospital or by others under arrangements."

As we indicated in our response to similar public comments in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51713 through 51714), we do not agree that the positive objectives of interfacility cooperation and collaboration in promoting efficiency in the delivery of health care are applicable to the existing arrangements that our revised policy is intended to address. We do not believe that the objective of efficiency in health care delivery would include moving inpatients of one hospital to another hospital, without being discharged from the first and admitted to the second, in order to provide routine services that are not available at the first hospital.

We do not disagree that there may be additional costs incurred by some providers because of building construction or restructuring in order to comply with the proposed policy. However, to our knowledge, this involves very few providers, and to allow particular service arrangements that we find contrary to statute and regulations to continue because changing the arrangement would mean additional cost to a few providers is not an appropriate rationale to rescind this policy. Furthermore, while complying with the revised policy may necessitate expending additional funds for some of the commenters, those commenters are generally receiving higher Medicare payments

as PPS-excluded providers by providing the routine services under arrangement, meaning such arrangements may inappropriately increase Medicare payments to those providers. In most cases that have come to our attention, the services are being provided at another hospital that is co-located with the hospital that is IPPS-excluded. If the hospitals are finding construction or restructuring costs too onerous, the hospital may want to consider becoming a unit of the IPPS hospital which would obviate the need for obtaining any services under arrangements from another hospital and may allow them to avoid the costs that they find burdensome.

Comment: Three of the PPS-excluded cancer hospitals, as well as the alliance representing the 11 PPS-excluded cancer hospitals, submitted comments more specific to their own situations. These commenters stated that CMS' proposed policy upset a longstanding care delivery model that was created at the direction of CMS, that CMS had given its express approval for the type of arrangements that it is now trying to disallow, and that CMS had "required" one of the hospitals to operate under this type of arrangement.

Response: CMS was involved, 15 to 20 years ago, at various times and to varying degrees, with three of the PPS-excluded cancer hospitals that wanted to ensure that they would retain their PPS-excluded status as they changed their physical and operational structures, to become hospitals-within-hospitals (HwH). Because two different payment systems are involved for the co-located hospitals, IPPS and reasonable cost subject to a limit, at the time, we focused on preventing possible abuse of this arrangement. Some CMS requirements articulated at that time may appear to be contrary to our revised policy

on services furnished under arrangements. However we have discretion to change our policy, and we believe this change is appropriate for the reasons described throughout this section and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714).

We believe the care delivery models that were carefully crafted years ago to protect against abuse of the payment systems and retain the separate identity of the HwHs have devolved over time to the point where the host hospital and PPS-excluded HwH are nearly indistinguishable from each other. Patients are moved from one hospital's bed to the other hospital's bed, and then back, not because of a particular service being provided, but because of bed availability or other reason unrelated to services. Patient care is administered by both entities or by the host hospital under contract. The PPS-excluded hospital has almost become a virtual hospital. Such arrangements do not merit special treatment under Medicare regulations. Moreover, as explained in more detail in a previous response in this section and in response to comments in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), our revised policy is consistent with the statute and reduces the opportunity for gaming. To the extent the PPS-excluded cancer hospital and the subsection (d) hospital with which it is co-located wish to retain their separate classifications, compliance with these requirements remains necessary and appropriate. To the extent that PPS excluded cancer hospitals are finding construction or restructuring costs too onerous, the hospitals may want to consider becoming one provider with the subsection (d) IPPS hospital.

Comment: The cancer hospitals and the cancer hospital alliance reiterated comments they made on last year's proposed rule (FY 2012 IPPS/LTCH PPS final rule

(76 FR 51713 through 51714) that CMS' proposed policy is more expensive to the Medicare program because it would result in more hospital discharges--the cancer hospital would have to discharge patients that need ICU services, the patient would then be admitted to the co-located hospital for the ICU services, discharged from the co-located hospital once ICU services are no longer needed, and then readmitted back to the cancer hospital. The commenters believed that this would be more costly, in the aggregate, to the Medicare program.

Response: We do not know that our revised policy will be more costly to the Medicare program, because although Medicare would be paying the IPPS hospital under the IPPS for the ICU services, it would not be paying the cancer hospital for those services based on reasonable cost. As explained in the FY 2012 IPPS/LTCH PPS final rule, some hospitals were furnishing certain routine services, including ICU services, under arrangement. For example, under certain arrangements, if an inpatient of an IPPS-excluded hospital ("hospital A") required ICU services, and the IPPS-excluded hospital could not provide these services, the patient was moved to an IPPS hospital ("hospital B") that could furnish these ICU services. In these situations, the patient was not transferred to hospital B but was moved from an inpatient bed of hospital A to an inpatient bed of hospital B. However, the IPPS-excluded hospital treated these services as being provided under arrangement and included the cost of those services on its cost report. Because the two hospitals in the example above are under two different payment systems, we believe this behavior could lead to inappropriate and excessive Medicare payment. This is because the IPPS-excluded hospital, hospital A, is paid on a reasonable

cost basis. This payment could be greater than if the hospital that provided the service were paid under the IPPS for the same patient.

Comment: The cancer hospitals and the cancer hospital alliance also expressed concern that if patients needing ICU services had to be discharged and admitted as described above, it could inflate the readmission rates.

Response: We do not believe that a hospital's readmission rates under the Hospital Readmissions Reduction Program would be affected by this policy for several reasons. Cancer hospitals are not included in the Program so admissions and readmissions to cancer hospitals are not included in an IPPS hospital's readmission rate. Furthermore, transfers to other providers are not included in the calculations of excess readmissions. Each of the measures used in the Hospital Readmissions Reduction Program has exclusions for transfers to other hospitals. Finally, currently, we are only measuring readmissions for heart attack, heart failure, and pneumonia.

Comment: Commenters requested that CMS adopt a grandfathering provision to allow hospitals that have been furnishing routine services under arrangements outside of the hospital to continue furnishing these services in this manner. Cancer hospitals requested that, if the policy is not rescinded, a grandfathering provision be implemented that allows existing arrangements to continue, or provides an exception for cancer hospitals.

Response: We do not believe it is appropriate to adopt a grandfathering provision. We are concerned that, without this policy change, Medicare will continue to pay inappropriately for these services. That is, payment to IPPS hospitals should be

based on the DRG payment amount, and payment to excluded hospitals should not be based in part on the costs of routine services that the hospital has not furnished directly to its patients.

After consideration of the public comments and for the reasons set forth above, we are finalizing our proposal to change the effective date of the revised policy. Therefore, effective for cost reporting periods beginning on or after October 1, 2013, routine services provided in the hospital to its inpatients are considered as being provided by the hospital. However, if services are provided outside the hospital, the services are considered as being provided under arrangement. Only therapeutic and diagnostic items and services may be furnished under arrangement outside of the hospital.

M. Technical Change

In an interim final rule that appeared in the November 27, 2007 **Federal Register** (72 FR 66895 through 66897), we made changes to the regulations governing the application of the emergency Medicare GME affiliation agreement rules in order to address the needs of hospitals located in the section 1135 emergency area in the aftermath of Hurricane Katrina and Rita. In that rule, we changed the length of emergency affiliation agreements from 3 years to 5 years under 42 CFR 413.79(f)(7) (then § 413.79(f)(6)); that is, we specified that the emergency Medicare GME affiliation agreement must terminate no later than the conclusion of 4 academic years following the academic year during which the section 1135 emergency period began. However, we inadvertently did not make a conforming change to 42 CFR 413.79(f)(7)(i)(B). In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27995), we proposed to change the

regulatory text specified § 413.79(f)(7)(i)(B) to make it consistent with the regulatory text under § 413.79(f)(7).

We did not receive any public changes on the proposed technical changes. Therefore, in this final rule, we are adopting the proposed changes as final.

V. Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services "in accordance with a prospective payment system established by the Secretary." Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. The IPPS for capital-related costs was initially implemented in the Federal fiscal year (FY) 1992 IPPS final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in § 412.312 of the regulations. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) x (DRG Weight) x (Geographic Adjustment Factor (GAF)) x (COLA for hospitals located in Alaska and Hawaii) x (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at §412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under §§ 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, as noted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725 and 51804), FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, § 412.300(b) of the regulations defines a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS a new hospital is paid 85 percent of its Medicare allowable capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Hospitals Located in Puerto Rico

Section 412.374 of the regulations provides for the use of a blended payment amount for prospective payments for capital-related costs to hospitals located in Puerto Rico. Accordingly, under the capital IPPS, we compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital-related costs. In general, hospitals located in Puerto Rico are paid a blend of the applicable capital IPPS Puerto Rico rate and the applicable capital IPPS Federal rate. Capital IPPS payments to hospitals located in Puerto Rico are computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. For additional details on capital IPPS payments to hospitals located in Puerto Rico, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

C. Prospective Adjustment for the FY 2010 Documentation and Coding Effect

1. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we established adjustments to both the national operating standardized amount and the national capital Federal rate to eliminate the estimated effect of changes in documentation and coding resulting from the adoption of the MS-DRGs that do not reflect real changes in case-mix. Specifically, we established prospective documentation and coding adjustments of -1.2 percent for FY 2008, -1.8 percent for FY 2009, and -1.8 percent for FY 2010. However, to comply with section 7(a) of Pub. L. 110-90, enacted on September 29, 2007, in a final rule published in the **Federal Register** on November 27, 2007 (72 FR 66886 through 66888), we modified the documentation and coding adjustment for FY 2008 to -0.6 percent, and consequently revised the FY 2008 IPPS operating and capital payment rates, factors, and thresholds accordingly, with these revisions effective October 1, 2007.

For FY 2009, section 7(a) of Pub. L. 110-90 required a documentation and coding adjustment of -0.9 percent instead of the -1.8 percent adjustment established in the FY 2008 IPPS final rule with comment period. As discussed in the FY 2009 IPPS final rule with comment period (73 FR 48447 and 48733 through 48774), we applied an additional documentation and coding adjustment of -0.9 percent to the FY 2009 IPPS national standardized amounts and the national capital Federal rate. The documentation and coding adjustments established in the FY 2009 IPPS final rule, as amended by Pub. L. 110-90, are cumulative. As a result, the -0.9 percent documentation and coding

adjustment in FY 2009 was in addition to the -0.6 percent adjustment in FY 2008, yielding a combined effect of -1.5 percent. (For additional details on the development and implementation of the documentation and coding adjustments for FY 2008 and FY 2009, we refer readers to section II.D. of this preamble and the following rules published in the **Federal Register**: August 22, 2007 (72 FR 47175 through 47186 and 47431 through 47432); November 27, 2007 (72 FR 66886 through 66888); and August 19, 2008 (73 FR 48447 through 48450 and 48773 through 48775).)

For the FY 2011 IPPS/LTCH PPS proposed and final rules, we performed a retrospective evaluation of the FY 2009 claims data updated through December 2009 using the same analysis methodology as we did for FY 2008 claims in the FY 2010 IPPS/RY 2010 LTCH PPS proposed and final rules. Based on this evaluation, our actuaries determined that the implementation of the MS-DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355), we implemented an additional adjustment to the FY 2011 national capital Federal rate of -2.9 percent to account for part of the effect of the estimated changes in documentation and coding under the MS-DRG system that occurred in FYs 2008 and 2009 that did not reflect real changes in case-mix. Consistent with past practice, this -2.9 percent adjustment was applied in a cumulative manner, which yielded a combined effect of -4.4 percent. (For additional information on our estimate of the 5.4 percent cumulative documentation effect under the MS-DRG system for FYs 2008 and 2009 and the additional -2.9 percent documentation and coding

adjustment applied to the national capital Federal rate in FY 2011, we refer readers to the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24014) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355).)

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51727), we made an additional -1.0 percent adjustment to the national capital Federal rate to account for the remainder of the 5.4 percent estimate of the cumulative effect of documentation and coding changes under the MS-DRG system that occurred during FYs 2008 and 2009. Consistent with past practice, this -1.0 percent adjustment was applied in a cumulative manner, which yielded a combined effect of -5.4 percent.

2. Prospective Adjustment for the Effect of Documentation and Coding in FY 2010

We continue to believe that it is appropriate to make adjustments to the capital IPPS rates to eliminate the effect of any documentation and coding changes as a result of the implementation of the MS-DRGs. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as payments that otherwise would have been made in those years absent the change to the MS-DRGs. Under section 1886(g) of the Act, the Secretary has broad authority in establishing and implementing the IPPS for acute-care hospital inpatient capital-related costs (that is, the capital IPPS). We have consistently stated since the initial implementation of the MS-DRG system that we do not believe it is appropriate for Medicare expenditures under the capital IPPS to increase due to MS-DRG related changes in documentation and coding. Accordingly, we believe that it is appropriate under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of

Pub. L. 110-90, to make adjustments to the national capital Federal rate to eliminate the full effect of the documentation and coding changes resulting from the adoption of the MS-DRGs. We believe that this is appropriate because, in absence of such adjustments, the effect of the documentation and coding changes resulting from the adoption of the MS-DRGs results in inappropriately high capital IPPS payments because that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs).

As discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27997), we analyzed claims data from FY 2010 to determine whether any additional adjustment would be required to ensure that the adoption of MS-DRGs was implemented in a budget neutral manner. Specifically, we analyzed FY 2010 data on claims paid through December 2011 using our existing methodology as described in section II.D.4. of this preamble. Based on this analysis, our actuaries determined that implementation of the MS-DRG system resulted in a 6.2 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2010. This is an estimated additional 0.8 percentage point increase over the 5.4 percent reduction currently applied to the national capital Federal rate.

Consistent with our proposal for the operating IPPS standardized amounts, we proposed, under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act, to reduce the national capital Federal rate in FY 2013 by an additional 0.8 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the

MS-DRG system that did not reflect an increase in case-mix severity in FY 2010. Under that proposal, we would leave the -0.8 percent adjustment in place for FY 2013 and subsequent fiscal years to account for the effect in those years.

In section II.D.10. of the preamble of this final rule, we discuss the public comments we received on our proposal to make a -0.8 percent adjustment to the operating IPPS standardized amounts and hospital-specific rates and the national capital Federal rate to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS-DRG system that did not reflect an increase in case-mix severity in FY 2010. In summary, numerous commenters objected to this proposal, and many commenters pointed to MedPAC's analysis, discussed in its comment letter on the FY 2011 IPPS/LTCH PPS proposed rule, that suggested that "negative documentation and coding" may have occurred under the CMS-DRGs, creating an overestimation of documentation and coding due to the introduction of MS-DRGs.

As discussed in greater detail in section II.D.10. of the preamble of this final rule, at this time, we believe that, while MedPAC's analysis suggested that a potential overestimate could have, in theory, occurred in our methodology, the estimates are theoretical maximums. It is not clear at this time that, based on the information submitted, to what extent the examples provided by the commenters substantiate these theoretical maximums or any change in adjustments. Nonetheless, we recognize that the methodological issues that surround this question are complex, and may merit further consideration. Therefore, consistent with the policy we are adopting for the operating IPPS standardized amounts and hospital-specific rates for FY 2013, we are not finalizing

our proposal to apply a -0.8 percent adjustment to the national capital Federal rate at this time until more analysis can be completed.

3. Documentation and Coding Adjustment to the Puerto Rico-Specific Capital Rate

Under § 412.74, Puerto Rico hospitals are currently paid based on 75 percent of the national capital Federal rate and 25 percent of the Puerto Rico-specific capital rate. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50358 through 50359), we discussed the retrospective evaluation of the FY 2009 claims data from the March 2010 update of the MedPAR file of hospitals located in Puerto Rico using the same methodology used to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals. This analysis shows that the change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico was approximately 2.6 percent. We also explained that we continue to believe that an adjustment for such increases is appropriate because all hospitals have the same financial incentives for documentation and coding improvements, and the same ability to benefit from the resulting increase in aggregate payments that do not reflect real changes in case-mix.

Given this case-mix increase due to changes in documentation and coding under the MS-DRGs, under the Secretary's broad authority under section 1886(g) of the Act, we established an adjustment to the Puerto Rico-specific capital rate of –2.6 percent in FY 2011 for the cumulative increase in case-mix due to changes in documentation and coding under the MS-DRGs for FYs 2008 and 2009. In addition, consistent with our implementation of other prospective MS-DRG documentation and coding adjustments to

the capital Federal rate and operating IPPS standardized amounts, we established that the -2.6 percent adjustment will remain in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS-DRGs do not lead to an increase in aggregate payments not reflective of an increase in real case-mix in subsequent years. Therefore, the -2.6 percent adjustment to the capital Puerto Rico-specific rate made in FY 2011 reflects the entire amount of our estimate at that time of the effects of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico.

As discussed above, for the proposed rule and this final rule, we analyzed FY 2010 data on claims paid through December 2011 using our existing methodology to determine if any additional adjustment for the effects of documentation and coding that did not reflect real changes in case-mix is warranted. Based on this analysis (which is described in greater detail in section II.D.10. of this preamble), we found no significant additional effect of documentation and coding that would warrant any additional adjustment. Therefore, we did not propose to make any additional adjustment to the capital Puerto Rico-specific rate for FY 2013 for the effect of documentation and coding that did not reflect real changes in case-mix.

D. Changes for Annual Update for FY 2013

The annual update to the capital PPS Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2013 is discussed in section III. of the Addendum to this final rule.

VI. Changes for Hospitals Excluded from the IPPS

A. Excluded Hospitals

Historically, hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount was multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to all categories of excluded providers, which included rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and IPPS-excluded cancer hospitals.

Payment to children's hospitals and cancer hospitals that are excluded from the IPPS continues to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a) of the regulations, RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27998), we proposed that the FY 2013 rate-of-increase percentage to be applied to the target amount for cancer and children's hospitals and RNHCIs would be the FY 2013 percentage increase in the IPPS

operating market basket. At the time of issuance of the proposed rule, the FY 2013 percentage increase in the IPPS operating market basket was estimated to be 3.0 percent. Beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's and cancer hospitals. As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), with IRFs, IPFs, and LTCHs being paid under their own PPS, the remaining number of providers being paid based on reasonable cost subject to a ceiling (that is, children's hospitals, 11 cancer hospitals, and RNHCIs) is too small and the cost report data are too limited to be able to create a market basket solely for these hospitals. For FY 2013, we proposed to continue to use the IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for the reasons discussed in the FY 2006 IPPS final rule.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27998), we proposed to use the FY 2006-based IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for FY 2013. Therefore, based on IHS Global Insight, Inc.'s 2012 first quarter forecast, with historical data through the 2011 fourth quarter, we estimated that the IPPS operating market basket update for FY 2013 would be 3.0 percent (that is, the estimate of the market basket rate-of-increase). We proposed that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2013. Therefore, based on IHS Global Insight, Inc.'s 2012 second quarter forecast, with historical data through the 2012 first quarter, we use the FY 2013 estimate of the IPPS operating market basket rate-of-increase of 2.6 percent. Moreover, consistent with our proposal that the

percentage increase in the rate-of-increase limits for cancer and children's hospitals and RNHCIs would be the percentage increase in the FY 2013 IPPS operating market basket, the FY 2013 rate-of-increase percentage that is applied to the FY 2012 target amounts in order to calculate the final FY 2013 target amounts for cancer and children's hospitals and RNHCIs is 2.6 percent, in accordance with the applicable regulations at 42 CFR 413.40.

We note that IRFs, IPFs, and LTCHs, which were paid previously under the reasonable cost methodology, now receive payment under their own prospective payment systems, in accordance with changes made to the statute. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provided transition periods of varying lengths during which time a portion of the prospective payment was based on cost-based reimbursement rules under Part 413. (However, certain providers do not receive a transition period or may elect to bypass the transition period as applicable under 42 CFR Part 412, Subparts N, O, and P.) We note that the various transition periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IV. of the Addendum to this final rule for the specific final update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2013. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

We did not receive any public comments on this section in the proposed rule.

B. Report on Adjustment (Exceptions) Payments

Section 4419(b) of Pub. L. 105-33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for a fiscal year in accordance with § 413.24(f)(2). The fiscal intermediary or MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the fiscal intermediary or MAC receives the hospital's request in accordance with applicable regulations, the fiscal intermediary or MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the applications are incomplete and additional information must be requested in order to have a completed application. However, in an attempt to provide interested parties with data on the most recent adjustments for which we do have data, we are publishing data on adjustment payments that were processed by the fiscal intermediary or MAC or CMS during FY 2011.

The table below includes the most recent data available from the fiscal intermediaries or MACs and CMS on adjustment payments that were adjudicated during

FY 2011. As indicated above, the adjustments made during FY 2011 only pertain to cost reporting periods ending in years prior to FY 2010. Total adjustment payments given to excluded hospitals during FY 2011 are $3,118,588. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of Hospital	**Number**	**Excess cost over ceiling**	**Adjustment payments**
Children's	2	$1,362,705	$1,303,381
Cancer	1	$7,805,148	$1,743,053
Religious Nonmedical Health Care Institution (RNHCI)	1	$72,154	$72,154
TOTAL			$3,118,588

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2013

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as "a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days." Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (LOS) (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a "per discharge" system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC-DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS-LTC-DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS-LTC-DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97-248) for payments for inpatient services provided by a LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR Part 413.) With the implementation of the PPS

for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98-21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in section VII. of this preamble, when we refer to discharges, the intent is to describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA System to payments under the LTCH PPS. During this 5-year transition period, a LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless a LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS

under 42 CFR Part 412, Subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51743) for a chronological summary of the main legislative and regulatory developments affecting the LTCH PPS through the annual update cycles prior to this FY 2013 rulemaking cycle.

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

Under the existing regulations at §§ 412.23(e)(1) and (e)(2)(i), which implement section 1886(d)(1)(B)(iv)(I) of the Act, to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare and must have an average Medicare inpatient LOS of greater than 25 days. Alternatively, § 412.23(e)(2)(ii) states that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days.

b. Hospitals Excluded from the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c), and therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR Part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90-248) (42 U.S.C. 1395b-1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92-603) (42 U.S.C. 1395b-1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). In the RY 2005 LTCH PPS final rule (69 FR 25676), we clarified that the discussion of beneficiary liability in the August 30, 2002 final rule was not meant to establish rates or payments for, or define Medicare-eligible expenses. Under § 412.507, if the Medicare payment to the LTCH is the full LTC-DRG payment amount, as consistent with other established hospital prospective payment systems, a LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83,

and 409.87 and for items and services as specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. Therefore, if the Medicare payment was for a SSO case (§ 412.529) that was less than the full LTC-DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH could also charge the beneficiary for services delivered on those uncovered days (§ 412.507).

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107-105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services "for which a claim is submitted other than in an electronic form specified by the Secretary." Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial "in such unusual cases as the Secretary finds appropriate" (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified as 45 CFR Parts 160 and 162, Subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires

covered entities, including covered health care providers, to conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS-LTC-DRG) Classifications and Relative Weights for FY 2013

1. Background

Section 123 of the BBRA requires that the Secretary implement a PPS for LTCHs (that is, a per discharge system with a diagnosis-related group (DRG)-based patient classification system reflecting the differences in patient resources and costs). Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine "the feasibility and the impact of basing payment under such a system [the long-term care hospital (LTCH) PPS] on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients, as well as the use of the most recently available hospital discharge data."

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system (that is, the CMS DRGs) that was utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the "long-term care diagnosis-related groups (LTC-DRGs)." Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect "the differences in patient resource use . . ." of LTCH patients (section 123(a)(1) of the BBRA (Pub. L. 106-113)).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS-DRGs and the Medicare severity long-term care diagnosis-related groups (MS-LTC-DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development and implementation and rationale for the use of the MS-DRGs and MS-LTC-DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR Part 412, Subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC-DRGs would be considered a reference to MS-LTC-DRGs. For the remainder of this section, we present the discussion in terms of the current MS-LTC-DRG patient classification system unless specifically referring to the previous LTC-DRG patient classification system that was in effect before October 1, 2007.)

The MS-DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS-DRG classifications are updated annually. As described in section II.G. of this preamble, for FY 2013, as we proposed, we are not creating or deleting any MS-DRGs, and as such we continue to have a total of 751 MS-DRG groupings for FY 2013.Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into

distinct MS-LTC-DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS-LTC-DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs. Below we provide a general summary of our existing methodology for determining the MS-LTC-DRG relative weights.

In a departure from the IPPS, and as discussed in greater detail below in section VII.B.3.f. of this preamble, we use low-volume MS-LTC-DRGs (that is, MS-LTC-DRGs with less than 25 LTCH cases) in determining the MS-LTC-DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. For purposes of determining the relative weights for the large number of low-volume MS-LTC-DRGs, we group all of the low-volume MS-LTC-DRGs into five quintiles based on average charge per discharge. (A detailed discussion of the initial development and application of the quintile methodology appears in the August 30, 2002 LTCH PPS final rule (67 FR 55978).) Under our existing methodology and as proposed, we account for adjustments to payments for SSO cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS-LTC-DRG). Furthermore, as proposed, we make adjustments to account for nonmonotonically increasing weights, when necessary. That is, theoretically, cases under the MS-LTC-DRG system that are more severe require greater expenditure of medical care resources and will result in higher average charges such that, in the severity levels within a base MS-LTC-DRG, the weights should increase monotonically with severity from the lowest to highest severity level. (We discuss

nonmonotonicity in greater detail and our methodology to adjust the MS-LTC-DRG relative weights to account for nonmonotonically increasing relative weights in section VII.B.3.g. (Step 6) of this preamble.)

2. Patient Classifications into MS-LTC-DRGs

a. Background

The MS-DRGs (used under the IPPS) and the MS-LTC-DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted above in this section, we refer to the DRGs under the LTCH PPS as MS-LTC-DRGs although they are structurally identical to the MS-DRGs used under the IPPS.

The MS-DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD-9-CM procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKG), or minor surgical procedures (for example, biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS-LTC-DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge and that payment varies by the MS-LTC-DRG to which a

beneficiary's stay is assigned. Cases are classified into MS-LTC-DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Through FY 2010, the number of secondary or additional diagnoses and the number of procedure codes considered for MS-DRG assignment was limited to nine and six, respectively. However, for claims submitted on the 5010 format beginning January 1, 2011, we increased the capacity to process diagnosis and procedure codes up to 25 diagnoses and 25 procedures. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. We refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule for a complete discussion of this change (75 FR 50127).

Upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). HIPAA Transactions and Code Sets Standards regulations at 45 CFR Parts 160 and 162 require that no later than October 16, 2003, all covered entities must comply with the applicable requirements of Subparts A and I through R of Part 162. Among other requirements, those provisions

direct covered entities to use the ASC X12N 837 Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, and the applicable standard medical data code sets for the institutional health care claim or equivalent encounter information transaction (45 CFR 162.1002 and 45 CFR 162.1102). For additional information on the ICD-9-CM Coding System, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47241 through 47243 and 47277 through 47281). We also refer readers to the detailed discussion on correct coding practices in the August 30, 2002 LTCH PPS final rule (67 FR 55981 through 55983). Additional coding instructions and examples are published in the Coding Clinic for ICD-9-CM, a product of the American Hospital Association. (We refer readers to section II.G.9. of this preamble for additional information on the annual revisions to the ICD-9-CM codes.)

With respect to the ICD-9-CM coding system, we have been discussing the conversion to the ICD-10-CM and the ICD-10-PCS coding systems for many years. In prior rules published in the **Federal Register** (for example, section II.G.11. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50122 through 50128)), we discussed the implementation date for the conversion to the ICD-10-CM and ICD-10-PCS coding systems. We refer readers to section II.G.9. of this preamble for additional information on the adoption of the ICD-10-CM and ICD-10-PCS systems.

To create the MS-DRGs (and by extension, the MS-LTC-DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of

MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS-DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare contractors (that is, fiscal intermediaries and MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS-LTC-DRG can be made. During this process, certain cases are selected for further development (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS-LTC-DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS-LTC-DRG assignment, the Medicare contractor determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS-LTC-DRG assignments made by the Medicare contractor and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS-LTC-DRG weights and to classify

current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS-DRG and MS-LTC-DRG classification changes and to recalibrate the MS-DRG and MS-LTC-DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS-LTC-DRGs for FY 2013

As specified by our regulations at § 412.517(a), which requires that the MS-LTC-DRG classifications and relative weights be updated annually and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, as we proposed, we are updating the MS-LTC-DRG classifications effective October 1, 2012, through September 30, 2013 (FY 2013) consistent with the changes to specific MS-DRG classifications presented in section II.G. of this preamble (that is, GROUPER Version 30.0). Therefore, the MS-LTC-DRGs for FY 2013 presented in this final rule are the same as the MS-DRGs that are being used under the IPPS for FY 2013. In addition, because the MS-LTC-DRGs for FY 2013 are the same as the MS-DRGs for FY 2013, the other changes that affect MS-DRG (and by extension MS-LTC-DRG) assignments under Version 30.0 of the GROUPER discussed in section II.G. of the preamble of this final rule, including the changes to the MCE software and the ICD-9-CM coding system, are also applicable under the LTCH PPS for FY 2013. We note that, we did not receive any public comments regarding the proposals presented under this section. The comments we received on the proposed changes to the

MS-DRG classifications for FY 2013 (GROUPER Version 30.0) are discussed in section II.G. of the preamble of this final rule.

3. Development of the FY 2013 MS-LTC-DRG Relative Weights

a. General Overview of the Development of the MS-LTC-DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment system rate by the applicable relative weight in determining payment to LTCHs for each case.

Although the adoption of the MS-LTC-DRGs resulted in some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, as proposed, the basic methodology used to develop the MS-LTC-DRG relative weights continues to be consistent with the general methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). (For additional details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) Under the LTCH PPS, relative weights for each MS-LTC-DRG are a primary

element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS-LTC-DRG have access to an appropriate level of services and to encourage efficiency, we calculated a relative weight for each MS-LTC-DRG that represents the resources needed by an average inpatient LTCH case in that MS-LTC-DRG. For example, cases in a MS-LTC-DRG with a relative weight of 2 will, on average, cost twice as much to treat as cases in a MS-LTC-DRG with a relative weight of 1.

b. Development of the MS-LTC-DRG Relative Weights for FY 2013

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28000 through 28007), we presented our proposals for the development of the MS-LTC-DRG relative weights for FY 2013, The basic methodology we proposed to use to develop the FY 2013 MS-LTC-DRG relative weights is the same as the methodology we used to develop the FY 2012 MS-LTC-DRG relative weights in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51738 through 51743) and is consistent with the general methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). Our proposed development of the FY 2013 MS-LTC-DRG relative weights included proposals related to the data, the hospital-specific relative value (HSRV) methodology, the treatment of severity levels in the MS-LTC-DRGs, low-volume and no-volume MS-LTC-DRGs, adjustment for nonmonotonicity, and the steps for calculating the MS-LTC-DRG relative weights with a budget neutrality factor. We did not receive any public comments on our proposals regarding the development of the MS-LTC-DRG relative weights for FY 2013, and are

adopting the proposals as final without modification in this final rule. (We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule for additional details on our proposals for the development of the FY 2103 MS-LTC-DRG relative weights (77 FR 28000 through 28007),) Below we present the finalized methodology that we used to determine the MS-LTC-DRG relative weights for FY 2013, which is consistent with the methodology presented in the proposed rule.

Beginning with the FY 2008 update, we established a budget neutrality requirement for the annual update to the MS-LTC-DRG classifications and relative weights at § 412.517(b) (in conjunction with § 412.503), such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the classification and relative weight changes (72 FR 26882 through 26884). Consistent with § 412.517(b) and as proposed, we continue to apply our established two-step budget neutrality methodology, which is based on the current year MS-LTC-DRG classifications and relative weights. We did not receive any public comments regarding this proposal. Thus, for this final rule, we continue to apply our established two-step budget neutrality methodology such that the annual update to the MS-LTC-DRG classifications and relative weights for FY 2013 are based on the FY 2012 MS-LTC-DRG classifications and relative weights established in Table 11 listed in section VI. of the Addendum to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51813). (For additional information on the established two-step budget neutrality methodology, we refer readers to the FY 2008 IPPS final rule (72 FR 47295 through 47296).)

c. Data

For the proposed rule, to calculate the MS-LTC-DRG relative weights for FY 2013, we obtained total charges from FY 2011 Medicare LTCH bill data from the December 2011 update of the FY 2011 MedPAR file, which were the best available data at that time, and used the proposed Version 30.0 of the GROUPER to classify LTCH cases. Consistent with our existing methodology, we also proposed that if more recent data became available, we would use those data and the finalized Version 30.0 of the GROUPER in establishing the FY 2013 MS-LTC-DRG relative weights in the final rule. Consistent with our proposal, to calculate the MS-LTC-DRG relative weights for FY 2013 for this final rule, we obtained total charges from FY 2011 Medicare LTCH bill data from the March 2012 update of the FY 2011 MedPAR file, which are the best available data, and used Version 30.0 of the GROUPER to classify LTCH cases.

As proposed and consistent with our historical methodology, we excluded the data from LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Pub. L. 90-248 or section 222(a) of Pub. L. 92-603. Furthermore, consistent with our historical practice, we excluded Medicare Advantage (Part C) claims, which are now included in the MedPAR files, in the calculations for the relative weights under the LTCH PPS that are used to determine payments for Medicare fee-for-service claims. Specifically, we did not use any claims from the MedPAR files that have a GHO Paid indicator value of "1," which effectively removes Medicare Advantage claims from the relative weight calculations (73 FR 48532). Accordingly, in the development of the

FY 2013 MS-LTC-DRG relative weights in this final rule, we excluded the data of 14 all-inclusive rate providers and the 2 LTCHs that are paid in accordance with demonstration projects that had claims in the March 2012 update of the FY 2011 MedPAR file, as well as any Medicare Advantage claims.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients and treatment of infections and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS-LTC-DRGs has the potential to inappropriately distort the measure of average charges. As proposed, to account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, we continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS-LTC-DRG relative weights for FY 2013. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduce the impact of the variation in charges across providers on any particular MS-LTC-DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each case to hospital-specific relative charge values and then adjust those values for the LTCH's case-mix. The adjustment for case-mix is needed to

rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix, so it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

We did not receive any public comments regarding this proposal. Thus, in accordance with our established methodology and as proposed, we continue to standardize charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. (Step 3) of this preamble) by the average adjusted charge for all cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS-LTC-DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH’s case-mix index to determine the standardized charge for the case (67 FR 55989).

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at a LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a

Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case at a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the MS-LTC-DRG Relative Weights

For purposes of determining the MS-LTC-DRG relative weights, under our historical methodology, there are three different categories of DRGs based on volume of cases within specific MS-LTC-DRGs. MS-LTC-DRGs with at least 25 cases are each assigned a unique relative weight; low-volume MS-LTC-DRGs (that is, MS-LTC-DRGs that contain between 1 and 24 cases based on a given year's claims data) are grouped into quintiles (as described below) and assigned the relative weight of the quintile. No-volume MS-LTC-DRGs (that is, no cases in the given year's claims data are assigned to those MS-LTC-DRGs) are cross-walked to other MS-LTC-DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS-LTC-DRG (as described in greater detail below). As proposed, we continue to utilize these same three categories of MS-LTC-DRGs for purposes of the treatment of severity levels in determining the MS-LTC-DRG relative weights for FY 2013. (We provide in-depth discussions of our policy regarding weight-setting for low-volume MS-LTC-DRGs in

section VII.B.3.f. of the preamble of this final rule and for no-volume MS-LTC-DRGs, under Step 5 in section VII.B.3.g. of this preamble.)

As also noted above, while the LTCH PPS and the IPPS use the same patient classification system, the methodology that is used to set the DRG relative weights for use in each payment system differs because the overall volume of cases in the LTCH PPS is much less than in the IPPS. In general, as proposed and consistent with our existing methodology we used the following steps to determine the FY 2013 MS-LTC-DRG relative weights: (1) if an MS-LTC-DRG has at least 25 cases, it is assigned its own relative weight; (2) if an MS-LTC-DRG has between 1 and 24 cases, it is assigned to a quintile for which we compute a relative weight for all of the MS-LTC-DRGs assigned to that quintile; and (3) if an MS-LTC-DRG has no cases, it is cross-walked to another MS-LTC-DRG based upon clinical similarities to assign an appropriate relative weight (as described below in detail in Step 5 of section VII.B.3.g. of this preamble). Furthermore, in determining the FY 2013 MS-LTC-DRG relative weights, when necessary, we make adjustments to account for nonmonotonicity, as discussed in greater detail below in Step 6 of section VII.B.3.g. of this preamble. We refer readers to the discussion in the FY 2010 IPPS/RY LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Low-Volume MS-LTC-DRGs

In order to account for MS-LTC-DRGs with low volume (that is, with fewer than 25 LTCH cases), as proposed and consistent with our existing methodology, for purposes of determining the FY 2013 MS-LTC-DRG relative weights, we continue to employ the

quintile methodology for low-volume MS-LTC-DRGs, such that we group the "low-volume MS-LTC-DRGs" (that is, MS-LTC-DRGs that contained between 1 and 24 cases annually) into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995 and 72 FR 47283 through 47288). In determining the FY 2013 MS-LTC-DRG relative weights in this final rule, in cases where the initial assignment of a low-volume MS-LTC-DRG to quintiles resulted in nonmonotonicity within a base-DRG, in order to ensure appropriate Medicare payments, consistent with our historical methodology, we made adjustments to the treatment of low-volume MS-LTC-DRGs to preserve monotonicity, as discussed in detail below in section VII.B.3.g. (Step 6) in this preamble.

In this final rule, using LTCH cases from the March 2012 update of the FY 2011 MedPAR file (which is currently the best available data), we identified 304 MS-LTC-DRGs that contained between 1 and 24 cases. This list of MS-LTC-DRGs was then divided into one of the 5 low-volume quintiles, each containing a minimum of 61 MS-LTC-DRGs (304/5 = 64 with 4 MS-LTC-DRGs as the remainder). We assigned a low-volume MS-LTC-DRG to a specific low-volume quintile by sorting the low-volume MS-LTC-DRGs in ascending order by average charge in accordance with our established methodology. Furthermore, because the number of MS-LTC-DRGs with less than 25 cases was not evenly divisible by 5, the average charge of the low-volume quintile was used to determine which of the low-volume quintiles contain the 4 additional low-volume MS-LTC-DRGs. Specifically, after organizing the MS-LTC-DRGs by ascending order by average charge, we assigned the first fifth (1^{st} through 60^{th}) of low-volume

MS-LTC-DRGs (with the lowest average charge) into Quintile 1. The MS-LTC-DRGs with the highest average charge cases were assigned into Quintile 5. Because the average charge of the 61st low-volume MS-LTC-DRG in the sorted list was closer to the average charge of the 60th low-volume MS-LTC-DRG (assigned to Quintile 1) than to the average charge of the 62nd low-volume MS-LTC-DRG (assigned to Quintile 3), we assigned it to Quintile 1 (such that Quintile 1 contains 61 low-volume MS-LTC-DRGs before any adjustments for nonmonotonicity, as discussed below). This process was repeated through the remaining low-volume MS-LTC-DRGs so that 4 of the 5 low-volume quintiles contain 61 MS-LTC-DRGs (Quintiles 1, 2, 3 and 4) and the other low-volume quintile contains 60 MS-LTC-DRGs (Quintiles 5). Table 13A, which is listed in section VI. of the Addendum to this final rule and is available via the Internet, lists the composition of the low-volume quintiles for MS-LTC-DRGs for FY 2013.

Accordingly, in order to determine the FY 2013 relative weights for the MS-LTC-DRGs with low volume, we used the 5 low-volume quintiles described above. The composition of each of the 5 low-volume quintiles shown in Table 13A (listed in section VI. of the Addendum to this final rule and available via the Internet) was used in determining the FY 2013 MS-LTC-DRG relative weights (as shown in Table 11 listed in section VI. of the Addendum to this final rule and available via the Internet). We determined a relative weight and (geometric) average length of stay for each of the 5 low-volume quintiles using the methodology that we applied to the MS-LTC-DRGs (25 or more cases), as described below in section VII.B.3.g. of this preamble. We assigned the same relative weight and average length of stay to each of the low-volume

MS-LTC-DRGs that made up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS-LTC-DRGs with a low volume of LTCH cases will vary in the future.

We note that we will continue to monitor the volume (that is, the number of LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS-LTC-DRG relative weights result in appropriate payment for such cases and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the FY 2013 MS-LTC-DRG Relative Weights

For this final rule, as we proposed, we determined the FY 2013 MS-LTC-DRG relative weights based on our existing methodology. (For additional information on the original development of this methodology, and modifications to it since the adoption of the MS-LTC-DRGs, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55995) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43951 through 43966).) In summary, to determine the FY 2013 MS-LTC-DRG relative weights, we grouped LTCH cases to the appropriate MS-LTC-DRG, while taking into account the low-volume quintile (as described above). After grouping the cases to the appropriate MS-LTC-DRG (or low-volume quintile), we calculated the FY 2013 relative weights by first removing statistical outliers and cases with a length of stay of 7 days or less (Steps 1 and 2 below). Next, we adjusted the number of cases in each MS-LTC-DRG (or low-volume quintile) for the effect of SSO cases (Step 3 below). After removing statistical outliers (Step 1 below) and cases with a length of stay of 7 days

or less (Step 2 below), the SSO adjusted discharges and corresponding charges were then used to calculate "relative adjusted weights" for each MS-LTC-DRG (or low-volume quintile) using the HSRV method.

Below we discuss in detail the steps for calculating the FY 2013 MS-LTC-DRG relative weights. We note that, as we discussed in section VII.B.3.c. of this preamble, we excluded the data of all-inclusive rate LTCHs, LTCHs that are paid in accordance with demonstration projects, and any Medicare Advantage claims in the March 2012 update of the FY 2011 MedPAR file.

Step 1--Remove statistical outliers.

The first step in the calculation of the FY 2013 MS-LTC-DRG relative weights is to remove statistical outlier cases. Consistent with our historical relative weight methodology, we continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS-LTC-DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among the MS-LTC-DRGs. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2--Remove cases with a length of stay of 7 days or less.

The MS-LTC-DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the FY 2013 MS-LTC-DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short stays. Therefore, consistent with our historical relative weight methodology, in determining the FY 2013 MS-LTC-DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3--Adjust charges for the effects of SSOs.

After removing cases with a length of stay of 7 days or less, we are left with cases that have a length of stay of greater than or equal to 8 days. As the next step in the calculation of the FY 2013 MS-LTC-DRG relative weights, consistent with our historical relative weight methodology, we adjusted each LTCH's charges per discharge for those remaining cases for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503).

We made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS-LTC-DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS-LTC-DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS-LTC-DRG.

Counting SSO cases as full discharges with no adjustment in determining the FY 2013 MS-LTC-DRG relative weights would lower the FY 2013 MS-LTC-DRG relative weight for affected MS-LTC-DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within an MS-LTC-DRG. This would result in an "underpayment" for non-SSO cases and an "overpayment" for SSO cases. Therefore, we adjusted for SSO cases under § 412.529 in this manner because it results in more appropriate payments for all LTCH cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4--Calculate the FY 2013 MS-LTC-DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we calculated the FY 2013 MS-LTC-DRG relative weights using the HSRV methodology, which is an iterative process. First, for each LTCH case, we calculated a hospital-specific relative charge value by dividing the SSO adjusted charge per discharge (see Step 3) of the LTCH

case (after removing the statistical outliers (see Step 1) and LTCH cases with a length of stay of 7 days or less (see Step 2)) by the average charge per discharge for the LTCH in which the case occurred. The resulting ratio was then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each MS-LTC-DRG, we calculated the FY 2013 relative weight by dividing the average of the adjusted hospital-specific relative charge values (from above) for the MS-LTC-DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated MS-LTC-DRG relative weights, each LTCH's average relative weight for all of its cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS-LTC-DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values (from above) were then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of MS-LTC-DRG relative weights across all LTCHs. This iterative process was continued until there was convergence between the weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5--Determine a FY 2013 relative weight for MS-LTC-DRGs with no LTCH cases.

As we stated above, we determined the FY 2013 relative weight for each MS-LTC-DRG using total Medicare allowable total charges reported in the best available LTCH claims data (that is, the March 2012 update of the FY 2011 MedPAR file for this

final rule). Using these data, we identified the MS-LTC-DRGs for which there are no LTCH cases in the database, such that no patients who would have been classified to those MS-LTC-DRGs were treated in LTCHs during FY 2011 and, therefore, no charge data are available for these MS-LTC-DRGs. Thus, in the process of determining the MS-LTC-DRG relative weights, we were unable to calculate relative weights for the MS-LTC-DRGs with no LTCH cases using the methodology described in Steps 1 through 4 above. However, because patients with a number of the diagnoses under these MS-LTC-DRGs may be treated at LTCHs, consistent with our historical methodology, we assigned a relative weight to each of the no-volume MS-LTC-DRGs based on clinical similarity and relative costliness (with the exception of "transplant" MS-LTC-DRGs and "error" MS-LTC-DRGs, as discussed below). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

In general, we determined FY 2013 relative weights for the MS-LTC-DRGs with no LTCH cases in the March 2012 update of the FY 2011 MedPAR file used in this final rule (that is, "no-volume" MS-LTC-DRGs) by cross-walking each no-volume MS-LTC-DRG to another MS-LTC-DRG with a calculated relative weight (determined in accordance with the methodology described above). Then, the "no-volume" MS-LTC-DRG was assigned the same relative weight (and average length of stay) of the MS-LTC-DRG to which it was cross-walked (as described in greater detail below).

Of the 751 MS-LTC-DRGs for FY 2013, we identified 212 MS-LTC-DRGs for which there are no LTCH cases in the database (including the 8 "transplant"

MS-LTC-DRGs and 2 "error" MS-LTC-DRGs). As stated above, we assigned relative weights for each of the 212 no-volume MS-LTC-DRGs (with the exception of the 8 "transplant" MS-LTC-DRGs and the 2 "error" MS-LTC-DRGs, which are discussed below) based on clinical similarity and relative costliness to one of the remaining 539 (751 - 212= 539) MS-LTC-DRGs for which we were able to determine relative weights based on FY 2011 LTCH claims data using the steps described above. (For the remainder of this discussion, we refer to the "cross-walked" MS-LTC-DRGs as the MS-LTC-DRGs to which we crosswalk one of the 213 "no volume" MS-LTC-DRGs for purposes of determining a relative weight.) Then, we assigned the no-volume MS-LTC-DRG the relative weight of the cross-walked MS-LTC-DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

For this final rule, we cross-walked the no-volume MS-LTC-DRG to an MS-LTC-DRG for which there are LTCH cases in the March 2012 update of the FY 2011 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. We evaluated the relative costliness in determining the applicable MS-LTC-DRG to which a no-volume MS-LTC-DRG is cross-walked in order to assign an appropriate relative weight for the no-volume MS-LTC-DRGs in FY 2013. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases

grouped to one of the no-volume MS-LTC-DRGs in FY 2013, the relative weights assigned based on the cross-walked MS-LTC-DRGs will result in an appropriate LTCH PPS payment because the crosswalks, which are based on similar clinical similarity and relative costliness, generally require equivalent relative resource use.

We then assigned the relative weight of the cross-walked MS-LTC-DRG as the relative weight for the no-volume MS-LTC-DRG such that both of these MS-LTC-DRGs (that is, the no-volume MS-LTC-DRG and the cross-walked MS-LTC-DRG) have the same relative weight for FY 2013. We note that if the cross-walked MS-LTC-DRG had 25 cases or more, its relative weight, which was calculated using the methodology described in Steps 1 through 4 above, was assigned to the no-volume MS-LTC-DRG as well. Similarly, if the MS-LTC-DRG to which the no-volume MS-LTC-DRG was cross-walked had 24 or less cases and, therefore, was designated to one of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS-LTC-DRG such that both of these MS-LTC-DRGs (that is, the no-volume MS-LTC-DRG and the cross-walked MS-LTC-DRG) have the same relative weight for FY 2013. (As we noted above, in the infrequent case where nonmonotonicity involving a no-volume MS-LTC-DRG resulted, additional adjustments as described in Step 6 were required in order to maintain monotonically increasing relative weights.)

For this final rule, a list of the no-volume MS-LTC-DRGs and the MS-LTC-DRG to which it is cross-walked (that is, the cross-walked MS-LTC-DRG) for FY 2013 is

shown in Table 13B, which is listed in section VI. of the Addendum to this final rule and is available via the Internet.

To illustrate this methodology for determining the relative weights for the FY 2013 MS-LTC-DRGs with no LTCH cases, we are providing the following example, which refers to the no-volume MS-LTC-DRGs crosswalk information for FY 2013 provided in Table 13B.

Example: There are no cases in the FY 2011 MedPAR file used for this final rule for MS-LTC-DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS-LTC-DRG 70 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to MS-LTC-DRG 61. Therefore, we assigned the same relative weight of MS-LTC-DRG 70 of 0.8209 for FY 2013 to MS-LTC-DRG 61 (obtained from Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS-LTC-DRGs with no volume of LTCH cases based on the system will vary in the future. We used the most recent available claims data in the MedPAR file to identify no-volume MS-LTC-DRGs and to determine the relative weights in this final rule.

Furthermore, for FY 2013, consistent with our historical relative weight methodology, we established MS-LTC-DRG relative weights of 0.0000 for the following transplant MS-LTC-DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS-LTC-DRG 1); Heart Transplant or Implant of Heart Assist System without

MCC (MS-LTC-DRG 2); Liver Transplant with MCC or Intestinal Transplant (MS-LTC-DRG 5); Liver Transplant without MCC (MS-LTC-DRG 6); Lung Transplant (MS-LTC-DRG 7); Simultaneous Pancreas/Kidney Transplant (MS-LTC-DRG 8); Pancreas Transplant (MS-LTC-DRG 10); and Kidney Transplant (MS-LTC-DRG 652). This is because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these eight transplant MS-LTC-DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS-LTC-DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS-LTC-DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).)

Step 6--Adjust the FY 2013 MS-LTC-DRG relative weights to account for nonmonotonically increasing relative weights.

As discussed earlier in this section, the MS-DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as "without CC/MCC." When data do not support the creation of three severity levels, the base MS-DRG is subdivided into either two levels or the base MS-DRG is not subdivided. The two-level subdivisions could

consist of the MS-DRG with CC/MCC and the MS-DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS-DRG with MCC and the MS-DRG without MCC.

In those base MS-LTC-DRGs that are split into either two or three severity levels, cases classified into the "without CC/MCC" MS-LTC-DRG are expected to have a lower resource use (and lower costs) than the "with CC/MCC" MS-LTC-DRG (in the case of a two-level split) or both the "with CC" and the "with MCC" MS-LTC-DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and will result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS-LTC-DRG, an MS-LTC-DRG with CC has a higher relative weight than one with MCC, or the MS-LTC-DRG "without CC/MCC" has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS-LTC-DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS-LTC-DRG (which are generally expected to have lower resource use and costs)**.** Consequently, in determining the FY 2013 MS-LTC-DRG relative weights in this final rule, consistent with our historical methodology, we combined MS-LTC-DRG severity levels within a base MS-LTC-DRG for the purpose of computing a relative weight when

necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2013 MS-LTC-DRG relative weights in this final rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet.

Step 7-- Calculate the FY 2013 budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS-LTC-DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS-LTC-DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS-LTC-DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS-LTC-DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). Under the budget neutrality requirement at §412.517(b), for each annual update, the MS-LTC-DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision,

we updated the MS-LTC-DRG classifications and relative weights for FY 2013 based on the most recent available LTCH data, and applied a budget neutrality adjustment in determining the FY 2013 MS-LTC-DRG relative weights.

To ensure budget neutrality in the update to the MS-LTC-DRG classifications and relative weights under § 412.517(b), we continued to use our established two-step budget neutrality methodology. In this final rule, in the first step of our MS-LTC-DRG budget neutrality methodology, for FY 2013, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments are not influenced by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS-LTC-DRG relative weights (that is, the process itself) neither increases nor decreases the average CMI.

To calculate the normalization factor for FY 2013 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) we used the most recent available LTCH claims data (FY 2011) and grouped them using the FY 2013 GROUPER (Version 30.0) and the recalibrated FY 2013 MS-LTC-DRG relative weights (determined in steps 1 through 6 of the Steps for Determining the FY 2013 MS-LTC-DRG Relative Weights above) to calculate the average CMI; (1.b.) we grouped the same LTCH claims data (FY 2011) using the FY 2012 GROUPER (Version 29.0) and FY 2012 MS-LTC-DRG relative weights and calculated the average CMI; and (1.c.) we computed the ratio of these average CMIs by dividing the average CMI for FY 2012 (determined in Step 1.b.) by the average CMI for FY 2013 (determined in Step 1.a.). In determining the

MS-LTC-DRG relative weights for FY 2013, each recalibrated MS-LTC-DRG relative weight was multiplied by 1.12412 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced "normalized relative weights."

In the second step of our MS-LTC-DRG budget neutrality methodology, we determined a budget neutrality factor to ensure that estimated aggregate LTCH PPS payments (based on the most recent available LTCH claims data) after reclassification and recalibration (that is, the FY 2013 MS-LTC-DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2012 MS-LTC-DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we used FY 2011 discharge data to simulate payments and compare estimated aggregate LTCH PPS payments using the FY 2012 MS-LTC-DRGs and relative weights to estimate aggregate LTCH PPS payments using the FY 2013 MS-LTC-DRGs and relative weights.

For this final rule, we determined the FY 2013 budget neutrality adjustment factor using the following three steps: (2.a.) we simulated estimated total LTCH PPS payments using the normalized relative weights for FY 2013 and GROUPER Version 30.0 (as described above); (2.b.) we simulated estimated total LTCH PPS payments using the FY 2012 GROUPER (Version 29.0) and the FY 2012 MS-LTC-DRG relative weights in Table 11 of the Addendum to the FY 2012 IPPS/LTCH PPS final rule available on the Internet (76 FR 51813); and (2.c.) we calculated the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2012 GROUPER (Version 29.0) and the FY 2012 MS-LTC-DRG relative weights (determined

in Step 2.b.) by the estimated total LTCH PPS payments using the FY 2013 GROUPER (Version 30.0) and the normalized MS-LTC-DRG relative weights for FY 2013 (determined in Step 2.a.). In determining the FY 2013 MS-LTC-DRG relative weights, each normalized relative weight was multiplied by a budget neutrality factor of 0.9880413 (determined in Step 2.c.) in the second step of the budget neutrality methodology to determine the budget neutral FY 2013 relative weight for each MS-LTC-DRG.

Accordingly, in determining the FY 2013 MS-LTC-DRG relative weights in this final rule, consistent with our existing methodology, we applied a normalization factor of 1.12412 and a budget neutrality factor of 0.9880413(computed as described above). Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet, lists the MS-LTC-DRGs and their respective relative weights, geometric mean length of stay, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the "IPPS Comparable Thresholds" (used in determining SSO payments under § 412.529(c)(3)), for FY 2013. The FY 2013 MS-LTC-DRG relative weights in Table 11, which is listed in section VI. of the Addendum to this final rule and available via the Internet, reflect both the normalization factor of 1.12412 and the budget neutrality factor of 0.9880413.

C. Use of a LTCH-Specific Market Basket under the LTCH PPS

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the "excluded hospital with capital" market basket. That

market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term "market basket" technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term "market basket," as used in this section, refers to an input price index.

Beginning with RY 2007, LTCH PPS payments were updated using a FY 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at § 413.40. Those types of hospitals are not paid under a PPS. Also, the FY 2002 cost structures for cancer and children's hospitals are noticeably different from the cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the FY 2002-based RPL market basket appears in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 21062), we expressed our interest in exploring the possibility of creating a stand-alone LTCH market basket that only reflects the cost structures for LTCHs. However, as we discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we were in

the process of conducting further research to assist us in understanding the underlying reasons for the variations in costs and cost structures between freestanding IRFs and hospital-based IRFs, as well as between freestanding IPFs and hospital-based IPFs. At this time, we remain unable to sufficiently explain the observed differences in costs and cost structures between hospital-based IRFs and freestanding IRFs and between hospital-based IPFs and freestanding IPFs.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756), we finalized the rebasing and revising of the FY 2002-based RPL market basket by creating and implementing an FY 2008-based RPL market basket. We also discussed that we were exploring the viability of creating two separate market baskets from the current RPL market basket: One market basket would include freestanding IRFs and freestanding IPFs and could be used to update payments under both the IPF and IRF payment systems. We continue our research in this area. The other market basket would be a stand-alone LTCH market basket. We stated that, depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle. We received several public comments in response to the FY 2012 proposed rule, all of which supported deriving a stand-alone LTCH market basket (76 FR 51756 through 51757).

As we routinely do, we have revisited the issue of the market basket used in the LTCH PPS. We previously did not estimate stand-alone market baskets for IRFs, IPFs, and LTCHs because of small sample sizes for freestanding facilities and the data concerns associated with the hospital-based facilities. Although we continue to do research in this area, at this time, we believe it is appropriate to move forward with a

proposal to create a LTCH-specific market basket. This is because we believe we have sufficiently robust data to create such a market basket, and no longer need to rely on the cost report data from IPPS hospitals or from IRFs, IPFs, and LTCHs combined. Specifically, over the last several years, the number of LTCH facilities submitting a Medicare cost report has increased, helping to address concerns regarding the size of the available pool of facilities. The completeness and quality of the Medicare cost reports that we have been evaluating over the last several years have improved as well. Therefore, consistent with our intention to use the latest available and complete cost report data, we believe that it would be appropriate to create a market basket that would specifically reflect the cost structures of LTCHs based on Medicare cost report data for FY 2009, which are for cost reporting periods beginning on and after October 1, 2008, and before October 1, 2009.

Therefore, under the LTCH PPS for FY 2013, as we proposed, in this final rule, we are creating a FY 2009-based LTCH-specific market basket as described below. As we proposed, for this final rule, we are using data from cost reports beginning in FY 2009 because these data are the latest available complete data and, therefore, we believe it will enable us to accurately calculate cost weights that specifically reflect the cost structures of LTCHs. In this FY 2013 final rule, we are finalizing our proposal to create a LTCH-specific market basket based solely on Medicare cost report data from LTCHs of which the majority of the reports are settled. In the following discussion, we provide an overview of the market basket and describe the methodologies we used for determining the operating and capital portions of the FY 2009-based LTCH-specific market basket.

2. Overview of the FY 2009-Based LTCH-Specific Market Basket

As we proposed and are adopting in this final rule, the FY 2009-based LTCH-specific market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured.

As we proposed and are adopting in this final rule, the index itself is constructed in the following three steps. First, a base period is selected (as proposed, in this final rule, we used FY 2009 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called "cost weights" or "expenditure weights." Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a "price proxy." In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

3. Development of a LTCH-Specific Market Basket

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28009), we invited public comments on our proposed methodology for deriving a LTCH-specific market basket. A summary of the public comments we received on the methodology for creating a LTCH-specific market basket are included in section VII.C.3.d. of the preamble of this final rule. Below we describe the methodology and data used to derive the cost categories, cost weights, and price proxies for the LTCH-specific market basket that we proposed and are adopting in this final rule.

a. Development of Cost Categories

(1) Medicare Cost Reports

As we proposed and are adopting in this final rule, the FY 2009-based LTCH-specific market basket consists of several major cost categories derived from the FY 2009 LTCH Medicare cost reports as described previously, including wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance, capital, and a residual. These FY 2009 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2008, and before October 1, 2009. As we proposed and are adopting in this final rule, we are using FY 2009 as the base year because we believe that the FY 2009 Medicare cost reports represent the most recent, complete set of Medicare cost report data available for LTCHs.

Medicare cost report data include costs for all patients, including Medicare, Medicaid, and private payer. As we proposed and are adopting in this final rule, because our goal is to measure cost shares for facilities that serve Medicare beneficiaries, and are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average length of stay that is within a comparable range of their total facility average length of stay. We believe this provides a more accurate reflection of the structure of costs for Medicare covered days. As we proposed and are adopting in this final rule, similar to our methodology for the FY 2008-based RPL market basket, we use the cost reports submitted by LTCHs with Medicare average lengths of stay within 15 percent (that is, 15 percent higher or lower) of the total facility

average length of stay for the hospital. This is the same edit we applied to derive the FY 2008-based RPL market basket and generally includes those LTCHs with Medicare average length of stay within approximately 5 days of the facility average length of stay of the hospital.

Using this set of Medicare cost reports, as we proposed and are adopting in this final rule, we then calculate cost weights for six cost categories, and a residual category as represented by all other costs, directly from the FY 2009 Medicare cost reports submitted by LTCHs (found in Table VII.C-1 below). As we proposed and are adopting in this final rule, these Medicare cost report cost weights are then supplemented with information obtained from other data sources (explained in more detail below) to derive the FY 2009-based LTCH-specific market basket cost weights.

The proposed and final methodology used to develop the FY 2009-based LTCH-specific market basket cost weights is generally the same methodology used to develop the FY 2008-based RPL market basket cost weights, with the exception of the employee benefits and contract labor cost weights. For the FY 2008-based RPL market basket, there was an issue with obtaining data specifically for employee benefits and contract labor from the set of FY 2008 Medicare cost reports, as IRFs, IPFs, and LTCHs were not required to complete the Medicare cost report worksheet from which these data were collected (Form CMS-2552-96, Worksheet S3, Parts II and III). As a result, only a proportion of the total number of IRFs, IPFs, and LTCHs reported data for employee benefits and contract labor; therefore, we developed these cost weights for the FY 2008-based RPL market basket using data obtained from IPPS Medicare cost reports.

However, when we reviewed LTCH Medicare cost reports for FY 2009, we found that a greater proportion of LTCHs submitted data for employee benefits and contract labor (approximately 40 percent of LTCHs, whose total costs account for approximately 50 percent of total costs for all LTCHs, submitted a cost report) compared to the proportion of IRFs and IPFs that submitted these data. We believe that it is better to use the LTCH-specific cost report data whenever possible to further our goal to create a market basket that represents the cost structures of LTCHs serving Medicare beneficiaries. Therefore, as we proposed and are adopting in this final rule, we use the LTCH-specific cost reports to derive the employee benefits and contract labor cost weights for the FY 2009-based LTCH-specific market basket, as opposed to using the IPPS Medicare cost reports as a proxy, as was done for the FY 2008-based RPL market basket.

TABLE VII.C-1.—MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM FY 2009 MEDICARE COST REPORTS

Major Cost Categories	FY 2009-Based LTCH-Specific Market Basket Cost Weights Obtained from Medicare Cost Reports (Percent)
Wages and Salaries	40.407
Employee Benefits	6.984
Contract Labor	6.947
Professional Liability Insurance (Malpractice)	0.830
Pharmaceuticals	8.877
Capital	9.829
All Other (Residual)	26.126

(2) Other Data Sources

In addition to the data from Medicare cost reports submitted by LTCHs, as we proposed and are adopting in this final rule, the other data source we use to develop the FY 2009-based LTCH-specific market basket cost weights is the 2002 Benchmark Input-Output (I-O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. We use the 2002 BEA Benchmark I-O data to disaggregate the "All Other (Residual)" cost category (26.126 percent) into more detailed hospital expenditure category shares. We note that we use these data to derive most of the CMS market baskets, including the FY 2008-based RPL and FY 2006-based IPPS market baskets. The BEA Benchmark I-O accounts provide the most detailed information on the goods and services purchased by an industry, which allows for a more detailed disaggregation of expenses in the market basket for which we can then proxy the appropriate price inflation.

The BEA Benchmark I-O data are generally scheduled for publication every 5 years. The most recent data available are for 2002. BEA also produces Annual I-O estimates; however, the 2002 Benchmark I-O data represent a much more comprehensive and detailed set of data that are derived from the 2002 Economic Census. We used the 2002 BEA Benchmark I-O data for the FY 2008-based RPL market basket. Because BEA has not released new Benchmark I-O data, and we believe the data to be comprehensive and complete as indicated above, we use the 2002 Benchmark I-O data in the FY 2009-based LTCH-specific market basket.

Instead of using the less detailed Annual I-O data, as we proposed and are adopting in this final rule, we age the 2002 Benchmark I-O data forward to 2009. As we proposed, the methodology we are using in this final rule to age the data forward involves applying the annual price changes from the respective price proxies to the appropriate cost categories. We repeat this practice for each year.

The "All Other" cost category expenditure shares are determined as being equal to each category's proportion to total "All Other" expenditures based on the aged 2002 Benchmark I-O data. For instance, if the cost for telephone services represented 10 percent of the sum of the "All Other" Benchmark I-O hospital expenditures, telephone services would represent 10 percent of the "All Other" cost category of the LTCH-specific market basket.

b. Cost Category Computation

As we proposed and are adopting in this final rule, for the FY 2009-based LTCH-specific market basket, we use data from the Medicare cost reports submitted by LTCHs to derive six major cost categories. The six major categories are: Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital, as shown above in Table V11.C-1. These represent the most detailed cost categories available from the Medicare cost reports. As stated above, as we proposed and are adopting in this final rule, we then utilize the Benchmark I-O data in order to further disaggregate expenses. This is the same methodology used to derive most of the CMS market baskets, including the FY 2008-based RPL and FY 2006-based IPPS market baskets. We obtained the same major cost categories from the Medicare cost report for

the FY 2009-based LTCH market basket as were obtained for the FY 2008-based RPL market basket (76 FR 51758), and two additional categories, Employee Benefits and Contract Labor.

c. Selection of Price Proxies

After computing the FY 2009 cost weights for the LTCH-specific market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proxies that we proposed and are adopting in this final rule for the operating portion of the FY 2009-based LTCH-specific market basket are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

Producer Price Indexes--Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because PPIs better reflect the actual price changes encountered by hospitals. For example, we use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. As we proposed and are adopting in this final rule, the PPIs that we are using measure price changes at the final stage of production.

Consumer Price Indexes--Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. As we proposed and are adopting in this final rule, because they may not represent the price encountered by a

producer, we use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is used as a proxy for contracted food services.

Employment Cost Indexes--Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

As we proposed and are adopting in this final rule, we evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe the PPIs, CPIs, and ECIs selected in this final rule meet these criteria.

Table VII.C-2 below sets forth the FY 2009-based LTCH-specific market basket, including the cost categories and their respective weights and price proxies that we proposed and are adopting for this final rule. For comparison purposes, the corresponding FY 2008-based RPL market basket cost weights also are listed. For example, “Wages and Salaries” are 46.330 percent of total costs under the

FY 2009-based LTCH-specific market basket compared to 49.447 percent under the FY 2008-based RPL market basket. "Employee Benefits" are 8.008 percent under the FY 2009-based LTCH-specific market basket compared to 12.831 percent under the FY 2008-based RPL market basket. As a result, compensation costs (wages and salaries plus employee benefits) under the FY 2009-based LTCH-specific market basket are 54.338 percent of total costs compared to 62.278 percent under the FY 2008-based RPL market basket. We note that the "Wages and Salaries" cost weight contained in Table VII.C-2 (46.330 percent) differs from that contained in Table VII.C-1 (40.407 percent). We attribute this difference to our allocation of the "Contract Labor" cost weight obtained from the Medicare cost reports (6.947 percent) proportionately across the "Wages and Salaries" and "Employee Benefits" cost weights obtained from the Medicare cost reports.

Following Table VII.C-2 is a summary of the proxies for the operating portion of the FY 2009-based LTCH-specific market basket that we proposed and are adopting for this final rule. We note that the proxies for the operating portion of the FY 2009-based LTCH-specific market basket are the same as those used under the FY 2008-based RPL market basket. Because these proxies meet our criteria of reliability, timeliness, availability, and relevance, we believe they are the best measures of price changes for the cost categories. For further discussion on the FY 2008-based RPL market basket, we refer readers to the discussion in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51759). For the capital-related portion of the FY 2009-based LTCH-specific market basket, the price proxies that we proposed and are adopting for this final rule are the same as those

used under the FY 2008-based RPL market basket (prior to any vintage weighting), as described in the FY 2012 IPPS/LTCH PPS final rule (75 FR 51765), and as described in more detail in the capital methodology discussion under section VII.C.3.d. of the preamble of this final rule.

TABLE VII.C-2.—FY 2009-BASED LTCH-SPECIFIC MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO FY 2008-BASED RPL MARKET BASKET COST WEIGHTS

Cost Categories	FY 2009-Based LTCH-Specific Market Basket Cost Weights	FY 2008-Based RPL Market Basket Cost Weights	FY 2009-Based LTCH Market Basket Price Proxies
1. Compensation	54.338	62.278	--
A. Wages and Salaries[1]	46.330	49.447	ECI for Wages and Salaries, Civilian Hospital Workers
B. Employee Benefits[1]	8.008	12.831	ECI for Benefits, Civilian Hospital Workers
2. Utilities	1.751	1.578	--
A. Electricity	1.367	1.125	PPI for Commercial Electric Power
B. Fuel, Oil, and Gasoline	0.281	0.371	PPI for Petroleum Refineries
C. Water and Sewage	0.103	0.082	CPI-U for Water and Sewerage Maintenance
3. Professional Liability Insurance	0.830	0.764	CMS Hospital Professional Liability Insurance Premium Index
4. All Other Products and Services	33.252	26.988	--
A. All Other Products	19.531	15.574	--
(1.) Pharmaceuticals	8.877	6.514	PPI for Pharmaceutical Preparations for Human Use (Prescriptions)

Cost Categories	FY 2009-Based LTCH-Specific Market Basket Cost Weights	FY 2008-Based RPL Market Basket Cost Weights	FY 2009-Based LTCH Market Basket Price Proxies
(2.) Food: Direct Purchases	3.409	2.959	PPI for Processed Foods and Feeds
(3.) Food: Contract Services	0.478	0.392	CPI-U for Food Away From Home
(4.) Chemicals[2]	1.275	1.100	Blend of Chemical PPIs
(5.) Medical Instruments	2.141	1.795	PPI for Medical, Surgical, and Personal Aid Devices
(6.) Rubber and Plastics	1.329	1.131	PPI for Rubber and Plastic Products
(7.) Paper and Printing Products	1.226	1.021	PPI for Converted Paper and Paperboard Products
(8.) Apparel	0.250	0.210	PPI for Apparel
(9.) Machinery and Equipment	0.127	0.106	PPI for Machinery and Equipment
(10.) Miscellaneous Products	0.419	0.346	PPI for Finished Goods less Food and Energy
B. All Other Services	13.721	11.414	--
(1.) Labor-Related Services	5.349	4.681	--
(a.) Professional Fees: Labor-Related	2.256	2.114	ECI for Compensation for Professional and Related Occupations
(b.) Administrative and Business Support Services	0.508	0.422	ECI for Compensation for Office and Administrative Services
(c.) All Other: Labor-Related Services	2.585	2.145	ECI for Compensation for Private Service Occupations
(2.) Nonlabor-Related Services	8.372	6.733	--
(a.) Professional Fees: Nonlabor-Related	5.332	4.211	ECI for Compensation for Professional and Related Occupations

Cost Categories	FY 2009-Based LTCH-Specific Market Basket Cost Weights	FY 2008-Based RPL Market Basket Cost Weights	FY 2009-Based LTCH Market Basket Price Proxies
(b.) Financial Services	1.013	0.853	ECI for Compensation for Financial Activities
(c.) Telephone Services	0.501	0.416	CPI-U for Telephone Services
(d.) Postage	0.779	0.630	CPI-U for Postage
(e.) All Other: Nonlabor-Related Services	0.747	0.623	CPI-U for All Items less Food and Energy
5. Capital-Related Costs	9.829	8.392	--
A. Depreciation	5.707	5.519	--
(1.) Building and Fixed Equipment	3.838	3.286	BEA chained price index for Nonresidential Construction for Hospitals and Special Care Facilities—vintage weighted (20 years)
(2.) Movable Equipment	1.869	2.233	PPI for Machinery and Equipment—vintage weighted (8 years).
B. Interest Costs	2.434	1.954	--
(1.) Government/Nonprofit	0.702	0.653	Average yield on Domestic Municipal Bonds (Bond Buyer 20 bonds)—vintage-weighted (20 years)
(2.) For Profit	1.732	1.301	Average yield on Moody's Aaa Bonds—vintage-weighted (20 years)
C. Other Capital-Related Costs	1.688	0.919	CPI–U for Residential Rent
Total	100.000	100.000	--

Note: Detail may not add to total due to rounding.

[1]Contract Labor is distributed to Wages and Salaries and Employee Benefits based on the share of total compensation that each category represents.

[2]To proxy the Chemicals cost category, we use a blended PPI composed of the PPI for Industrial Gas Manufacturing, the PPI for Other Basic Inorganic Chemical Manufacturing, the PPI for Other Basic

Organic Chemical Manufacturing, and the PPI for Soap and Cleaning Compound Manufacturing. For more detail about this proxy, we refer readers to the FY 2012 IPPS/LTCH final rule (76 FR 51761).

(1) Wages and Salaries

As we proposed and are adopting in this final rule, we use the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU1026220000000I) to measure the price growth of this cost category.

(2) Employee Benefits

As we proposed and are adopting in this final rule, we use the ECI for Employee Benefits for Hospital Workers (All Civilian) to measure the price growth of this cost category.

(3) Electricity

As we proposed and are adopting in this final rule, we use the PPI for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category.

(4) Fuel, Oil, and Gasoline

As we proposed and are adopting in this final rule, we use the PPI for Petroleum Refineries (BLS series code PCU324110324110) to measure the price growth of this cost category. We believe that it is appropriate to use this proxy for the same reasons set forth in the FY 2012 IPPS/LTCH final rule when this proxy was adopted for use under the FY 2008-based RPL market basket (76 FR 51761).

(5) Water and Sewage

As we proposed and are adopting in this final rule, we use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category.

(6) Professional Liability Insurance

As we proposed and are adopting in this final rule, we determine price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collect commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This method is also used to proxy PLI price changes in the Medicare Economic Index (75 FR 73268).

(7) Pharmaceuticals

As we proposed and are adopting in this final rule, we use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category.

(8) Food: Direct Purchases

As we proposed and are adopting in this final rule, we use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category.

(9) Food: Contract Services

As we proposed and are adopting in this final rule, we use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category.

(10) Chemicals

As we proposed and are adopting in this final rule, we use a blended PPI composed of the PPI for Industrial Gas Manufacturing (NAICS 325120) (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (NAICS 325180) (BLS series code PCU32518-32518-), the PPI for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519-32519), and the PPI for Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561-32561). We believe that it is appropriate to use this blended index for the reasons set forth in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51761) when this proxy was adopted for use under the FY 2008-based RPL market basket.

(11) Medical Instruments

As we proposed and are adopting in this final rule, we use the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156) to measure the price growth of this cost category. We believe that it is appropriate to use this index for the reasons set forth in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51761 through 51762) when this proxy was adopted for use under the FY 2008-based RPL market basket.

(12) Rubber and Plastics

As we proposed and are adopting in this final rule, we use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure the price growth of this cost category.

(13) Paper and Printing Products

As we proposed and are adopting in this final rule, we use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category.

(14) Apparel

As we proposed and are adopting in this final rule, we use the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category.

(15) Machinery and Equipment

As we proposed and are adopting in this final rule, we use the PPI for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category.

(16) Miscellaneous Products

As we proposed and are adopting in this final rule, we use the PPI for Finished Goods Less Food and Energy (BLS series code WPUSOP3500) to measure the price growth of this cost category.

(17) Professional Fees: Labor-Related

As we proposed and are adopting in this final rule, we use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series

code CIS2020000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services.

(18) Administrative and Business Support Services

As we proposed and are adopting in this final rule, we use the ECI for Compensation for Office and Administrative Support Services (Private Industry) (BLS series code CIU2010000220000I) to measure the price growth of this category. We believe this compensation index appropriately reflects the changing price of labor associated with the provision of Administrative and Business Support Services.

(19) All Other: Labor-Related Services

As we proposed and are adopting in this final rule, we use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category.

(20) Professional Fees: Nonlabor-Related

As we proposed and are adopting in this final rule, we use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. This is the same price proxy that we used for the Professional Fees: Labor-related cost category.

(21) Financial Services

As we proposed and are adopting in this final rule, we use the ECI for Compensation for Financial Activities (Private Industry) (BLS series code CIU201520A000000I) to measure the price growth of this cost category. We believe that this compensation index appropriately reflects the changing price of labor associated with the provision of Financial Services.

(22) Telephone Services

As we proposed and are adopting in this final rule, we use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category.

(23) Postage

As we proposed and are adopting in this final rule, we use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category.

(24) All Other: Nonlabor-Related Services

As we proposed and are adopting in this final rule, we use the CPI for "All Items Less Food and Energy" (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for "All Items Less Food and Energy" avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket.

d. Methodology for the Capital Portion of the FY 2009-Based LTCH-Specific Market Basket

In order to ensure consistency in the FY 2009-based LTCH-specific market basket, as we proposed and are adopting in this final rule, we calculated the capital-related cost weights using the same set of FY 2009 Medicare cost reports used to develop the operating cost weights with the same length-of-stay edit as applied when calculating the operating cost weights as described in section VII.C.3.a. of this preamble. The resulting capital-related cost weight for the FY 2009 base year is 9.829 percent. Using the methodology that we proposed and are adopting in this final rule, we then separated the total capital-related cost weight into more detailed cost categories.

As we proposed and are adopting in this final rule, we derived cost weights for depreciation, interest, lease, and other capital-related expenses from the Medicare cost reports. Lease expenses are unique in that they are not broken out as a separate cost category in the LTCH-specific market basket, but rather are proportionally distributed among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As was done under the FY 2008-based RPL market basket, and as we proposed and are adopting in this final rule, we assume 10 percent of lease expenses represents overhead and assign those costs to the Other Capital-Related Costs category accordingly. As we proposed and are adopting in this final rule, the remaining lease expenses are distributed across the three cost categories based on the respective weights of depreciation, interest, and other capital-related, not including lease

expenses. This is the same method that was applied under the FY 2008-based RPL market basket.

As we proposed and are adopting in this final rule, the "Depreciation" cost category contains two subcategories: (1) Building and Fixed Equipment (or Fixed Assets); and (2) Movable Equipment. Under the FY 2008-based RPL market basket, we disaggregated total depreciation expenses into Building and Fixed Equipment and Movable Equipment, using depreciation data from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs. Based on FY 2009 LTCH Medicare cost report data, we have determined that depreciation costs for building and fixed equipment account for 42 percent of total depreciation costs, while depreciation costs for movable equipment account for 58 percent of total depreciation costs. As mentioned above, we proposed and are adopting in this final rule to allocate lease expenses among the "Depreciation," "Interest," and "Other Capital" cost categories. We determined that leasing building and fixed equipment expenses account for 80 percent of total leasing expenses, while leasing movable equipment expenses account for 20 percent of total leasing expenses. As we proposed and are adopting in this final rule, we sum the depreciation and leasing expenses for building and fixed equipment together, as well as sum the depreciation and leasing expenses for movable equipment. This results in the final building and fixed equipment depreciation cost weight (after leasing costs are included) being 67 percent of total depreciation costs and the movable equipment depreciation cost weight (after leasing costs are included) being 33 percent of total

depreciation costs. We note that total leasing costs account for approximately one-half of total capital-related expenses.

As we proposed and are adopting in this final rule, the total "Interest" cost category is split between government/nonprofit interest and for-profit interest. The FY 2008-based RPL market basket allocated 33 percent of the total "Interest" cost weight to government/nonprofit interest and proxied that category by the average yield on domestic municipal bonds. The remaining 67 percent of the "Interest" cost weight was allocated to for-profit interest and was proxied by the average yield on Moody's Aaa bonds (76 FR 51760). This was based on the FY 2008 Medicare cost report data on interest expenses for government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs. Under the FY 2009-based LTCH-specific market basket, as we proposed and are adopting in this final rule, we use the FY 2009 Medicare cost report data on interest expenses for government/nonprofit and for-profit LTCHs. Based on these data, we calculated a 29/71 split between government/nonprofit and for-profit interest. We believe it is important that this split reflects the latest relative cost structure of interest expenses for LTCHs.

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. As we proposed and are adopting in this final rule, the vintage-weighted capital-related portion of the FY 2009-based LTCH-specific market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the

proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. As we proposed and are adopting in this final rule, we use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Vintage weights are an integral part of the FY 2009-based LTCH-specific market basket. Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for Medicare capital-related costs. As we proposed and are adopting in this final rule, the capital-related component of the FY 2009-based LTCH-specific market basket reflects the underlying stability of the capital-related acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we needed a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, the AHA does provide a consistent

database of total expenses back to 1963. Consequently, as we proposed and are adopting in this final rule, we used data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then used data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2009.

In order to estimate capital-related purchases using data on depreciation expenses, the expected life for each cost category (Building and Fixed Equipment, Movable Equipment, and Interest) is needed to calculate vintage weights. Under the FY 2008-based RPL market basket, we used FY 2008 Medicare cost reports for IPPS hospitals to determine the expected life of building and fixed equipment and movable equipment (76 FR 51763). The FY 2008-based RPL market basket was based on an expected average life of building and fixed equipment of 26 years and an expected average life of movable equipment of 11 years, which were both calculated using data for IPPS hospitals. We believed that this data source reflected the latest relative cost structure of depreciation expenses for hospitals at the time and was analogous to freestanding IRFs, freestanding IPFs, and LTCHs.

The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. As we proposed and are adopting for this final rule, following a similar method to what was applied under the

FY 2008-based RPL market basket, we determined the average expected life of building and fixed equipment to be equal to 20 years, and the average expected life of movable equipment to be equal to 8 years. These expected lives are calculated using a 3-year average of data from Medicare cost reports for LTCHs for FY 2007 through FY 2009. We believe that using LTCH-specific data to calculate the expected lives of assets best reflects the cost structures of LTCH facilities.

As we proposed and are adopting in this final rule, we also used the "Building and Fixed Equipment" and "Movable Equipment" cost weights derived from FY 2009 Medicare cost reports for LTCHs to separate the depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation. As we proposed and are adopting in the final rule, year-end asset costs for building and fixed equipment and movable equipment were determined by multiplying the annual depreciation amounts by the expected life calculations. We then calculated a time series, back to 1963, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs. As we proposed, for this final rule, from this capital-related purchase time series, we calculated the vintage weights for building and fixed equipment and for movable equipment. Each of these sets of vintage weights is explained in more detail below.

As we proposed and are adopting in this final rule, for the building and fixed equipment vintage weights, we use the real annual capital-related purchase amounts for building and fixed equipment to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual capital-related purchase amount for

building and fixed equipment is produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities. This is the same proxy used under the FY 2008-based RPL market basket. Because building and fixed equipment have an expected average life of 20 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 20-year periods. As we proposed and are adopting in this final rule, with real building and fixed equipment purchase estimates available from 2009 back to 1963, we averaged twenty-seven 20-year periods to determine the average vintage weights for building and fixed equipment that are representative of average building and fixed equipment purchase patterns over time. As proposed, for this final rule, vintage weights for each 20-year period are calculated by dividing the real building and fixed capital-related purchase amount in any given year by the total amount of purchases in the 20-year period. As proposed, for this final rule, this calculation is done for each year in the 20-year period, and for each of the twenty-seven 20-year periods. As proposed, for this final rule, we use the average of each year across the twenty-seven 20-year periods to determine the average building and fixed equipment vintage weights for the FY 2009-based LTCH-specific market basket.

As we proposed and are adopting for this final rule, for the movable equipment vintage weights, the real annual capital-related purchase amounts for movable equipment are used to capture the actual amount of the physical acquisition, net of price inflation. As proposed, for this final rule, this real annual capital-related purchase amount for

movable equipment is calculated by deflating the nominal annual purchase amounts by the movable equipment price proxy, the PPI for Machinery and Equipment. This is the same proxy used for the FY 2008-based RPL market basket. Based on our determination that movable equipment has an expected average life of 8 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over an 8-year period. As proposed, for this final rule, with real movable equipment purchase estimates available from 2009 back to 1963, we averaged thirty-nine 8-year periods to determine the average vintage weights for movable equipment that are representative of average movable equipment purchase patterns over time. As proposed, for this final rule, vintage weights for each 8-year period are calculated by dividing the real movable capital-related purchase amount for any given year by the total amount of purchases in the 8-year period. As proposed, for this final rule, this calculation is done for each year in the 8-year period and for each of the thirty-nine 8-year periods. As we proposed and are adopting for this final rule, we use the average of each year across the thirty-nine 8-year periods to determine the average movable equipment vintage weights for the FY 2009-based LTCH-specific market basket.

As proposed, for this final rule, for the interest vintage weights, the nominal annual capital-related purchase amounts for total equipment (building and fixed, and movable) are used to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). The vintage weights for interest should represent the average purchase pattern of total equipment over 20-year periods, which is the average useful life of building and fixed equipment as calculated using the LTCH Medicare cost report data.

We believe vintage weights for interest should represent the average useful life of buildings and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. As proposed, for this final rule, with nominal total equipment purchase estimates available from 2009 back to 1963, we averaged twenty-seven 20-year periods to determine the average vintage weights for interest that are representative of average capital purchase patterns over time. As proposed, with this final rule, vintage weights for each 20-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 20-year period. As proposed, for this final rule, this calculation is done for each year in the 20-year period and for each of the twenty-seven 20-year periods. As proposed, for this final rule, we use the average of each year across the twenty-seven 20-year periods to determine the average interest vintage weights for the FY 2009-based LTCH-specific market basket. As we proposed and are adopting in this final rule, the vintage weights for the capital-related portion of the FY 2008-based RPL market basket and the FY 2009-based LTCH-specific market basket are presented in Table VII.C-4 below.

TABLE VII.C-4.--FY 2008 RPL AND FY 2009 LTCH VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	FY 2008 26 years	FY 2009 20 years	FY 2008 11 years	FY 2009 8 years	FY 2008 26 years	FY 2009 20 years
1	0.021	0.034	0.071	0.102	0.010	0.021
2	0.023	0.037	0.075	0.108	0.012	0.024
3	0.025	0.039	0.080	0.114	0.014	0.026

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	FY 2008 26 years	FY 2009 20 years	FY 2008 11 years	FY 2009 8 years	FY 2008 26 years	FY 2009 20 years
4	0.027	0.042	0.083	0.123	0.016	0.029
5	0.028	0.043	0.085	0.129	0.018	0.032
6	0.030	0.045	0.089	0.134	0.020	0.035
7	0.031	0.046	0.092	0.142	0.021	0.037
8	0.033	0.047	0.098	0.149	0.024	0.040
9	0.035	0.049	0.103	--	0.026	0.043
10	0.037	0.051	0.109	--	0.029	0.047
11	0.039	0.053	0.116	--	0.033	0.050
12	0.041	0.053	--	--	0.035	0.053
13	0.042	0.053	--	--	0.038	0.055
14	0.043	0.054	--	--	0.041	0.059
15	0.044	0.055	--	--	0.043	0.062
16	0.045	0.057	--	--	0.046	0.068
17	0.046	0.059	--	--	0.049	0.073
18	0.047	0.059	--	--	0.052	0.077
19	0.047	0.061	--	--	0.053	0.082
20	0.045	0.062	--	--	0.053	0.086
21	0.045	--	--	--	0.055	--
22	0.045	--	--	--	0.056	--
23	0.046	--	--	--	0.060	--
24	0.046	--	--	--	0.063	--
25	0.045	--	--	--	0.064	--
26	0.046	--	--	--	0.068	--
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

As proposed, for this final rule, after the capital-related cost category weights are computed, it is necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. As we proposed and are adopting in this final rule, we use the same price proxies (prior to any vintage weighting) for the capital-related portion of the FY 2009-based LTCH-specific market basket that were used under the FY 2008-based RPL market. We believe these are the most appropriate proxies for hospital

capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

The price proxies (prior to any vintage weighting) for each of the capital-related cost categories, as shown in Table VII.C-2 above, are the same as those used under the FY 2008-based RPL market basket, as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51765), as well as the FY 2006-based Capital Input Price Index (CIPI) as described in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857). The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table VII.C-4 is applied to the most recent data point. We have provided on the CMS Web site an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at the following link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled "Weight Calculations as described in the IPPS FY 2010 Proposed Rule".

Below is a summary of the public comments we received on the methodology we proposed to derive the LTCH-specific market basket and our responses.

Comment: One commenter stated that CMS should now be able to identify the cost differences between hospitals-within-hospitals (HwHs) and freestanding LTCHs. The commenter asked whether CMS could further detail the cost categories by differentiating the major costs incurred by HwHs from the major costs incurred by freestanding LTCHs, as there is still a fundamental cost difference between these types of providers.

Response: For the methodology to derive the LTCH-specific market basket that we proposed and are adopting in this final rule without modification, we began with the universe of cost reports for LTCHs (both HwHs and freestanding facilities). After analyzing the major cost category weights obtained from the Medicare cost reports, we found that the weights obtained for HwHs and freestanding LTCHs were similar. Therefore, given that the market basket is intended to reflect the national average distribution of the costs of goods and services that hospitals purchase to furnish inpatient care, and that the weights are similar, we believe it is appropriate to derive the LTCH-specific market basket by using Medicare cost reports from both of these types of facilities. We do not believe that it is appropriate to further subdivide the cost categories of the LTCH-specific market basket on the basis of whether a LTCH is a HwH or a freestanding facility.

Comment: One commenter asked whether there are any provider-type or provider-dominant issues that need to be factored into the calculation of the LTCH-specific market basket because the LTCH industry is dominated by two large chains.

Response: As stated above, the market basket cost weights are intended to capture the national average cost distribution of LTCHs. For each individual cost weight, we reviewed the Medicare cost report data and analyzed the univariate distributions. We then trimmed the Medicare cost report data prior to calculating the final cost weight to attempt to remove any outliers. As a result, we believe the cost weights for the LTCH-specific market basket are representative of a typical cost structure for providers in the

LTCH industry. Therefore, we do not believe any provider-type or provider-dominant issues should be factored into the calculation of the LTCH-specific market basket. The purpose of the market basket update (as measured by the percent increase) is to update the base payment to reflect price inflation in the inputs required to provide medical care across all LTCH providers.

e. FY 2013 Market Basket Update for LTCHs

For FY 2013 (that is, October 1, 2012, through September 30, 2013), we proposed to use an estimate of the proposed FY 2009-based LTCH-specific market basket to update payments to LTCHs based on the best available data. Consistent with our historical practice of using the most recent data available, we estimated the proposed LTCH-specific market basket update for the LTCH PPS based on IHS Global Insight, Inc.'s (IGI's) most recent forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's first quarter 2012 forecast with history through the fourth quarter of 2011, the projected market basket update for FY 2013 was 3.0 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we proposed a market basket update of 3.0 percent for FY 2013. Furthermore, because the proposed FY 2013 annual update was based on the most recent market basket estimate for the 12-month period, we also proposed that if more recent data are subsequently available (for example, a more recent estimate of the market basket), we

would use such data, if appropriate, to determine the FY 2013 annual update in the final rule.

For this final rule, consistent with our proposal to use updated data, if appropriate, to determine the FY 2013 annual update, we are incorporating a more recent estimate of the market basket update. Based on IGI's second quarter 2012 forecast with history through the first quarter of 2012, the projected market basket update (as measured by the percentage increase) for FY 2013 is 2.6 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are establishing a market basket update of 2.6 percent for FY 2013. We note that the final market basket update for FY 2013 (2.6 percent) is lower than the proposed market basket update (3.0 percent) due to a lower inflationary outlook on wage and energy prices. The wage price revision mostly reflects an expectation of a slower labor market recovery compared to the previous forecast. (As discussed in greater detail in section V.A.2. of the Addendum to this final rule, we are establishing an annual update of 1.8 percent to the LTCH PPS standard Federal rate for FY 2013 under § 412.523(c)(3)(viii) of the regulations.)

Using the current FY 2008-based RPL market basket and IGI's second quarter 2012 forecast for the market basket components, the FY 2013 market basket update (as measured by the percentage increase) would be 2.7 percent (before taking into account any statutory adjustments). Table VII.C-5 below compares the FY 2008-based RPL market basket and the FY 2009-based LTCH-specific market basket percent changes based on IGI's second quarter 2012 forecast. For a comparison of the FY 2008-based

RPL market basket and the FY 2009-based LTCH-specific market basket percent changes based on IGI's first quarter 2012 forecast, we refer readers to Table VII.C-5 of the FY 2013 IPPS/LTCH proposed rule (77 FR 28016).

TABLE VII.C-5.--FY 2008-BASED RPL MARKET BASKET AND FY 2009-BASED LTCH MARKET BASKET PERCENT CHANGES; FY 2008 THROUGH FY 2015

Fiscal Year (FY)	FY 2008-Based RPL Market Basket Index Percent Change	FY 2009-Based LTCH-Specific Market Basket Index Percent Change
Historical data:		
FY 2008	3.7	3.9
FY 2009	2.7	2.8
FY 2010	2.2	2.2
FY 2011	2.5	2.6
Average 2008-2011	2.8	2.9
Forecast:		
FY 2012	2.2	2.4
FY 2013	2.7	2.6
FY 2014	2.8	2.7
FY 2015	3.1	3.0
Average 2012-2015	2.7	2.7

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Insight, Inc. second quarter 2012 forecast.

For FY 2013, the FY 2009-based LTCH-specific market basket update (2.6 percent, as measured by the percentage increase) is forecasted to be slightly lower than the market basket update based on the FY 2008-based RPL market basket at 2.7 percent. The lower total compensation weight in the FY 2009-based LTCH-specific market basket (54.338 percent) relative to the FY 2008-based RPL market basket (62.278 percent), absent other factors, would have resulted in a slightly lower market basket update for FY 2013 using the FY 2009-based LTCH-specific market basket.

However, this impact is partially offset by the impact of the larger cost weights associated with the Pharmaceuticals and All Other Services cost categories. The net effect of these offsetting factors is that the market basket update for the FY 2009-based LTCH-specific market basket is forecasted to be slightly lower for FY 2013 than the market basket update based on the current FY 2008-based RPL market basket.

Comment: Several commenters supported the use of a LTCH-specific market basket. One commenter stated that this market basket more accurately reflects costs of those services for LTCHs. A few commenters stated that the new market basket will more closely align market-basket updates under the LTCH PPS with actual LTCH cost structures, which will produce greater accuracy in aggregate Medicare payments to LTCHs. One commenter supported the proposal to identify a 3.0 percent market basket update for FY 2013.

Response: We agree with the commenters that the use of a LTCH-specific market basket is an improvement for the reasons set forth in section VII.C.1 of the preamble of this final rule. We do note that, based on more recent data, the final market basket update is 2.6 percent (and not 3.0 percent, as supported by one commenter). We are adopting the use of a LTCH-specific market basket in this final rule, as proposed.

f. FY 2013 Labor-Related Share

As discussed in section V.B. of the Addendum to this final rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS

standard Federal rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index.

As proposed, for this final rule, the labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. As proposed in the FY 2013 IPPS/LTCH proposed rule (77 FR 28016), and are adopting in this final rule, and similar to the FY 2008-based RPL market basket and FY 2006 IPPS market basket (74 FR 43850), we are classifying a cost category as labor-related and including it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. Given this, based on our definition of the labor-related share, we proposed and are adopting in this final rule to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, All Other: Labor-related Services, and a portion of the Capital-Related cost weight. These are the same cost categories that were proposed and adopted in the FY 2012 labor-related share using the FY 2008-based RPL market basket, as we continue to believe these categories meet our criteria of being labor-intensive and whose costs vary with the local labor market. For a more detailed discussion of the selection of cost categories for inclusion in the FY 2012 labor-related share, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766). As proposed, for this final rule, we note that the wages and salaries and benefit cost weights

reflect allocated contract labor costs, similar to the FY 2008-based RPL market basket and as described above.

For the FY 2008-based RPL market basket rebasing, in an effort to more accurately determine the share of professional fees for services such as accounting and auditing services, engineering services, legal services, and management and consulting services that should be included in the labor-related share, we obtained data from a survey of IPPS hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market. The results from this survey were then used to separate a portion of the Professional Fees cost category into labor-related and nonlabor-related costs. These results and our allocation methodology are discussed in more detail in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766).

As we proposed and are adopting in this final rule, for the FY 2009-based LTCH-specific market basket, we will apply these results from the survey of IPPS hospitals using this same methodology to separate the Professional Fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We believe using the survey results serves as an appropriate proxy for the purchasing patterns of professional services for LTCHs as they also are providers of institutional care.

In addition to the professional services listed above, we also proposed and are adopting for this final rule to classify expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories, as was done for the FY 2008-based RPL market basket. The NAICS 55 industry is mostly comprised of corporate, subsidiary, and

regional managing offices (otherwise referred to as home offices). As stated above, we classify a cost category as labor-related and include it in the labor-related share if the cost category is labor-intensive and if its costs vary with the local labor market. We believe many of the costs associated with NAICS 55 are labor-intensive and vary with the local labor market. However, data indicate that not all LTCHs with home offices have home offices located in their local labor market. Therefore, as we proposed and are adopting in this final rule, we will include in the labor-related share only a proportion of the NAICS 55 expenses based on the methodology described below.

For the FY 2008-based RPL market basket, we used data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices) and determined that 19 percent of the total number of freestanding IRFs, freestanding IPFs, and LTCHs that had home offices had those home offices located in their respective local labor markets--defined as being in the same Metropolitan Statistical Area (MSA). For a detailed discussion of this analysis, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51767).

As we proposed and are adopting in this final rule, for the FY 2009-based LTCH-specific market basket, we conducted a similar analysis of home office data. However, instead of using data on freestanding IRF, freestanding IPF, and LTCHs, we began with the initial set of LTCH Medicare cost reports that were used to derive the cost weights for the proposed FY 2009-based LTCH-specific market basket. As we proposed, for this final rule, for consistency, we believe it is important for our analysis on home office data

to be conducted on the same LTCHs used to derive the FY 2009 LTCH-specific market basket cost weights.

The Medicare cost report requires a hospital to report information regarding their home office provider. Approximately 82 percent of LTCHs reported some type of home office information on their Medicare cost report for FY 2009 (for example, home office number, city, state, zip code, or name). For the majority of these providers, we were able to identify in which MSA the LTCH's home office was located using the HOMER database and the Medicare cost reports. We then compared the home office MSA with the MSA in which the LTCH was located.

We found that 13 percent of the LTCHs with home offices had those home offices located in the same MSA as their facilities. We then concluded that these providers were located in the same local labor market as their home office. As a result, we proposed and are adopting for this final rule to apportion the NAICS 55 expense data by this percentage. Thus, we proposed and are adopting for this final rule to classify 13 percent of these costs into the "Professional Fees: Labor-related Services" cost category and the remaining 87 percent into the "Professional Fees: Nonlabor-related Services" cost category.

Using the methodology described above and IGI's first quarter 2012 forecast of the proposed FY 2009-based LTCH-specific market basket, the proposed LTCH labor-related share for FY 2013 was the sum of the FY 2013 relative importance of each labor-related cost category. Consistent with our proposal to update the labor-related share with the most recent available data, the labor-related share for this final rule reflects

IGI's second quarter 2012 forecast of the FY 2009-based LTCH-specific market basket. Table VII.C-6 below shows the FY 2013 labor-related share relative importance using IGI's second quarter 2012 forecast of the FY 2009-based LTCH-specific market basket and the FY 2012 labor-related share relative importance using the FY 2008-based RPL market basket. For a comparison of the FY 2012 labor-related share and the FY 2013 proposed labor-related share based on IGI's first quarter 2012 forecast that was provided in the FY 2013 IPPS/LTCH proposed rule, we refer readers to Table VII.C-6 of the proposed rule (77 FR 28017).

TABLE VII.C-6.--COMPARISON OF THE FY 2012 LABOR-RELATED SHARE RELATIVE IMPORTANCE BASED ON THE FY 2008-BASED RPL MARKET BASKET AND THE FY 2013 LABOR-RELATED SHARE RELATIVE IMPORTANCE BASED ON THE FY 2009-BASED LTCH-SPECIFIC MARKET BASKET

	FY 2012 Labor-Related Share Relative Importance[1]	**FY 2013 Labor-Related Share Relative Importance[2]**
Wages and Salaries	48.984	45.470
Employee Benefits	12.998	8.146
Professional Fees: Labor-Related	2.072	2.217
Administrative and Business Support Services	0.416	0.503
All Other: Labor-Related Services	2.094	2.507
Subtotal	66.564	58.843
Labor-Related Portion of Capital Costs (46%)	3.635	4.253
Total Labor-Related Share	**70.199**	**63.096**

[1]Published in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51767) and based on the second quarter 2011 IGI forecast.
[2]Based on the second quarter 2012 IGI forecast.

As we proposed and are adopting in this final rule, the labor-related share for FY 2013 is the sum of the FY 2013 relative importance of each labor-related cost

category, and reflects the different rates of price change for these cost categories between the base year (FY 2009) and FY 2013. For this final rule, the sum of the relative importance for FY 2013 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, and All Other: Labor-related Services) is 58.843 percent, as shown in Table VII.C-6 above. As we proposed and are adopting in this final rule, the portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied under the FY 2008-based RPL market basket. For this final rule, because the most recent forecast of the relative importance for capital-related costs is 9.246 percent of the FY 2009-based LTCH-specific market basket in FY 2013, we took 46 percent of 9.246 percent to determine the labor-related share of capital-related costs for FY 2013 (.46 * 9.246). The result is 4.253 percent, which we are adding to 58.843 percent for the operating cost amount to determine the total labor-related share for FY 2013 in this final rule. Thus, the labor-related share that we are establishing under the LTCH PPS for FY 2013 is 63.096 percent. This labor-related share was determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

Comment: One commenter requested that CMS reconsider its proposal to decrease the labor-related share from 70.199 percent for FY 2012 to 63.217 percent for FY 2013, stating that this decrease would unfairly penalize LTCHs in urban areas and reward LTCHs in rural areas.

Response: We believe that the revision to the labor-related share using data exclusively from LTCHs, which we proposed and are finalizing, is an improvement over the current labor-related share based on the RPL market basket. We believe a labor-related share for LTCHs that is based on Medicare cost report data obtained exclusively from the universe of LTCH providers appropriately reflects the national average cost structures of LTCHs. While we recognize that this downward revision to the labor-related share will have an effect on the distribution of payments, the decision to revise the labor-related share was based on what was most appropriate for LTCHs given the sufficiently robust data available and that the completeness and the quality of the Medicare cost reports we have been evaluating over the last several years have improved. For the reasons stated above, we believe a labor-related share based on the FY 2009-based LTCH –specific market basket (reflecting LTCH-specific Medicare cost report data) is an improvement. Thus, we are adopting our proposal to revise the labor-related share as described in the proposed rule.

Comment: A few commenters were concerned about the significant reduction in the labor-related share from FY 2012 to FY 2013 and its impact on providers, particularly those in high wage index areas. One commenter requested that CMS communicate the driving factors that contribute to such a significant decrease, and evaluate the appropriateness of those contributing factors. One commenter questioned the significant difference between the compensation weights for the FY 2009-based market basket (54.338 percent) and the FY 2008-based RPL market basket (62.278 percent) after there was already a significant decrease in the labor-related share from FY 2011 to FY 2012.

One commenter expressed support for phasing-in the reduction in the labor-related share over 3 years to help minimize that impact. Another commenter requested that CMS spread the impact of this change over a longer period of time instead of having it apply all at once.

Response: The principal factors contributing to the difference in the labor-related shares between the proposed and final FY 2009-based LTCH-specific market basket and the FY 2008-based RPL market basket are the base year cost weight differences found in two categories; Wages and Salaries, and Benefits. These weights (as proposed and adopted in this final rule) are shown above in Table VII. C-2. The lower share of costs attributable to wages, salaries, and benefits found in the proposed and final FY 2009-based LTCH-specific market basket is a direct result of incorporating cost data exclusively from LTCHs, as opposed to incorporating cost report data from freestanding IRFs, freestanding IPFs, and LTCHs combined (as is the case in the RPL market basket). For the reasons provided previously, we believe using data solely from LTCHs is appropriate and results in a market basket that better reflects the cost structure of the LTCH industry.

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We generally do not phase-in changes to the labor-related share. As explained above, the labor-related share is determined from the relative importance of each labor-related cost category under the FY 2009-based LTCH-specific market basket, which is developed exclusively from cost data from LTCHs. Because the labor-related

share will now be based on data obtained exclusively from the universe of LTCH providers (reflecting the national average cost structures of only LTCHs as compared to the cost structures of freestanding IRFs, freestanding IPFs, and LTCHs combined as is the case in the current LTCH PPS market basket), we believe it appropriately identifies the labor-related portion of the LTCHs' costs that are influenced by the local labor market and, therefore, will result in the most accurate payments to LTCHs in FY 2013 (when making the area wage level adjustment provided for under § 412.525(c). Therefore, we continue to believe that adopting a labor-related share based on the FY 2009-based LTCH-specific market basket will result in the most appropriate LTCH PPS payments. In addition, we do not believe that a phase-in of the change in the LTCH PPS labor-related share is necessary because the majority of LTCHs (approximately 80 percent) are located in areas where the FY 2013 wage index value is less than 1.0 and, therefore, are estimated to experience an increase in LTCH PPS payments as a result of the change to the labor-related share from FY 2012 to FY 2013. Of the approximately 20 percent of LTCHs that are estimated to experience a decrease in LTCH PPS payments as a result of the change to the labor-related share in FY 2013, we estimate that those LTCHs, on average, will experience a 0.5 percent decrease in LTCH PPS payments as a result of the change to the labor-related share under the FY 2009-based LTCH-specific market basket, which is similar in magnitude (and fiscal impact) to changes to aggregate LTCH PPS payments in the past due to annual updates to the adjustment for area wage levels (for which we have not provided a phase-in).

Comment: One commenter stated that the downward revision to the labor-related share creates ongoing future challenges to urban providers and urged CMS to continue to assess if more recent data is available before the FY 2013 annual update is established.

Response: We proposed to use data from cost reports beginning in FY 2009 because these data are the latest available complete data and, therefore, we continue to believe that it will enable us to accurately calculate cost weights that specifically reflect the cost structures of LTCHs. We are finalizing our proposed use of these data for the reasons set forth above. We will continue to monitor the cost weights of the LTCH-specific market basket over time. We note that using the most recent data available at the time of the FY 2013 IPPS/LTCH PPS proposed rule, we proposed a FY 2013 market basket update (as measured by the percentage increase) for LTCHs of 3.0 percent. We also proposed to use more recent data for the final rule, if available and appropriate. As proposed, we have incorporated a more recent forecast from IGI for this final rule, which results in a FY 2013 market basket update of 2.6 percent.

D. Changes to the LTCH Payment Rates for FY 2013 and Other Changes to the LTCH PPS for FY 2013

1. Overview of Development of the LTCH Payment Rates

The basic methodology for determining LTCH PPS Federal prospective payment rates is set forth at § 412.515 through § 412.536. In this section, we discuss the factors that we used to update the LTCH PPS standard Federal rate for FY 2013, that is, effective for LTCH discharges occurring on or after October 1, 2012 through September 30, 2013.

For further details on the development of the FY 2003 standard Federal rate when the LTCH PPS was initially implemented, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS Federal rate, we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); and FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773).

The update to the LTCH PPS standard Federal rate for FY 2013 is presented in section V.A. of the Addendum to this final rule. The components of the annual market basket update to the LTCH PPS standard Federal rate for FY 2013 are discussed below. Furthermore, as discussed in section VII.E.4. of this preamble, for FY 2013, in addition to the update factor, we made a one-time prospective adjustment to the standard Federal rate for FY 2013 so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years under existing § 412.523(d)(3) (this adjustment will not apply to payments made for discharges occurring on or before December 28, 2012, consistent with the statute). Furthermore, as discussed in section V.A. of the Addendum of this final

rule, we made an adjustment to the standard Federal rate to account for the estimated effect of the changes to the area wage level adjustment for FY 2013 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28018 through 28019), we presented our proposals for the development of the annual update to the LTCH PPS standard Federal rate for FY 2013, including proposals related to the annual market basket update, the revision of certain market basket updates required by the statute, and the methodology for calculating and applying the MFP adjustment. We did not receive any public comments on our proposals regarding the development of the annual update to the LTCH PPS standard Federal rate for FY 2013, and are adopting the proposals as final without modification in this final rule. (We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule for additional details on our proposals for the development of the annual update to the LTCH PPS standard Federal rate for FY 2013 (77 FR 28018 through 28019), The other adjustments we proposed to apply in determining the FY 2013 LTCH PPS standard Federal rate (in addition to the annual update), such as the one-time prospective adjustment discussed in section VII.E.4. of this preamble and the budget neutrality adjustment for changes in the area wage levels discussed in section V.A. of the Addendum of this final rule, are discussed in those respective sections of this final rule.) Below we present the finalized methodology that we used to develop the annual update to the LTCH PPS standard Federal rate for FY 2013, which is consistent with the methodology presented in the proposed rule.

2. FY 2013 LTCH PPS Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. As discussed in section VII.C. of this preamble, as proposed, we are adopting the newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to section VII.C.1. of this preamble.

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the standard Federal rate and refers to the timeframes associated with such adjustments as a "rate year." (The adjustments are discussed in more detail in section VII.D.2.b. of this preamble.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as "rate year," consistent with our change in the terminology used under the LTCH PPS from "rate year" to "fiscal year," for purposes of clarity, when discussing the annual update for

the LTCH PPS, including the provisions of the Affordable Care Act, we employ "fiscal year" rather than "rate year" for 2011 and subsequent years.

b. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the "other adjustment" specified in sections 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as "the multifactor productivity (MFP) adjustment") described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

Section 1886(b)(3)(B)(xi)(II) of the Act defines the MFP adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). Under our methodology, the end of the 10-year moving average of changes in the MFP coincides with the end of the appropriate FY update period. In addition, the MFP adjustment that is applied in determining any annual update to the

LTCH PPS standard Federal rate is the same adjustment that is required to be applied in determining the applicable percentage increase under the IPPS under section 1886(b)(3)(B)(i) of the Act as they are both based on a fiscal year. The MFP adjustment is derived using a projection of MFP that is currently produced by IHS Global Insight, Inc. (For additional details on the development of the MFP adjustment and its application under the LTCH PPS, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51691 through 51692 and 51770 through 51771).)

We did not receive any public comments and for FY 2013, we continue to use our methodology for calculating and applying the MFP adjustment to determine the annual update to the LTCH PPS standard Federal rate for FY 2013. (For details on the development of the MFP, including our finalized methodology for calculating and applying the MFP adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692).)

c. Market Basket under the LTCH PPS for FY 2013

For FY 2013, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are adopting a newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013 because we believe it more appropriately reflects the cost structure of LTCHs. The FY 2009-based LTCH-specific market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. For additional details on the development of the FY 2009-based LTCH-specific market basket, we refer readers to section VII.C. of this preamble.

d. Annual Market Basket Update for LTCHs for FY 2013

Consistent with our historical practice, we estimate the market basket update and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's second quarter 2012 forecast, the FY 2013 full market basket estimate for the LTCH PPS using the FY 2009-based LTCH-specific market basket is 2.6 percent (for additional details, we refer readers to section VII.C.3.e. of this preamble). Using our established methodology for determining the MFP adjustment, the current estimate of the MFP adjustment for FY 2013 based on IGI's second quarter 2012 forecast is 0.7 percent (for additional details, we refer readers to section VII.D.2.b. of this preamble).

For FY 2013, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the standard Federal rate be reduced by the productivity adjustment ("the MFP adjustment") described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, as proposed, in this final rule we reduced the full FY 2013 market basket update by the FY 2013 MFP adjustment. As proposed, in this final rule, to determine the market basket update for LTCHs for FY 2013, as reduced by the MFP adjustment, consistent with our established methodology, we subtracted the FY 2013 MFP adjustment from the FY 2013 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act requires that any annual update to the standard Federal rate for FY 2013 be reduced by the "other adjustment" described in paragraph (4), which is 0.1 percentage point for FY 2013. Therefore, as proposed, for this final rule, following application of the productivity adjustment, we reduced the adjusted market basket update (that is, the full market basket increase less the MFP adjustment) by the "other

adjustment" specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (For additional details on our established methodology for adjusting the market basket increase by the MFP and the "other adjustment" required by the statute, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

In this final rule, in accordance with the statute and as proposed, we reduced the FY 2013 full market basket estimate of 2.6 percent (based on the second quarter 2012 forecast of the FY 2009-based LTCH-specific market basket) by the FY 2013 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2013, as described in section VII.D.2.b. of the preamble of this final rule) of 0.7 percentage point (based on IGI's second quarter 2012 forecast). Following application of the productivity adjustment, the adjusted market basket update of 1.9 percent (2.6 percent minus 0.7 percentage point) was then reduced by 0.1 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act. Therefore, in this final rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are establishing an annual market basket update under the LTCH PPS for FY 2013 of 1.8 percent (that is, the most recent estimate of the LTCH PPS market basket update at this time of 2.6 percent less the MFP adjustment of 0.7 percentage point less the 0.1 percentage point required under section 1886(m)(4)(C) of the Act). Accordingly, we are revising § 412.523(c)(3) by adding a new paragraph (ix), which specifies that the standard Federal rate for FY 2013 is the standard Federal rate for the previous LTCH PPS year updated by 1.8 percent, and as further adjusted, as appropriate, as described in § 412.523(d). In addition, consistent with the policy we are establishing under section

VII.E.4. of this preamble to adjust the FY 2013 standard Federal rate by a one-time prospective adjustment, we are revising the regulations to specify under § 412.523(c)(3)(ix)(B) that with respect to discharges occurring on or after October 1, 2012, and before December 29, 2012, payments are based on the standard Federal rate in § 412.523(c)(3)(ix)(A) without regard to the one-time prospective adjustment provided for under § 412.523(d)(3)(iii). (We note that we also adjusted the FY 2013 standard Federal rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum of this final rule).)

3. LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), we established a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States (67 FR 56022). Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels.

Historically, we have used the most recent updated COLA factors obtained from the U.S. Office of Personnel Management (OPM) Web site at http://www.opm.gov/oca/cola/rates.asp to adjust the payments for LTCHs in Alaska and Hawaii. Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense

Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111-84, October 28, 2009) transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Pub. L. 111-84, locality pay is being phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay. As we discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51809), we did not believe it was appropriate to use either the 2010 or 2011 reduced factors to adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii for Medicare payment purposes. Therefore, for FY 2012, we continued to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii.

As we discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28019 through 28090), we continue to believe it is appropriate to use "frozen" COLA factors to adjust payments in FY 2012 while we explored alternatives for updating the COLA in the future because we believe those COLA factors appropriately adjusted the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii, consistent with § 412.523(b) (76 FR 51809). In that same proposed rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we proposed to continue to use the same "frozen" COLA factors used in FY 2012 for FY 2013 and to update the COLA factors for Alaska and Hawaii, beginning in FY 2014, based on a comparison of the growth in the consumer price indices (CPIs) for Anchorage,

Alaska and Honolulu, Hawaii relative to the growth in the CPI for the average U.S. city as published by the BLS. This proposal was consistent with the proposals made for the COLA factors used under the IPPS discussed in section II.B.2. of the Addendum to this final rule.

We did not receive any public comments on these proposals for the COLA factors (that is, our proposal for FY 2013 to continue to use the same COLA factors used in FY 2012, and our proposal for FY 2014 to begin updating the COLA factors for Alaska and Hawaii based on a comparison of the growth in the CPIs for Anchorage, Alaska and Honolulu, Hawaii relative to the growth in the CPI for the average U.S. city. In this final rule, we are adopting these proposals as final without modification because we believe these COLA factors will appropriately adjust the nonlabor-related portion of the standard Federal rate in for LTCHs located in Alaska and Hawaii, consistent with § 412.523(b) (as we discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28019 through 28020). Both our finalized policy for FY 2013 and our finalized policy for FY 2014 and subsequent years are described in detail below.

In this final rule, for FY 2013, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we will use the same "frozen" COLA factors used in FY 2012 (which are based on OPM's 2009 COLA factors) for FY 2013 to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii. Therefore, for FY 2013, a COLA will be applied to the standard Federal rate for LTCHs located in Alaska and Hawaii, consistent with § 412.525(b), by multiplying the

nonlabor-related portion of the standard Federal rate by the factors listed in the chart shown in section V.C. of the Addendum to this final rule.

In addition, in this final rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are establishing that, beginning in FY 2014, we will update the COLA factors published by OPM that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay. Under this updated methodology, we use a comparison of the relative growth in the overall CPI for Anchorage, Alaska and Honolulu, Hawaii to update the COLA factors for all areas in Alaska and Hawaii, respectively, because the BLS publishes CPI data only for the cities of Anchorage and Honolulu. We believe that the relative price differences between these cities and the United States are appropriate and necessary proxies for the relative price differences of the "other areas" of Alaska and Hawaii.

Although the BLS publishes the CPI for "All Items" for Anchorage, Honolulu, and for the average U.S. city, under this methodology, we will create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for "All Items" for all the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is comprised of approximately 60 percent commodities and 40 percent services. Therefore, we will create reweighted indexes for Anchorage, Honolulu, and the average U.S. city using the respective CPI commodities index and CPI services index to comprise the approximate 60/40 share obtained from the

IPPS market basket. As we explained in the proposed rule, we believe that using the underlying composition of the IPPS market basket nonlabor-related share to reweight CPIs for each of the respective areas is an appropriate proxy for determining the COLAs for LTCHs because both LTCHs and IPPS hospitals are required to meet the same certification criteria set forth in section 1861(e) of the Act to participate as a hospital in the Medicare program and generally experience similar nonlabor-related costs for providing inpatient hospital services. We also note that the composition of the nonlabor-related share of the LTCH-specific market basket is not significantly different from the approximate 60/40 share obtained from the IPPS market basket.

As we explained in the proposed rule, we believe this methodology is appropriate because we will be able to continue updating COLA factors for hospitals located in Alaska and Hawaii using the relative price differences as a proxy for relative cost differences. We believe this is an appropriate alternative methodology given the discontinuation of COLA factors being published by OPM. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent, and since the inception of the LTCH PPS, we have exercised our discretionary authority to adjust payments to LTCHs located in Alaska and Hawaii by incorporating this cap. Consistent with our existing policy, our approach for FY 2014 will continue to use such a cap, as our policy is based on OPM's COLA factors (updated by the methodology described above). We note that this policy is consistent with the policy we are adopting for IPPS hospitals discussed in section II.B.2. of the Addendum to this final rule.

Lastly, under this policy and as finalized, we will update the COLA factors using the methodology described above every 4 years (beginning in FY 2014), consistent with the policy we are establishing for updating the COLA factors under the IPPS discussed in section II.B.2. of the Addendum to this final rule. Under the IPPS, we also are adopting a policy to update the COLA factors used to adjust the nonlabor-related portion of the standard Federal rate for Alaska and Hawaii every 4 years (beginning in FY 2014) concurrently with the update to the labor-related share under the IPPS market basket. The labor-related share of the IPPS market basket currently is not scheduled to be updated until FY 2014. At the time of development of the FY 2014 proposed rule, we expect to have CPI data available through 2012. Therefore, under this methodology as updated, we expect the proposed FY 2014 COLA factors for Alaska and Hawaii to be based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city.

E. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Facilities and the Increase in Number of Beds in LTCHs and LTCH Satellite Facilities

1. Background

Moratoria on the implementation of certain LTCH payment policies and on the development of new LTCHs and LTCH satellite facilities and on bed increases in existing LTCHs and LTCH satellite facilities established under sections 114(c) and (d) of the MMSEA (Pub. L. 110-173), as amended by section 4302 of the ARRA

(Pub. L. 111-5) and further amended by sections 3106 and 10312 of the Affordable Care Act, are set to expire during CY 2012, under current law.

The moratoria established by these provisions delayed the full implementation of the following policies for 5 years beginning at various times in CY 2007:

- The full application of the "25-percent payment adjustment threshold" to certain LTCHs, including hospitals-within-hospitals (HwHs) and LTCH satellite facilities for cost reporting periods beginning on or after July 1, 2007, and before July 1, 2012, or cost reporting periods beginning on or after October 1, 2007, and before October 1, 2012, as applicable under the regulations at §§ 412.534 and 412.536.

- The inclusion of an "IPPS comparable" option for payment determinations under the short-stay outlier (SSO) adjustment under § 412.529 of the regulations for LTCH discharges occurring on or after December 29, 2007, but prior to December 29, 2012.

- The application of any one-time prospective adjustment to the LTCH PPS standard Federal rate provided for in § 412.523(d)(3) of the regulations from December 29, 2007, until December 29, 2012.

- In general, the development of new LTCHs and LTCH satellite facilities, or increases in the number of beds in existing LTCHs and LTCH satellite facilities from December 29, 2007, and ending December 28, 2012, unless one of the specified exceptions to the particular moratorium was met. (We refer readers to the May 22, 2008 interim final rule with comment period for the MMSEA (73 FR 29699, 29704 through 29707, and 29709), the interim final rule for the ARRA (74 FR 43990 through 43992 and

43997), and the finalizing of the Affordable Care Act changes in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399 through 50400, and 50416) for a complete description of this moratorium.)

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28021 and 28022), we proposed a 1-year continuation of the existing delay of the full implementation of the 25-percent payment adjustment threshold; that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, as applicable. We also proposed to make a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) of the regulations. We proposed to phase in this one-time prospective adjustment to the standard Federal rate over a 3-year period, beginning in FY 2013; however, consistent with the statute, this adjustment would not apply to payments made for discharges occurring on or before December 28, 2012. We did not propose to make any changes to the SSO policy as it currently exists in the regulations at § 412.529. Accordingly, consistent with the existing regulations at § 412.529(c)(3), for SSO discharges occurring on or after December 29, 2012, the "IPPS comparable" option at § 412.529(c)(3)(i)(D) would apply to payment determinations as appropriate for certain short-stay cases. The moratoria on the development of new LTCHs or LTCH satellite facilities and on an increase in the number of beds in existing LTCHs or LTCH satellite facilities mandated by section 114(d) of the MMSEA, as amended by section 4302(b) of the ARRA and further amended by section 3106 and 10312 of the Affordable Care Act, are set to expire on December 29, 2012, under current law.

2. The 25-Percent Payment Adjustment Threshold

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28021 and 28022), we proposed to provide a 1-year extension (that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013) on the moratorium on the application of the 25-percent payment adjustment threshold policy as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act. We proposed to revise §§ 412.534 and 412.536 of the regulations to reflect this extension. Specifically, we proposed to change "2012" to "2013" in the heading of paragraph § 412.534(c)(1); in paragraph (c)(1)(i) and in paragraph (c)(1)(ii); in the heading of paragraphs (c)(2) and (d)(1); in paragraph (d)(1)(i) and in the headings of paragraphs (d)(2), and (e)(1); in paragraph (e)(1)(i); and in the heading of paragraph (e)(2) to incorporate this change. In addition, we proposed to revise the headings at §§ 412.534(c)(3), (d)(3), and (e)(3), and make conforming changes to (h)(4) and (5) and § 412.536(a)(2) to reflect this extension. This extension would continue the existing statutory exemption of grandfathered HwHs and freestanding LTCHs from the 25-percent payment adjustment threshold and the continued statutory increase in the percentage threshold to 50 or 75 percent, as applicable, for those LTCHs and LTCH satellite facilities presently so affected. For a detailed description of the moratorium on the 25-percent payment adjustment threshold policy, we refer readers to the May 22, 2008 interim final rule with comment period (73 FR 29699 through 29704) and the interim final rule with comment period for the ARRA (74 FR 43990 through 43992).

Although we proposed to extend the moratorium relating to the application of the 25-percent payment adjustment threshold policy effective for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, we noted that the existing moratorium will expire for certain LTCHs prior to the effective date of the extension. Specifically, under existing regulations, the moratoria for an LTCH described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f) and a satellite facility of a LTCH described under § 412.22(h)(3)(i) (that is, a grandfathered HwH and a grandfathered LTCH satellite facility, respectively), and the moratoria for a "freestanding" LTCH as described in § 412.23(e)(5), will expire effective for cost reporting periods beginning on or after July 1, 2012. In addition, under existing regulations, the moratorium on the 25-percent payment adjustment threshold policies for a LTCH or a LTCH satellite facility that, as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Act at the off-campus location also expires beginning with discharges occurring in cost reporting periods beginning on or after July 1, 2012,. Therefore, under our proposed policy, there would be a period during which some of the above-described LTCHs and LTCH satellite facilities must comply with §§ 412.534 and 412.536 before becoming subject to the moratoria again. Specifically, the above-described LTCHs and LTCH satellite facilities with a cost reporting period beginning on or after July 1, 2012, and before October 1, 2012, would be required to comply with the applicable 25-percent payment adjustment threshold policy under §§ 412.534 and 412.536 for discharges occurring in the LTCH's or LTCH satellite facility's first cost

reporting period beginning from July 1, 2012, through September 30, 2012. Then, those same LTCHs and LTCH satellite facilities would be subject to the regulatory moratorium effective for discharges occurring in their first cost reporting period beginning on or after July 1, 2013, and before October 1, 2013.

Comment: Commenters supported the proposed 1-year delay in the full application of the 25-percent payment adjustment threshold policy. Some of the commenters requested that CMS consider extending this delay for 2 years rather than the proposed 1-year extension.

Response: We appreciate the commenters' support of our proposed policy. While we understand the commenters' desire to extend this policy beyond the hospital's first cost reporting period beginning on or after October 1, 2012, and before October 1, 2013, we believe that it is appropriate to only consider extending a moratorium on the 25-percent payment adjustment threshold policy through FY 2013. Accordingly, in this final rule, we are finalizing our proposed 1-year extension of the existing moratorium for applicable LTCHs for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013. However, as discussed below, in this final rule, we are also revising our regulations to address the situation of those LTCHs that have cost reporting periods beginning on or after July 1, 2012, and before October 1, 2012.

Comment: Many commenters expressed concern about the impact of the proposed effective date of the regulatory moratorium on the 25-percent payment adjustment threshold policy (that is, for cost reporting periods beginning on or after

October 1, 2012, and before October 1, 2013) in light of the July 1, 2012 expiration of the statutory moratorium on certain LTCH providers with cost reporting periods beginning from July 1, 2012, and before October 1, 2012. They pointed out that this group of LTCHs would be required to comply with the fully-implemented 25-percent payment adjustment threshold policy for their first cost reporting period beginning on or after July 1, 2012, and before October 1, 2012. Those hospitals would not benefit from the extension of the moratorium on the 25-percent payment adjustment threshold policy until their first cost reporting period beginning on or after October 1, 2012, and before October 1, 2013, which for these providers would start between July 1, 2013 and September 30, 2013. Requiring them to comply with the fully reinstated policy in the interim, several commenters noted, would contradict CMS' assertion in the proposed rule, where CMS indicated that "…we could be in a position within the near future to propose revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary." Further, "[i]n light of this potential result, we believe it is prudent to avoid requiring LTCHs (or CMS payment processing systems) to retool in order to implement the full reinstatement of the policy for what could be a relatively short period of time." The commenters asserted that this statement further argued for the development of a solution to avoid "subjecting" approximately 130 LTCHs to the "substantial logistic, administrative, and financial burden" of compliance with the fully implemented policy for a single cost reporting period. Several commenters also noted that the particular group of LTCHs and LTCH satellite facilities that would be effected by the "gap" between the July 1, 2012 expiration of the statute and the

October 1, 2012 implementation of our proposed policy are those freestanding and grandfathered HwHs that have never actually been subject to the policy and, therefore, would find compliance for one cost reporting period even more burdensome.

In urging consistent treatment for this group of providers and requesting that CMS not delay relief to them under the proposed extension of the moratorium, a number of commenters submitted suggestions regarding how to avoid the "gap" period for this group of LTCHs. Suggestions made by commenters can be grouped into two categories: those that focused on how CMS could revise the mechanics of execution of the payment adjustment in order to immediately cover those affected LTCHs and LTCH satellite facilities in the proposed extension of the moratorium or at least limit the impact of the "gap" between statutory and regulatory protection for such entities; and those focusing on the Secretary's authority to implement the extension of the moratorium effective for cost reporting periods beginning on July 1, 2012, notwithstanding the rulemaking schedule under the LTCH PPS which establishes an October 1, 2012 implementation date for policies promulgated in the FY 2013 IPPS/LTCH PPS final rule.

Several commenters suggested that CMS issue an interim final rule with comment period as soon as possible that would provide immediate relief for those LTCHs that would be affected by the "gap" referenced previously, by accelerating the implementation date of the proposed extension of the moratorium. Other commenters recommended that CMS "refrain from enforcing the policy." A number of commenters suggested that affected LTCHs be allowed to elect to have the 12-month period beginning on October 1, 2012, for the purposes of calculating its compliance with the 25-percent

payment adjustment threshold policy. One commenter offered a specific remedy for those LTCHs that would be subject to the "gap": that the moratoria on full implementation of the 25-percent payment adjustment threshold policy could be applied to Medicare patient discharges occurring on and after October 1, 2012. Therefore, this commenter suggested that the 25-percent payment adjustment threshold policy would only apply to those "gap" LTCHs for 1 to 3 months of their cost reporting periods, that is, the months from the beginning of their cost reporting period (from July 1, 2012 through September 30, 2012) until October 1, 2012, when the proposed regulatory moratorium would go into effect.

Several commenters suggested that for CMS to choose July 1, 2012 as the proposed effective date of the extension of the existing statutory moratorium on the full implementation of the 25-percent payment adjustment threshold policy was not actually "retroactive rulemaking" because the actual payment adjustment would be applied in the future, upon cost report reconciliation. These and other commenters also argued in the alternative that even if such action constituted retroactive rulemaking, generally the courts disallow it only if it results in "harm," is "a substantive change from an agency's prior regulatory practice," and would "impair any right, or create any new obligation, duty or disability." Furthermore, the commenters argued that the Secretary has the authority to engage in retroactive rulemaking if the public interest is served. A number of commenters urged CMS to eliminate the 25-percent payment adjustment threshold policy entirely for cost reporting periods beginning on or after October 1, 2012, and rather focus

on developing and using patient and facility-level criteria to determine which patients are appropriate for LTCH treatment.

Response: We appreciate the suggestions made by the commenters detailed above regarding possible resolutions of the situation faced by those LTCHs subject to the July 1, 2012 expiration of the statutory moratorium, but we believe that the suggestion to apply the extension of the moratorium effective for discharges occurring on or after October 1, 2012, instead of cost reporting periods beginning on or after October 1, 2012 for those LTCHs that would be effected by the "gap," addresses most, if not all, of the concerns raised by the commenters, including that these facilities were being subject—for even a short time—to a policy that we may be reevaluating. We understand the commenters' concerns that gap entities, including freestanding and grandfathered HwHs that have never been subjected to the policy, will have to comply with the full application of the policy for a period of time; that is from 1 to 3 months. Nonetheless, we do not believe that being subjected to the policy for this short period of time will require these entities to have to "retool" nor do we think it will impose a "substantial logistic, administrative, and financial burden" upon LTCHs that are admitting appropriate patients, that is, extremely sick patients who continue to require hospital-level care at an LTCH following a course of treatment at a referring hospital. We also believe that, as discussed below, in applying the supplemental moratorium to the gap entities prior to their first cost reporting period for which they would be subjected to our regulatory moratorium, as suggested by a commenter, we are for the most part, bridging the gap for these LTCHs. As we note below, we believe that it is highly unlikely that any of the gap

entities will exceed the 25-percent threshold during the time prior to the October 1, 2012 effective date of the supplemental moratorium.

Accordingly, while we are not adopting any of the other suggestions detailed in the comment above, we believe that the suggested discharge-based supplemental moratorium for this specific group of effected LTCHs provides a narrow and "targeted" remedy for those particular LTCHs subject to the "gap" between the expiration of the statutory moratorium, that is, cost reporting periods beginning on or after July 1, 2012, and the effective date of the regulatory moratorium, that is, for cost reporting periods beginning on or after October 1, 2012, which we believe is superior to other solutions recommended by the commenters.

Accordingly, as revised in this final rule, the statutory moratorium and the regulatory moratorium will be implemented as follows: For those LTCHs for which the statutory moratorium will expire effective with the hospitals' cost reporting periods beginning on or after October 1, 2012, the regulatory moratorium will seamlessly provide for an additional moratorium for the hospitals' first cost reporting period beginning on or after October 1, 2012. For LTCHs and LTCH satellite facilities for which the statutory moratorium expires effective with the hospital's cost reporting periods beginning on or after July 1, 2012, we will apply a regulatory moratorium as follows: For hospitals with cost reporting periods beginning on or after October 1, 2012, the proposed moratorium will be finalized effective for the hospital's first cost reporting period beginning on or after October 1, 2012. In addition, for hospitals with cost reporting periods beginning on or after July 1, 2012, and before October 1, 2012, we are finalizing a regulatory

moratorium effective with discharges occurring beginning October 1, 2012, through the end of the hospital cost reporting period (that is, the end of the cost reporting period that began on or after July 1, 2012, and before October 1, 2012).

We provide the following as an example of how this policy will be applied. Assume that LTCH A is a freestanding LTCH that has a cost reporting period beginning August 1, 2012. The statutory moratorium will expire for this LTCH on July 31, 2012. For its FY 2013 cost reporting period, it discharges 200 patients. Because the statutory moratorium expired for LTCH A on July 31, 2012 (which was the completion of its cost reporting period that ended on or after July 1, 2012), the hospital is allowed to admit up to 50 patients from any one referring hospital under the 25-percent payment adjustment threshold policy before the LTCH PPS adjusted payment would be applied for additional patients. Therefore, if LTCH A discharges 35 patients admitted from IPPS Hospital B during August and September, no payment adjustment would be applied. If LTCH A discharges an additional 25 patients after October 1, 2012, no adjustment would be applied to any of the discharges that had been admitted from IPPS Hospital A, effective with discharges occurring on or after October 1, when the regulatory moratorium goes into effect and LTCH B would be permitted to exceed the 50 patient limit under revised § 412.536(a)(3)(1). This LTCH would not be subject to the 25-percent payment adjustment threshold policy until its cost reporting period beginning on or after August 1, 2014 as described in revised § 412.536(a)(2).

Therefore, we will finalize the proposed regulatory moratorium on the full application of the 25-percent payment adjustment threshold policy for LTCHs with

reporting periods beginning on or after October 1, 2012, and we will also establish a discharge-based moratorium on the application of the 25-percent payment adjustment threshold policy solely for those LTCHs that would have been effected by the "gap" for discharges occurring on or after October 1, 2012, and through the end of their first cost reporting period beginning on or after July 1, 2012, and before October 1, 2012.

We do not agree with the commenters who suggested that we eliminate the 25-percent payment adjustment threshold policy at this time even as we are evaluating revisions to the LTCH PPS that may more accurately target the types of patients who we believe are appropriate for treatment in an LTCH. We adopted the 25-percent payment adjustment threshold policy to limit the percentage of patients an LTCH may admit from another hospital, in order to address our concerns that LTCHs were functioning as step-down units of referring IPPS hospitals and that Medicare was, therefore, paying twice (first to the IPPS hospital and then to the LTCH) for what was essentially one episode of patient care. We believe that the original objectives of the 25-percent payment adjustment threshold policy continue to be valid even though we are presently temporarily extending the moratorium on the policy's full implementation.

Comment: A number of commenters requested that CMS provide more information about the two projects that appear to be moving toward addressing the concerns and perhaps realizing the goals of establishing LTCH facility and patient-level criteria that MedPAC articulated in its 2004 recommendations and that could "render the 25-percent payment adjustment threshold policy unnecessary."

Response: We continue to share MedPAC's concerns regarding the treatment of medically appropriate patients in LTCHs. In its March 2012 Report to Congress, MedPAC noted, "…if medically complex cases in LTCHs are, in essence, indistinguishable from medically complex cases in acute care hospitals, then Medicare must ensure that its payments for the same set of services are equitable, regardless of where the services are provided. …policymakers must consider whether certain models of care will best serve the needs of medically complex patients. These steps will help ensure that Medicare beneficiaries receive appropriate, high quality care in the least costly setting consistent with their clinical conditions." (p. 273). CMS agrees with MedPAC and has been undertaking research to determine whether there are patient level criteria that can be used to determine patients that are appropriately treated in an LTCH or in an IPPS hospital at a higher than the traditional IPPS payment consistent with their higher costs. Generally, preliminary research by our contractor seems to indicate that focusing on a subset of patients who are "chronically critically ill," that is, who have been in intensive or coronary care units for a significant period of time at IPPS hospitals immediately preceding the admission to the LTCH, may prove to be an important step at this point. We are also researching whether under the IPPS it is appropriate to carve out these patients as a separate category within the MS-DRGs, calculating separate relative weights for these patients. As we have in the past, when this research reaches the appropriate stage, we intend to reach out to hospital industry stakeholders for reactions and feedback.

In this final rule, our regulations are revised under §§ 412.534 and 412.536 to reflect our finalized policies. We note that, in each regulatory provision, we specify that the determination as to whether a payment adjustment is applicable for discharges occurring during the months that an LTCH or LTCH satellite facility will be subject to the gap, that were admitted from a particular referring hospital (that have not achieved high-cost outlier status at the referring hospital), will be based upon whether or not those discharges exceed 25 percent (or 50 percent, as applicable) of total discharges during that cost reporting period.

Although those with cost reporting periods beginning on or after July 1 and before October 1 will be "technically" subject to the payment adjustment until October 1, 2012, we believe that very few, if any, LTCHs will actually be disadvantaged because these LTCHs would rarely, if ever admit more than 25 percent of their discharges from any one referring hospital during the limited period of 1 to 3 months (depending on the hospital's cost reporting beginning date) that the 25-percent payment adjustment threshold policy would technically be in effect. For discharges occurring on or after October 1, 2012, they would be protected by our new regulation and would not have to wait until the start of their next cost reporting period for relief. In addition, we would note that because we believe that the application of the 25-percent payment adjustment threshold policy would virtually have no impact on those hospitals for the period of July 1, 2012, through September 30, 2012, we do not intend to expend limited audit dollars to pursue this issue for discharges occurring during that period.

We are revising the regulations at §§ 412.534 and 412.536 to reflect these finalized policies.

3. The "IPPS Comparable Per Diem Amount" Payment Option for Very Short Stays under the Short-Stay Outlier (SSO) Policy

Prior to the enactment of section 114(c)(3) of the MMSEA, for LTCH short stay outlier (SSO) cases with a covered length of stay that was equal to or less than one standard deviation from the geometric average length of stay for the same MS-DRG under the IPPS (that is, the "IPPS comparable threshold"), the SSO payment adjustment determination included an additional option, the "IPPS comparable amount per diem amount" (72 FR 26906). This policy was implemented in our regulations at § 412.529(c)(3)(i) in the RY 2008 LTCH PPS final rule (72 FR 26904 through 26908).

Section 114(c)(3) of the MMSEA, as amended by section 3106(a) of the Affordable Care Act, provided a 5-year moratorium from the application of the "IPPS comparable amount" option under the SSO payment adjustment, which is scheduled to expire for discharges beginning on or after December 29, 2012 (75 FR 50399 through 50400). With the expiration of the moratorium, payment for an SSO discharge occurring on or after December 29, 2012, the Medicare payment will be based on the least of the following:

- 100 percent of the estimated cost of the case.
- 120 percent of the MS-LTC-DRG specific per diem amount multiplied by the covered length of stay of the particular case.
- The full MS-LTC-DRG per diem amount.

● Comparing the covered length of stay for as an SSO case and the "IPPS comparable threshold," one of the following:

(a) The blend of the 120 percent of the MS-LTC-DRG specific per diem amount (specified in § 412.529(d)(1)) and an amount comparable to the IPPS per diem amount (specified in § 412.529(d)(4)), for cases where the covered length of stay for an SSO case is greater than the "IPPS comparable threshold" (as specified under § 412.529(c)(3)(ii)).

(b) An amount comparable to the IPPS comparable per diem amount (specified in § 412.529(d)(4)), if the covered length of stay for an SSO case is equal to or less than one standard deviation from the geometric average length of stay for the same MS-DRG under the IPPS (the "IPPS comparable threshold"), as specified under § 412.529(d)(4).

For a comprehensive discussion of the SSO policy, including the payment for very short stays under the SSO policy, we refer readers to the May 6, 2008 interim final rule with comment period (73 FR 24874 through 24881).

The FY 2013 "IPPS comparable threshold" (that is, one standard deviation from the geometric average length of stay for the same MS-DRG under the IPPS) used in determining SSO payments for discharges occurring on or after December 29, 2012, under § 412.529(c)(3) of the regulations are provided in Table 11, which is listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site.

Comment: A large number of commenters expressed concern about our application of the "IPPS comparable amount" option under the SSO payment adjustment policy in light of the expiration of the 5-year statutory moratorium.

Response: In the proposed rule, we did not propose to make any changes in our policy under § 412.529(c)(3) for LTCH discharges occurring on or after December 29, 2012, that related to these public comments. Therefore, we will not address the commenters' concerns regarding this policy at this time but we will take them into consideration should we contemplate changes to the SSO policy in the future.

Technical change. With the expiration of the moratorium on the application of the "IPPS comparable per diem amount" option at § 412.529(c)(3)(i)(D) on the determination of the payment adjustment under the SSO policy, described above, we proposed a technical change to the regulation text at § 412.529(d)(i)(C) in order to clarify the application of our policy. Specifically, at § 412.529(d)(4)(i)(C), we proposed to remove the following introductory phrase that appears at the beginning of the paragraph: "For purposes of the blend amount described in paragraph (c)(2)(iv) of this section," so that the provision of the paragraph is not limited only to the "blend amount" option under the SSO policy at § 412.529(c)(2)(iv), but is also applicable to the "IPPS comparable per diem amount" option at § 412.529(c)(3)(i)(D).

In the proposed rule, we proposed to clarify this policy by revising the language of paragraph (d)(4)(i)(C) of § 412.529 to read as follows:

"(C) The payment amount specified under paragraph (d)(4)(i)(B) of this section may not exceed the full amount comparable to what would otherwise be paid under the hospital inpatient prospective payment system determined under paragraph (d)(4)(i)(A) of this section."

We proposed this technical correction in order to clarify that, payment for a case based solely on the "IPPS comparable per diem amount" described at § 412.529(d)(4) is calculated in the same way that it is calculated when payment for a case will be based on the "blend amount" (under § 412.529(c)(2)(iv)) of the "IPPS comparable per diem amount" and the "120 percent of the LTC-DRG specific per diem payment amount." When we finalized the "IPPS comparable per diem amount" option to the SSO payment adjustment in the RY 2008 LTCH PPS final rule (72 FR 26907), we stated in the preamble that "the IPPS comparable per diem amount [was] capped at the full IPPS comparable amount that is used under the blend option of the current SSO policy...." However, we neglected, at that time, to revise the regulation text. Therefore, we proposed to clarify our regulations at § 412.529(d)(4)(i)(C) to reflect existing policy that the "IPPS comparable per diem amount" is calculated as a per diem that is capped at an amount comparable to what would have been a full payment under the inpatient prospective payment system, such that an SSO payment made under the "IPPS comparable per diem amount" option may also not exceed the full amount comparable to what would otherwise be paid under the inpatient prospective payment system.

We did not receive any public comments on this technical change and are finalizing the proposed technical change to § 412.529(d)(4)(i)(C) as described above.

4. One-Time Prospective Adjustment to the Standard Federal Rate under § 412.523(d)(3)

a. Overview

In the August 30, 2002 LTCH PPS final rule (67 FR 55954), we set forth regulations implementing the LTCH PPS, based upon the broad authority granted to the Secretary, under section 123 of the BBRA (as amended by section 307(b) of the BIPA). Section 123(a)(1) of the BBRA required that the system "maintain budget neutrality." The statute requires the LTCH PPS to be budget neutral in FY 2003, so that estimated aggregate payments under the LTCH PPS for FY 2003 would be equal to the estimated aggregate payments that would have been made if the LTCH PPS were not implemented for FY 2003. The methodology for determining the LTCH PPS standard Federal rate for FY 2003 that would "maintain budget neutrality" is described in considerable detail in the August 30, 2002 final rule (67 FR 56027 through 56037). Our methodology for estimating payments for the purposes of budget neutrality calculations used the best available data, and necessarily reflected several assumptions (for example, costs, inflation factors and intensity of services provided) in estimating aggregate payments that would be made if the LTCH PPS was not implemented. In performing our budget neutrality calculations, we took into account the statute's requirement that certain statutory provisions that affect the level of payments to LTCHs in years prior to the implementation of the LTCH PPS shall not be taken into account in the development and implementation of the LTCH PPS. Specifically, section 307(a)(2) of the BIPA requires that the increases to the target amounts and the increases to the cap on the target amounts for LTCHs provided for by section 307(a)(1) of the BIPA (as set forth in

section 1886(b)(3)(J) of the Act) and the enhanced continuous improvement bonus (CIB) payments for LTCHs provided for by section 122 of the BBRA (as set forth in section 1886(b)(2)(E) of the Act) are not to be taken into account in the development and implementation of the LTCH PPS.

In the August 30, 2002 final rule, we also stated our intentions to monitor LTCH PPS payment data to evaluate whether later data varied significantly from the data available at the time of the original budget neutrality calculations (for example, data related to inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS). To the extent the later data significantly differ from the data employed in the original calculations, the aggregate amount of payments during FY 2003 based on later data may be higher or lower than the estimates upon which the budget neutrality calculations were based. Therefore, in that same final rule, under the broad authority conferred upon the Secretary in developing the LTCH PPS, including the authority for establishing appropriate adjustments, provided by section 123(a)(1) of the BBRA, as amended by section 307(b) of BIPA, we provided in § 412.523(d)(3) of the regulations for the possibility of making a one-time prospective adjustment to the LTCH PPS rates by a deadline of October 1, 2006, so that the effect of any significant difference between actual payments and estimated payments for the first year of the LTCH PPS would not be perpetuated in the LTCH PPS rates for future years. This deadline was revised to July 1, 2008, in the RY 2007 LTCH PPS final rule because sufficient time had not elapsed since the start of the LTCH PPS for new data to be generated that would have enabled us to conduct a comprehensive reevaluation of our budget neutrality calculations

(71 FR 27842 through 27844). Therefore, we did not implement the one-time prospective adjustment provided under § 412.523(d)(3) at that time. However, we stated that we would continue to collect and interpret new data as they became available in order to determine whether we should propose such an adjustment in the future. Furthermore, we revised § 412.523(d)(3) by changing the original October 1, 2006 deadline to July 1, 2008, to postpone the prospective one-time adjustment due to the time lag in the availability of Medicare data upon which a proposed adjustment would be based, noting that there is a lag time between the submission of claims data and cost report data, and the availability of that data in the MedPAR files and HCRIS, respectively. We also explained that we believed that postponing the deadline of the one-time prospective adjustment to the LTCH PPS rates provided for in § 412.523(d)(3) to July 1, 2008, would allow our decisions regarding a possible adjustment to be based on more complete and up-to-date data (71 FR 27842 through 27845).

Section 114(c)(4) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173) (MMSEA) provides that the "Secretary shall not, for the 3-year period beginning on the date of the enactment of this Act, make the one-time prospective adjustment to long-term care hospital prospective payment rates provided for in section 412.523(d)(3) of title 42, Code of Federal Regulations, or any similar provision." That provision delayed the effective date of any one-time prospective adjustment until no earlier than December 29, 2010. Accordingly, we revised § 412.523(d)(3) of the regulations to conform with this requirement (73 FR 26801 through 26804 and 26839). Then, section 3106 of the Affordable Care Act amended section 114(c) of the MMSEA

by specifying an additional 2-year delay in the one-time prospective adjustment to the standard Federal rate at § 412.523(d)(3). Thus, under current law, the Secretary is precluded from making the one-time adjustment to the standard Federal rate until December 29, 2012. Therefore, we revised § 412.523(d)(3) to conform with this requirement (75 FR 50399 and 50416).

Prior to the statutory delay in the application of any one-time prospective adjustment required when the MMSEA was enacted on December 29, 2007, we had developed a methodology for evaluating whether to propose a one-time prospective adjustment under § 412.523(d)(3) of the regulations. In order to inform the public of our thinking, and to stimulate comments for our consideration during the statutory delay in implementing any one-time prospective adjustment, we discussed our analysis and its results in the RY 2009 LTCH PPS proposed rule and final rule (73 FR 5353 through 5360 and 26800 through 26804, respectively).

Evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) requires a thorough review of the relevant LTCH data (as described below). As we discussed in the RY 2009 LTCH PPS proposed and final rules, we conducted a thorough review of the relevant data, that is, cost data from FY 2002, representing the final year LTCHs were paid under the TEFRA payment system. The cost report data for FY 2002 is comprised of a high proportion of settled and audited cost reports submitted by LTCHs. We also have payment data on the first year of the LTCH PPS (that is, FY 2003). On the basis of our review of these data sources, we discussed a potential methodology for determining whether the one-time prospective adjustment

provided for under § 412.523(d)(3) of the regulations should be proposed and the computation of such adjustment, if appropriate, based on that potential methodology. We also discussed that, under that potential methodology, our analysis indicated that a permanent adjustment factor of 0.9625 to the LTCH PPS standard Federal rate could be warranted. Consistent with the requirements of section 114(c)(4) of the MMSEA, which delayed the implementation of such an adjustment, we did not propose any one-time prospective adjustment to the standard Federal rate. However, we presented our analysis and welcomed public comment to inform the public of our analysis if and when we decide to propose (and ultimately finalize) such an adjustment under § 412.523(d)(3).

As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26803), our policy objective in providing for this one-time prospective adjustment has always been to ensure that computations based on the earlier, necessarily limited (but at that time best available) data available at the inception of the LTCH PPS would not be built permanently into the rates if data available at a later date could provide more accurate results. When we established the FY 2003 standard Federal rate in a budget neutral manner, we used the most recent LTCH cost data available at that time (that is, FY 1999 data), and trended that data forward to estimate what Medicare would have paid to LTCHs in FY 2003 under the TEFRA payment system if the PPS were not implemented for FY 2003. As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26803), after a thorough evaluation of the currently available data in light of this stated policy objective, we believe that the most appropriate methodology for evaluating an adjustment to the original budget neutrality adjustment would be to compare estimated payments in the first

year under the LTCH PPS to what estimated payments would have been under the prior TEFRA payment system for that year based on the best available data. Accordingly, in that same final rule, we revised § 412.523(d)(3) to provide for the possibility of making a one-time prospective adjustment to LTCH PPS rates so that "the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years." As noted above, the statutory moratoria that delayed the implementation of the application of any one-time prospective adjustment to the LTCH PPS standard Federal rate provided for in § 412.523(d)(3) of the regulations for 5 years (from December 29, 2007, until December 29, 2012) is set to expire during FY 2013.

In order to determine whether a one-time prospective adjustment under § 412.523(d)(3) would be warranted, we evaluated several issues regarding the data to use for this purpose. These issues, our proposals related to these issues (as presented in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28025 through 28032)), and a summary of the public comments and our responses related to these issues are presented below. As indicated in the proposed rule, we previously discussed these issues in the RY 2009 LTCH PPS proposed and final rules.

b. Data Used to Estimate Aggregate FY 2003 TEFRA Payments

As we discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28025 through 28032), as we considered the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, it is necessary to

estimate both aggregate payments under the LTCH PPS for FY 2003 and the estimated aggregate payments that would have been made if the LTCH PPS were not implemented in FY 2003 (that is, estimated FY 2003 TEFRA payments). While it is possible to determine actual TEFRA payments to LTCHs for FY 2002, the last year of payment under that methodology, it is necessary to estimate what TEFRA payments would have been in FY 2003 if the new LTCH PPS had not been implemented. In developing our proposed methodology for evaluating a one-time prospective adjustment, we considered whether we should use actual FY 2003 costs to calculate estimated TEFRA payments for FY 2003 or use costs for FY 2002 trended forward to FY 2003 as the basis for the calculation. As we discussed in that same proposed rule (77 FR 28025), basing the estimate on actual FY 2003 costs would have the considerable advantage of avoiding the need to inflate FY 2002 costs to FY 2003 costs. However, there is also a potentially serious disadvantage to using actual FY 2003 costs. Because FY 2003 was the first year of payment under the LTCH PPS, the cost experience of LTCHs in that year would reflect their response to the incentives provided by the new payment system, instead of reflecting behavior under the reasonable cost payment system. Indeed, implementation of an LTCH PPS should directly affect the behavior of LTCHs, and, therefore, the level of costs in LTCHs. One of the incentives of a PPS is to improve efficiency in the delivery of care, which generally results in decreased cost per discharge. For this reason, using FY 2003 costs directly could be a poor basis for estimating payments that "would have been made if the LTCH PPS were not implemented." On balance, however, we believe that trending the costs incurred under the last year of the TEFRA payment system

forward for 1 year poses a smaller prospect for distortion than using costs incurred during the subsequent year, when the incentives faced by LTCHs to reduce costs could have had a significant effect. We also noted that some LTCH stakeholders have expressed concern that using FY 2003 costs directly would provide a poor basis upon which to estimate payments that "would have been made if the LTCH PPS were not implemented" for precisely the reasons discussed above. We believe that basing the estimate of FY 2003 TEFRA payments on FY 2002 costs trended forward should satisfy these concerns. For the reasons discussed above, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28025 through 28026), in evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, we proposed to base our calculation of the estimated aggregate payments that would have been made if the LTCH PPS were not implemented (that is, estimated FY 2003 TEFRA payments) on FY 2002 costs trended forward.

We did not receive any public comments on our proposal to base our calculation of the estimated aggregate payments that would have been made if the LTCH PPS were not implemented (that is, estimated FY 2003 TEFRA payments) on FY 2002 costs trended forward for purposes of evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3). We are adopting this policy as final, without modification, for the reasons discussed above. (We discuss the specific methodology we are adopting in this final rule to trend forward FY 2002 costs to estimated FY 2003 TEFRA payments, which is the same as the methodology we proposed below in this section.)

In this final rule, under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, we based our calculation of the estimated aggregate payments that would have been made if the LTCH PPS were not implemented (that is, estimated FY 2003 TEFRA payments) on FY 2002 costs trended forward for the reasons discussed above. Specifically, as we proposed, under the methodology we are adopting in this final rule, we trended forward the most recent available LTCH FY 2002 costs to FY 2003 using the excluded hospital market basket, because we believe these data best reflect the price changes in hospital inpatient costs realized by LTCHs from FY 2002 to FY 2003. We believe that using the excluded hospital market basket to update FY 2002 reasonable cost-based (TEFRA) payments in order to estimate FY 2003 TEFRA payments is appropriate because the TEFRA payment system under which LTCHs were paid prior to the implementation of the LTCH PPS utilized the excluded hospital market basket to update the hospital-specific limits on payment for operating costs of LTCHs. In addition, we used the excluded hospital market basket to update the inpatient hospital operating and capital costs of LTCHs when we developed the initial LTCH PPS standard Federal rate for FY 2003 (67 FR 56029 through 56031). As we asserted in the proposed rule, we believe that the LTCH cost report data for FY 2002 currently available are appropriate to use for this purpose because, as noted above, they are comprised of settled and audited cost reports submitted by LTCHs. (We noted that this is the same methodology for evaluating the appropriateness of the possible one-time prospective adjustment under

§ 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule and final rule (73 FR 5356 and 26802, respectively).)

c. Data Used to Estimate Aggregate FY 2003 LTCH PPS Payments

As discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28025) and as discussed above, to determine whether a one-time prospective adjustment under § 412.523(d)(3) was warranted, we believe that an estimate of the payments that would have been made in FY 2003 under the TEFRA payment system methodology should be compared to estimated payments under the new LTCH PPS in FY 2003. Specifically, we explained that the most direct way to determine payments under the new LTCH PPS is simply to aggregate the actual payments calculated under the LTCH PPS methodology for the discharges that occurred during the first year of the LTCH PPS (FY 2003). However, that approach raises an issue of consistency because the discharges for which Medicare payments were made under the LTCH PPS during FY 2003 are not the same as the discharges for which costs were incurred during the last year of payment under the TEFRA methodology, FY 2002. For these reasons discussed above, we believe that the best way to estimate the TEFRA payments that would have been made to LTCHs during FY 2003 is to use inflated FY 2002 costs as a proxy for FY 2003 costs. Comparing actual FY 2003 LTCH PPS payments to FY 2003 TEFRA payments estimated on the basis of FY 2002 discharges would amount to a comparison between payments related to two different sets of discharges, potentially skewing the results. Therefore, for the purpose of consistency, rather than comparing TEFRA payments based on FY 2002 costs updated to FY 2003, to aggregate LTCH PPS payments for discharges that actually

occurred in FY 2003, we believe it is preferable to compare estimated TEFRA payments based on updated FY 2002 costs to the estimated payments that would have been made under LTCH PPS methodology in FY 2003 for those same FY 2002 discharges. For these reasons, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28025), we proposed to base our estimate of FY 2003 LTCH PPS payments on the same set of discharges (from FY 2002) which are the basis for the estimate of what would have been paid in FY 2003 under the reasonable cost-based (TEFRA) payment system.

We did not receive any public comments on our proposal to base the estimate of FY 2003 LTCH PPS payments on the same set of discharges (from FY 2002) for purposes of evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3). We are adopting this policy as final, without modification for the reasons discussed above. (We discuss the methodology we are adopting in this final rule to estimate of FY 2003 LTCH PPS payments using those FY 2002 discharges, which is the same as the methodology we proposed below in this section.)

In this final rule, under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, as we proposed, in evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, we are using the same set of discharges (from FY 2002) to base our estimate of FY 2003 LTCH PPS payments and our estimate of what would have been paid in FY 2003 under the reasonable cost-based (TEFRA)

payment system for purposes of evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3).

d. Methodology to Evaluate Whether a One-Time Prospective Adjustment under § 412.523(d)(3) is Warranted

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR), to evaluate the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, we proposed to compare estimated aggregate FY 2003 TEFRA payments (calculated on the basis of FY 2002 costs, updated to FY 2003) to estimated aggregate payments that would have been made in FY 2003 under the LTCH PPS methodology (by applying the FY 2003 LTCH payment rules to the discharges that occurred in FY 2002). As we asserted in the proposed rule, we believe that this approach would ensure that we are comparing the estimated FY 2003 TEFRA payments, which are based on updated costs incurred for FY 2002 discharges, to the estimated PPS payments that would have been made for those same FY 2002 discharges under the new LTCH PPS payment methodology. (We note that this is the same methodology for evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations that we presented in the RY 2009 LTCH PPS proposed rule and final rule (73 FR 5356 and 73 FR 26802, respectively).) We discuss the public comments and our responses to these proposals below in this section.

To evaluate whether a one-time prospective adjustment under § 412.523(d)(3) was warranted, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28024 through 28025), we proposed to consider as "significant" any difference greater than or equal to a

0.25 percentage point difference between the original budget neutrality calculations and budget neutrality calculations based on the more recent data now available. As we discussed in that same proposed rule, the regulations at § 412.523(d)(3) provide that the Secretary may make a one-time prospective adjustment to the LTCH PPS rates in order to ensure that any "significant" difference is not perpetuated in the LTCH PPS rates for future years. The regulation does not specifically define what constitutes a significant difference for this purpose.

We did not receive any public comments on our proposal to establish that any difference greater than or equal to 0.25 percentage points is "significant" for purposes of determining whether the one-time prospective adjustment provided under § 412.523(d)(3) is warranted. Therefore, we are adopting this policy as final without modification.

In this final rule, as we proposed, in evaluating whether a one-time prospective adjustment under § 412.523(d)(3) was warranted, we will consider as "significant" any difference greater than or equal to a 0.25 percentage point difference between the original budget neutrality calculations for FY 2003 and budget neutrality calculations for FY 2003 based on the more recent data now available. As we discussed in the proposed rule (77 FR 28024 through 28025), we believe this threshold will avoid making an adjustment to account for very minor deviations between earlier and later estimates of budget neutrality. It is also consistent with thresholds that we employ for similar purposes in other prospective payment systems. For example, under the capital IPPS, we make a forecast error correction in the framework used to update the capital Federal rate if a previous forecast of input prices varies by at least a 0.25 percentage point from actual

input price changes (72 FR 47425). We do not believe that we should treat differences greater than or equal to 0.25 percent as not "significant," because the effect of any difference would be magnified as the rates are updated each year.

e. Methodology to Estimate FY 2003 LTCH Payments under the TEFRA Payment System

To estimate FY 2003 LTCH payments under the TEFRA payment system, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28026), we proposed to use a methodology that is similar in concept to the methodology we used to estimate FY 2003 LTCH total payments under the TEFRA payment system when we determined the initial standard Federal rate in the August 30, 2002 final rule (67 FR 56030 through 56033). Specifically, we proposed to estimate total LTCH payments under the TEFRA payment system in FY 2003 using the following steps:

- Estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003, including continuous bonus improvement payments;
- Estimate each LTCH's payment per discharge for capital-related costs for FY 2003; and
- Sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payments per discharge.

We did not receive any public comments on our proposed methodology for estimating aggregate FY 2003 LTCH TEFRA payments for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3). We are adopting this methodology

as final, without modification, for the reasons discussed in the proposed rule and reiterated below. (We discuss the specific steps of the methodology we are adopting in this final rule to estimate total FY 2003 TEFRA payment system payments per discharge, which is the same as the methodology we proposed below under "Step 1".)

f. Methodology to Estimate FY 2003 LTCH PPS Payments

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28030), we proposed to estimate FY 2003 LTCH PPS payments using the same general methodology that we used to estimate FY 2003 payments under the LTCH PPS (without a one-time prospective adjustment) when we determined the initial standard Federal rate in the August 30, 2002 final rule (67 FR 56032). We proposed to estimate FY 2003 LTCH PPS payments for each LTCH by simulating payments on a case-by-case basis by applying the final FY 2003 payment policies established in the August 30, 2002 final rule that implemented the LTCH PPS (67 FR 55954), which generally include the established FY 2003 LTC-DRGs and relative weights (Version 22.0), adjustments for differences in area wage levels, adjustments for SSO cases, additional payments for HCO cases that were applied in determining LTCH PPS payments to discharges occurring in FY 2003. We also proposed to use LTCH case-specific discharge information from the FY 2002 MedPAR files, and we proposed to use LTCH provider-specific data from the FY 2003 Provider-Specific File (PSF), as these were the data used by fiscal intermediaries to make LTCH payments during the first year of the LTCH PPS (FY 2003). To determine total estimated PPS payments for all LTCHs, we summed the individual estimated LTCH PPS payments for each LTCH. (We note that this is the same methodology we used to

estimate FY 2003 payments under the LTCH PPS for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule (73 FR 5359 through 5360).)

We did not receive any public comments on our proposed methodology for estimating aggregate FY 2003 LTCH PPS payments for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3). We are adopting this methodology as final, without modification. (We note that we did receive public comments that suggested that we take into account other policy considerations in determining the necessity and magnitude of the one-time prospective adjustment. A summary of these comments and our responses can be found below.)

g. Methodology for Calculating the One-Time Prospective Adjustment under § 412.523(d)(3)

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28023 through 28032), we described in detail the methodology and the data that we proposed to use to calculate a one-time budget neutrality adjustment factor. In general, under our proposed methodology for evaluating a possible one-time prospective adjustment under § 412.523(d)(3), we proposed to determine a case-weighted average estimated TEFRA payment, consistent with the methodology used when we determined the initial standard Federal rate in the FY 2003 LTCH PPS final rule (68 FR 56032). Then we proposed that each LTCH's estimated total FY 2003 TEFRA payment per discharge would be determined by summing its estimated FY 2003 operating and capital payments under the TEFRA payment system based on FY 2002 cost report data , and dividing that amount by

the number of discharges from the FY 2002 cost report data. Next, we proposed to determine each LTCH's average estimated TEFRA payment weighted for its number of discharges in the FY 2002 MedPAR file (for the purpose of estimating FY 2003 LTCH PPS payments) by multiplying its average estimated total TEFRA payment per discharge by its number of discharges in the FY 2002 MedPAR file. We then proposed to estimate total case-weighted TEFRA payments by summing each LTCH's (MedPAR) case-weighted estimated FY 2003 TEFRA payments. Under our proposed methodology, we compared these estimated FY 2003 total TEFRA payments to estimated FY 2003 total LTCH PPS payments in order to determine whether a one-time prospective adjustment would be appropriate. (We also noted that this is the same methodology we used to compare estimated FY 2003 total TEFRA payments to estimated FY 2003 total LTCH PPS payments for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule (73 FR 5360).) For additional details on our proposed methodology and the data proposed to use to calculate a one-time budget neutrality adjustment factor, we refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28025 through 28031). (As we noted above, we did receive public comments that suggested that we take into account other policy considerations in determining the necessity and magnitude of the one-time prospective adjustment. A summary of these comments and our responses can be found below.)

Based on approximately 91,300 LTCH discharges for 250 LTCHs, under the proposed methodology and data present in the proposed rule, we calculated that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated

payments to the same LTCHs in FY 2003 if the LTCH PPS had not been implemented (that is, estimated total FY 2003 TEFRA payment system payments) (77 FR 28031). This 2.5 percent difference exceeded our proposed 0.25 percentage points threshold of what we would consider to be a "significant difference" for purposes of determining whether the one-time prospective adjustment provided under § 412.523(d)(3) would be warranted. Although we projected that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated FY 2003 TEFRA payments, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28031), we explained that proposing to reduce the standard Federal rate by 2.5 percent would not "maintain budget neutrality" for FY 2003 (that is, estimated FY 2003 LTCH PPS payments would not be equal to estimated FY 2003 TEFRA payments) because a considerable number of LTCH discharges are projected to have received a LTCH PPS payment in FY 2003 based on the estimated cost of the case (rather than a payment based on the standard Federal rate) under the payment adjustment for SSO cases at § 412.529. Specifically, under our proposed methodology, our payment analysis indicates that nearly 20 percent of estimated FY 2003 LTCH PPS payments are SSO payments that were paid based on estimated cost and not based on the LTCH PPS standard Federal rate. These SSO cases that receive a payment based on the estimated cost of the case are generally unaffected by any changes to the standard Federal rate because the estimated cost of the case is determined by multiplying the Medicare allowable charges by the LTCH's CCR (§ 412.529(d)(2)). In other words, if we had proposed to reduce the standard Federal rate by 2.5 percent, estimated total FY 2003 LTCH PPS payments would still be greater than

estimated total FY 2003 TEFRA payments (that is, would not be budget neutral), and this difference would be perpetuated in the LTCH PPS payment rates for future years. This is because the estimated LTCH PPS payments for those SSO cases that in FY 2003 were estimated to have been paid 120 percent of the estimated cost of the case generally are not affected (that is, in this case, not lowered) by any one-time prospective adjustment budget neutrality factor that would be applied to the standard Federal rate because those payments are not derived from the standard Federal rate (as explained above). Therefore, it was necessary to propose to offset the standard Federal rate by a factor that is larger than 2.5 percent in order to ensure that estimated total FY 2003 LTCH PPS payments would be equal to estimated total FY 2003 TEFRA payments in order to "maintain budget neutrality." To determine the necessary adjustment factor that would need to be applied to the standard Federal rate in order to "maintain budget neutrality," under the proposed methodology we presented in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28030), we simulated FY 2003 LTCH PPS payments using the same general methodology that we used to estimate FY 2003 LTCH PPS payments when we determined the initial standard Federal rate by simulating payments on a case-by-case basis using the final FY 2003 LTCH PPS payment rates and policies as established when we implemented the LTCH PPS in the August 30, 2002 final rule (67 FR 56032). Using iterative payment simulations using the data from the 250 LTCHs in our database, we determined that we would need to apply a factor of 0.9625 (that is, a reduction of approximately 3.75 percent rather than 2.5 percent) to the standard Federal rate in order to make estimated total FY 2003 LTCH PPS payments equal to estimated total FY 2003

TEFRA payments consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3) (that is, to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years). (We also noted that the proposed adjustment of approximately -3.75 percent is the same result of the evaluation of the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule and final rule (73 FR 5360 and 26804, respectively).) In that same proposed rule (77 FR 258031), we stated (as we did in the RY 2009 LTCH PPS proposed and final rules), that in the years following the initial implementation of the LTCH PPS, we have adopted some revised policies and adjustments to LTCH PPS payment levels. However, none of these revised policies and payment adjustments have addressed the intended purpose of the one-time prospective adjustment allowed under § 412.523(d)(3) of the regulations, to ensure that any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 are not perpetuated in the LTCH PPS rates for future years. For example, the adjustments that we have made to account for coding changes in excess of real severity increases in RYs 2007 through 2010 were made to account for changes in coding behavior in the years following the implementation of the LTCH PPS, and not to address any issue regarding the budget neutrality calculations that were used to establish the base rate for the LTCH PPS. (As we noted above, we received public comments that suggested that we take into account other policy

considerations in determining the necessity and magnitude of the one-time prospective adjustment. A summary of these comments and our responses can be found below.)

Based on the general methodology described above, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28031 through 28032), under the broad authority granted to the Secretary under section 123 of the BBRA, as amended by section 307(b) of the BIPA, we proposed to make a one-time prospective adjustment of 0.9625, which would permanently reduce the standard Federal rate by approximately 3.75 percent so to reflect the estimated difference between projected aggregate LTCH PPS payments in FY 2003 and the projected aggregate payments that would have been made in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented. Consistent with current law, we also proposed that this adjustment would not apply to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012. Furthermore, given the magnitude of this adjustment and in acknowledgement of hopeful research outcomes (discussed in section VII.E.2. of the preamble of that proposed rule), we proposed to phase-in this approximate 3.75 percent reduction to the standard Federal rate over a 3-year period. Furthermore, we proposed to revise the regulations under § 412.523(d)(3) to specify that the standard Federal rate would be permanently reduced by 3.75 percent (that is, an adjustment of 0.9625) to reflect the estimated difference between projected aggregate LTCH PPS payments in FY 2003 and the projected aggregate payments that would have been made in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented, and this adjustment would be phased-in over 3 years.

We also explained that although the adjustment to the standard Federal rate provided for at § 412.523(d)(3) is called a "one-time" prospective adjustment, as stated above, this adjustment would be permanently applied to the standard Federal rate so that the effect of the estimated difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years. Under this proposal, we proposed that we would make a one-time prospective adjustment by applying a factor of 0.98734 to the standard Federal rate in FY 2013 (which would not be applicable to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, consistent with current law), FY 2014, and FY 2015 to completely account for our estimate (determined using the methodology described above) that a factor of 0.9625 (that is 0.98734 x 0.98734 x 0.98734 = 0.9625) needs to be applied to the standard Federal rate in order to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years, consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3).

The public comments we received on our proposal to make a one-time prospective adjustment of 0.9625, which would permanently reduce the standard Federal rate by approximately 3.75 percent, including our proposed 3-year phase-in of this adjustment, and our responses are presented below.

h. Public Comments and CMS' Responses

Comment: Many commenters objected to the proposed one-time prospective adjustment. Some commenters expressed concern about the financial impact of the proposed reduction to the standard Federal rate with the application of the proposed one-time prospective adjustment in light of LTCH margins for certain providers as cited in MedPAC's March 2012 Report to Congress. Other commenters asserted that, in keeping with CMS' policy goal that any difference between LTCH PPS aggregate payments and estimated TEFRA aggregate payments in the first year of LTCH PPS is not perpetuated in future years, the policy objective behind the one-time prospective adjustment has already been accomplished as a result of other adjustments and payment policy changes under the LTCH PPS since its initial implementation in FY 2003. Some commenters pointed to various payment adjustments made since the inception of the LTCH PPS, including the recalibration of DRG weights, adjustments made to account for changes in documentation and coding that did not reflect actual changes in case mix, elimination of the annual payment updates in interim years, or payment updates that are less than the market basket increase. A number of commenters pointed to the changes made to the SSO policy made in RY 2007 which changed the SSO cost payment option from 120 percent of cost to 100 percent of cost as an adjustment that would preclude CMS from the need to apply the one-time prospective adjustment. Based on an analysis provided by some commenters, they believed that if CMS had paid 100 percent of cost for SSO cases at the time of the LTCH PPS implementation in FY 2003, there would not have been a 2.5 percent difference between aggregate payments made under LTCH PPS and TEFRA payments. These commenters also stated that the SSO policy change in RY 2007

resulted in a reduction in total LTCH payments by 3.6 percent, and argued, therefore, that the SSO policy change essentially accomplishes the intended goal of the one-time prospective adjustment by bringing LTCH spending to at least (or below) the budget neutrality baseline (that is, what current aggregate LTCH PPS payments would be had estimated total FY 2003 LTCH PPS payments been 2.5 percent lower).

In addition, these commenters urged CMS to review and adjust the proposed methodology for calculating the one-time prospective adjustment in a manner that incorporates the SSO policy changes made since the implementation of the LTCH PPS in assessing whether the one-time prospective adjustment is warranted, and believed that doing so would yield a reduced one-time prospective adjustment or eliminate the need for one altogether. These same commenters asserted that CMS must also consider the changes in the SSO policy when calculating the one-time prospective adjustment factor because the SSO policy changes and the one-time prospective adjustment are policies that are aligned because they both were derived from the same broad authority under the statute to make "appropriate adjustments" to LTCH PPS. Some commenters also pointed out that, in the past, CMS had indicated that certain payment adjustments, for example the zero percent update to the standard Federal rate for RY 2007, may make the one-time prospective adjustment to the standard Federal rate "unnecessary. " These commenters also stated that CMS only cited the adjustments made for documentation and coding to account for the effects of changes in coding that did not reflect actual increase in patient severity in RYs 2007 through 2010 as adjustments that do not address any issue regarding the budget neutrality calculations that were used to establish the base rate for the LTCH

PPS. Therefore, these commenters believed that the payment impact of policy changes and adjustment that have been made since the implementation of the LTCH PPS should be taken into consideration when evaluating whether a one-time prospective adjustment is necessary.

Response: We understand the commenters' concern regarding the impact of a reduction to the standard Federal rate due to the application of the proposed one-time prospective adjustment. However, as we discuss below, we believe that a one-time prospective adjustment to the standard Federal rate of approximately 3.75 percent is necessary to ensure that any difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the LTCH PPS rates for future years, and will, therefore, result in appropriate LTCH PPS payments. In light of the magnitude of the proposed one-time prospective adjustment, we proposed to phase-in the adjustment over a 3-year period, which should mitigate the impact of this reduction to the standard Federal rate. In response to the comment regarding the financial impact on LTCH margins for certain providers, as cited in MedPAC's March 2012 Report to Congress in its rationale for its recommendation to eliminate the update to the LTCH PPS payment rate for FY 2013 in that same report MedPAC noted that LTCH "margins for 2010 were positive, and […] expect they will remain so. These trends suggest that LTCHs are able to operate within current payment rates." (p. 272). We note that, under the proposed phase-in of the proposed one-time prospective adjustment, in conjunction with the proposed market basket update and the subsequent final market basket update (adjusted

as required by statute), the proposed update to the LTCH PPS standard Federal rate would result in a slight increase to the LTCH PPS payment rate for FY 2013. Therefore, we believe that the positive update to the standard Federal rate coupled with overall positive LTCH margins (as reported by MedPAC) and the proposed phase-in of the one-time prospective adjustment will act to mitigate the financial impact of the one-time prospective adjustment.

We disagree with commenters that payment policy changes and adjustments made since the implementation of the LTCH PPS have already served as a substitute for the one-time prospective adjustment, and we continue to believe that a one-time prospective adjustment is necessary to ensure that any significant difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates (that is, the standard Federal rate) in future years. The various payment policy changes and adjustments established since the inception of the LTCH PPS were never made to address any budget neutrality requirement related to the initial implementation of the LTCH PPS, nor were they ever presented as such. Our regulations at § 412.523(d)(3) clearly state that the Secretary "may make a one-time prospective adjustment to the long-term care hospital prospective payment system *rates*…so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment system *rates* for future years.." (emphasis added). Our policy has always been that the one-time prospective adjustment be applied to the standard Federal rate. As we discussed

in the RY 2009 LTCH PPS final rule (73 FR 26803), our policy objective in providing for this one-time prospective adjustment has always been to ensure that computations based on the earlier, necessarily limited (but at the time best available) data available at the inception of the LTCH PPS would not be built permanently into the rates if data available at a later date could provide more accurate results. The intended goal of the one-time prospective adjustment is to establish the LTCH PPS standard Federal rate in a manner that results in bringing current estimated aggregate LTCH PPS payments to the level they would have been had the estimated total FY 2003 LTCH PPS payments been 2.5 percent lower. The policy changes and adjustments that have been made to the LTCH PPS since its inception are part and parcel of fine-tuning a new prospective payment system, and were made to address explicitly stated policy goals, none of which were duplicative of the stated purpose and end-result of the one-time prospective adjustment, which ensures that any significant difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates(that is, the standard Federal rate) in future years.

In the RY 2007 LTCH PPS final rule, we modified the SSO policy, changing the SSO cost payment option from 120 percent of cost to 100 percent of cost, effective beginning July 1, 2006 (RY 2007). We clearly stated that we believed that by providing a reduced payment for SSO cases, we would discourage hospitals from admitting patients for whom they would not provide complete treatment to maximize Medicare payments. We believed that the previous SSO policy may have unintentionally provided a financial

incentive for LTCHs to admit patients more appropriately treated in other settings (71 FR 27845). This policy change was not intended to address the one-time prospective adjustment in any way (nor does it duplicate the stated purpose or effect of the one-time prospective adjustment), but was intended to prevent inappropriate patient movement to LTCHs. The commenters are correct in that both the change to the SSO policy and the one-time prospective adjustment are authorized by the same broad statutory authority to make appropriate adjustments. However, each of these adjustments is proper in its own context, serves different purposes, and reflects different policy concerns. Consequently, we disagree with the commenters that we must consider the changes in the SSO policy when calculating the one-time prospective adjustment factor because the SSO policy changes and the one-time prospective adjustment are policies that were both derived from the same broad authority under the statute to make "appropriate adjustments" under the LTCH PPS for the reasons discussed above.

We acknowledge that we have stated in the past (such as in the RY 2007 final rule when we established a 0.0 percent update to the standard Federal rate for RY 2007) that we may consider other payment adjustments when deciding whether or not to implement the one-time prospective adjustment. However, such statements were made prior to the first comprehensive discussion of the stated purpose of the one-time prospective adjustment or the development of a methodology under which to determine whether such an adjustment is warranted (first presented in the RY 2009 proposed and final rules). In the RY 2009 proposed and final rules (73 FR 5354 and 26801), we did, in fact, state that none of revised policies and payment adjustments that were made in the years following

the initial implementation of the LTCH PPS addressed the intended purpose of the one-time prospective adjustment allowed under § 412.523(d)(3) of the regulations, to ensure that any significant difference between the original estimates and calculations based on more recent data are not perpetuated in the LTCH PPS rates for future years. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28031), we referenced the documentation and coding adjustment which was made to account for the effects of changes in coding that did not reflect actual increase in patient severity in RYs 2007 through 2010. These adjustments were noted merely as examples of payment adjustments made in the years following the implementation of the LTCH PPS that did not address any issue regarding the budget neutrality calculations that were used to establish the base rate for the LTCH PPS, and were not presented as an exhaustive list of policy changes and payment adjustments that had been implemented since FY 2003.

We continue to believe that the one-time prospective adjustment is based on the difference in payment between what would have otherwise been paid under the TEFRA payment system and payments made under the LTCH PPS as it was implemented in FY 2003, only, as is consistent with our policy goal of the one-time prospective adjustment. Therefore, we disagree with commenters' assertions that the payment impact of policy changes and adjustment that have been made since the implementation of the LTCH PPS should be taken into consideration when evaluating whether a one-time prospective adjustment is necessary. In the RY 2007 LTCH PPS final rule (71 FR 27864), we stated that it has been our consistent interpretation that the statutory requirement for budget neutrality applies exclusively to FY 2003 when the LTCH PPS

was implemented. Accordingly, we are finalizing our methodology for calculating for the one-time prospective adjustment, as proposed, without accounting for any revised policies and payment adjustments that have been made in the years following the initial implementation of the LTCH PPS, including the SSO policy changes.

Comment: Some commenters stated that CMS correctly identified that SSO cases have an impact on the calculation of the one-time perspective adjustment (that is, the proposed adjustment to reduce the standard Federal rate by approximately 3.75 percent was higher than the estimated 2.5 percent difference between LTCH PPS payments and TEFRA payments in FY 2003 in order to account for SSO cases that are not paid based on the standard Federal rate). However, these commenters believed that CMS specifically needs to consider the percentage of LTCH PPS payments that are paid as SSOs and how that percentage has changed over time, highlighting the fact that in 2012 only 30 percent of cases were SSO cases versus 48 percent in 2003. These commenters believed that the proposed 3.75 percent one-time perspective adjustment is overstated because CMS' proposed methodology does not account for the fact that there are currently fewer SSO cases than there were in FY 2003, and specifically requested that CMS recalculate the one-time prospective adjustment to include an adjustment to reflect the current level of SSO case. By accounting for current levels of SSO cases (30 percent versus 48 percent) in CMS' proposed methodology, the commenters calculated a one-time perspective adjustment of 2.75 percent (instead of 3.75 percent).

Response: As mentioned above, although we agree that the levels of SSO cases have changed since the inception of the LTCH PPS, the policy objective behind the one-

time prospective adjustment has always been to ensure that any significant difference between the data used in the original computation of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 are not perpetuated in the LTCH PPS rates for future years. Consistent with this policy objective, our proposed methodology for determining a one-time prospective adjustment compares estimated payments that would have been made in FY 2003 under the TEFRA payment system to estimated payments under the LTCH PPS in FY 2003. Thus, the data and methodology that we have employed for this purpose is limited to the types of Medicare cases projected to have been treated in LTCHs in 2003, and the 2012 levels of SSO cases are not germane to the computations of budget neutrality for FY 2003 under the one-time prospective adjustment under §412.523(d)(3). As discussed above, we continue to believe that the one-time prospective adjustment should be based on any difference in payment between what would have otherwise been paid under the TEFRA payment system and payments made under the LTCH PPS as it was implemented in FY 2003, only. The current level of SSO cases has no relationship to estimated FY 2003 LTCH PPS payments, which were used to evaluate and calculate the proposed one-time prospective adjustment under § 412.523(d)(3). For these reasons, we disagree with the commenters' assertions that the proposed 3.75 percent one-time prospective adjustment is overstated, and are not adopting the commenters' suggestion to make an adjustment to our methodology for calculating the one-time prospective adjustment to account for the current level of SSO cases. Therefore, as stated above, we are finalizing our

methodology for calculating for the one-time prospective adjustment, as proposed, without modification.

Comment: One commenter believed that CMS is inconsistent in its treatment of "the one-time adjustment" across various PPSs, specifically citing that a Inpatient Rehabilitation Facility (IRF) policy that reduced the standard Federal rate to account for changes in coding that did not reflect changes in case-mix index. The commenter stated that such adjustments to account for changes in coding that did not reflect changes in case-mix index have been adopted under both the IRF PPS and the LTCH PPS. However in the case of the IRF PPS, CMS considered that adjustment to have satisfied "its responsibility to perform a one-time adjustment" under the IRF PPS while a similar adjustment to account for changes in coding that did not reflect changes in case-mix index made under the LTCH PPS did not negate CMS' need to impose a one-time prospective adjustment under § 412.523(d)(3). They requested a full explanation on why LTCHs are being treated differently than IRFs and suggested that this inconsistency is inequitable.

Response: We believe that the commenter has mistakenly assumed that the adjustment to account for coding or classification changes that did not reflect real changes in case-mix under the IRF PPS is the same as the one-time prospective adjustment under § 412.523(d)(3). Under the IRF PPS, we established a reduction to the standard payment amount of 1.9 percent to account for coding changes consistent with the requirement set forth in section 1886(j)(2)(C)(ii) of the Act that directs the Secretary to adjust the per payment unit payment rate for IRF services to eliminate the effect of

coding or classification changes that do not reflect real changes in case-mix if the Secretary determines that changes in coding or classification of patients' severity of illnesses have resulted or will result in changes in aggregate payments under the classification system (70 FR 47904 through 47908). In the discussion of the development of the IRF standard payment conversion factor for FY 2006 in that same final rule (70 FR 47937, 47939, and 47950), we referred to that "adjustment" as "a ***one-time*** reduction to the standard payment amount of 1.9 percent to adjust for coding changes that increased payments to IRFs" (emphasis added). We believe that because the term "one-time" was used in conjunction with the 1.9 percent reduction that was applied in determining the IRF standard payment conversion factor for FY 2006, that the commenter mistakenly believed that adjustment serves the same purpose as the one-time prospective adjustment under § 412.523(d)(3).

As discussed in the FY 2006 IRF PPS final rule (70 FR 47904 through 47908), the "one-time" reduction to the standard payment amount of 1.9 percent was based on an analysis that showed that there was an increase in FY 2003 IRF PPS payments due to documentation and coding changes that did not reflect real changes in case-mix, and we believed that changes in payment amounts should accurately reflect changes in IRFs' patient case-mix (that is, the true cost of treating patients), and should not be influenced by changes in coding practices. As the commenter pointed out, the purpose of the "one-time" 1.9 percent reduction made to the FY 2006 IRF standard payment amount is similar in purpose to the documentation and coding adjustments that have been made under the LTCH PPS. However, the purpose of those documentation and coding

adjustments made under the LTCH PPS (that is, to account for increases in LTCH PPS payments that were due to documentation and coding changes that do not reflect real changes in case-mix) is separate and distinct from that of the stated purpose of the LTCH PPS one-time prospective adjustment under § 412.523(d)(3) (that is, to ensure that any significant difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years). Therefore, we disagree with the commenter that we have been inconsistent or inequitable in our treatment in applying adjustments, including the one-time prospective adjustment provided for at § 412.523(d)(3), across various PPSs. We also note that we responded to a similar comment on our proposal to extend the regulatory timeframe for making the possible one-time prospective adjustment under § 412.523(d)(3) in the RY 2007 LTCH PPS final rule (27842 through 27843), where we believe that the commenter mistakenly assumed that the adjustment to account for changes in documentation and coding practices that did not reflect real changes in case-mix is the same as the one-time prospective adjustment under § 412.523(d)(3). In response, we explained that because the intended purposes of those adjustments are different, we do not believe that we acted in an inconsistent manner by making two separate adjustments under the LTCH PPS that have separate and distinct purposes. Similarly, we disagree with the commenter that CMS is inconsistent in its treatment of "the one-time adjustment" across various PPSs since the purposes of those adjustments are separate and distinct (as explained above).

Comment: One commenter objected to the one-time prospective adjustment because a budget neutrality factor is already being applied during the MS-LTC-DRG recalibration process. The commenter believed that applying the one-time prospective adjustment would place providers in double jeopardy because if they are coding accurately, they will get penalized on an annual basis from the MS-LTC-DRG recalibration budget neutrality factors and the one-time prospective adjustment "budget neutrality factor."

Response: CMS' regulations under § 412.517(b) require that, "the annual changes to the LTC-DRG classifications and recalibration of the weighting factors…are made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected." We established this requirement in order to mitigate fluctuations in aggregate LTCH PPS payments resulting from the annual update to the MS-LTC–DRG classifications and relative weights that reflect changes in relative resource use based on the latest available data (72 FR 26880 through 26882). The purpose of the annual MS-LTC-DRG recalibration budget neutrality factor is separate and distinct from that of the one-time prospective adjustment, and is not germane to ensuring that any significant difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years. Therefore, we disagree with the commenter that applying both the one-time prospective adjustment and the annual MS-LTC-DRG recalibration budget neutrality factor would result in a double adjustment to LTCHs for accurate coding.

Comment: Many commenters commended our proposal to phase-in the one-time prospective adjustment over 3 years. Some commenters requested that CMS phase-in the adjustment over 4 years. One commenter requested a 5-year phase-in. One commenter, who supported the 3-year phase-in, requested that the one-time prospective adjustment that would be applied to the standard Federal rate for each year for FYs 2013 through 2015 be removed before establishing the initial base rates each year for FYs 2014 and 2015 so as not to create a compounding effect of the reduction in those years.

Response: We appreciate the commenters' support to phase-in the one-time prospective adjustment. In recognition of the magnitude of this adjustment, we proposed to phase-in the adjustment over a 3 year period, which should mitigate the impact of this reduction to the standard Federal rate, and we continue to believe that 3 years is a sufficient amount of time for providers to adjust to the effect on their LTCH PPS payments resulting from this adjustment.

As we explained in the proposed rule (77 FR 28031), the proposed one-time prospective adjustment of 0.9625 would be *permanently* applied to the standard Federal rate so that the effect of the estimated difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years. To achieve a permanent adjustment of 0.9625, we proposed to apply a factor of 0.98734 to the standard Federal rate in each year of the 3-year phase-in, that is, in FY 2013 (which would not be applicable to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, consistent with current law),

FY 2014, and FY 2015. By applying a permanent factor of 0.98734 to the standard Federal rate in each year for FYs 2013, 2014, and 2015, we will completely account for the entire 3.75 percent adjustment by having applied a cumulative factor of 0.9625 (calculated as 0.98734 × 0.98734 × 0.98734 = 0.9625). Consequently, applying a factor of 0.98734 in each of FYs 2013 through 2015 would create a compounding effect of the reduction and it is not appropriate to remove the prior year's factor before establishing the standard federal rate for FYs 2014 and 2015. As discussed above, a factor of 0.9625 (or approximately a 3.75 percent reduction) to the standard Federal rate is necessary to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3). As discussed below in this section, we are revising our proposed revision to § 412.523(d)(3) to clarify the standard Federal rate will be permanently adjusted by to account for the estimated difference between projected aggregate FY 2003 LTCH PPS payments and the projected aggregate FY 2003 TEFRA payments.

i. Final Policy Regarding the One-Time Prospective Adjustment under § 412.523(d)(3)

After consideration of the public comments we received, we are finalizing our proposal to make a one-time prospective adjustment to the standard Federal rate so that it will be permanently reduced by approximately 3.75 percent to account for the estimated difference between projected aggregate FY 2003 LTCH PPS payments and the projected aggregate payments that would have been made in FY 2003 under the TEFRA payment

system if the LTCH PPS had not been implemented. Based on approximately 91,300 LTCH discharges for 250 LTCHs, under the methodology and data presented above, we calculated that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated payments to the same LTCHs in FY 2003 if the LTCH PPS had not been implemented (that is, estimated total FY 2003 TEFRA payment system payments). This 2.5 percent difference exceeds the 0.25 percentage points threshold of what we consider to be a "significant difference" for purposes of determining whether the one-time prospective adjustment provided under § 412.523(d)(3) is warranted, as discussed above in this final rule. As also discussed in greater detail above, because of the estimated LTCH PPS payments for certain SSO cases are generally not affected by any one-time prospective adjustment factor that is applied to the standard Federal rate, it is necessary to offset the standard Federal rate by a factor that is larger than 2.5 percent in order to ensure that estimated total FY 2003 LTCH PPS payments would be equal to estimated total FY 2003 TEFRA payments in order to "maintain budget neutrality" , thereby ensuring that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the LTCH prospective payment rates for future years.

To determine the necessary adjustment factor to apply to the standard Federal rate to make the one-time prospective adjustment under § 412.523(d)(3), using the methodology we are adopting in this final rule (as described in this section), we simulated FY 2003 LTCH PPS payments by simulating payments on a case-by-case basis using the

final FY 2003 LTCH PPS payment rates and policies as established when we implemented the LTCH PPS in the August 30, 2002 final rule (67 FR 56032). Using iterative payment simulations using the data from the 250 LTCHs in our database, we determined that we need to apply a factor of 0.9625 (that is, a reduction of approximately 3.75 percent rather than 2.5 percent) to the standard Federal rate in order to make estimated total FY 2003 LTCH PPS payments equal to estimated total FY 2003 TEFRA payments consistent with our stated policy goal of the one-time prospective adjustment under § 412.523(d)(3) (that is, to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years).

Furthermore, given the magnitude of this adjustment and in acknowledgement of hopeful research outcomes, we are finalizing our proposal to phase-in this approximate 3.75 percent reduction to the standard Federal rate over a 3-year period. Although the adjustment to the standard Federal rate provided for at § 412.523(d)(3) is called a "one-time" prospective adjustment, as stated above, this adjustment will be permanently applied to the standard Federal rate so that the effect of the estimated difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years. During this 3-year period, we intend to further explore potential revisions to certain LTCH PPS payment policies as discussed above in section VII.E.2. of this preamble. Below, we describe the methodology that we are establishing in this final rule determine the one-time prospective adjustment under

§ 412.523(d)(3) of the regulations. (We note that, as discussed above, this is the same methodology we proposed in the FY 2013 IPPS/LTCH PPS proposed rule.)

In this final rule, to evaluate a one-time prospective adjustment under § 412.523(d)(3) of the regulations, we based our estimate of FY 2003 LTCH PPS payments on the same set of discharges (from FY 2002) which are the basis for the estimate of what would have been paid in FY 2003 under the reasonable cost-based (TEFRA) payment system. Specifically, we compared--

- Estimated aggregate FY 2003 TEFRA payments calculated on the basis of FY 2002 costs, updated to FY 2003, to
- Estimated aggregate payments that would have been made in FY 2003 under the LTCH PPS methodology, by applying the FY 2003 LTCH payment rules to the discharges that occurred in FY 2002.

As discussed above, we believe that this approach will ensure that we are comparing the estimated FY 2003 TEFRA payments, which are based on updated costs incurred for FY 2002 discharges, to the estimated PPS payments that would have been made for those same FY 2002 discharges under the new LTCH PPS payment methodology.

Under the policy we are adopting in this final rule to use FY 2002 LTCH costs as a basis for estimating FY 2003 LTCH TEFRA payments in evaluating whether to establish a one-time prospective adjustment under § 412.523(d)(3), as we proposed, we are updating LTCHs' FY 2002 costs for inflation to FY 2003 by our Office of the Actuary's current estimate of the actual increase in the excluded hospital market basket

from FY 2002 to FY 2003 of 4.2 percent. This updated amount serves as the proxy for actual FY 2003 costs under the TEFRA payment system in the budget neutrality computation for purposes of the one-time prospective adjustment at § 412.523(d)(3). We note that, as we proposed, under our methodology to estimate reasonable cost-based payments under the TEFRA payment system, we updated LTCHs' TEFRA target amounts from FY 2002 to FY 2003 using the forecasted market basket percentage increase of 3.5 percent, as discussed in greater detail below. This approach maintains consistency with the approach taken in the FY 2003 IPPS final rule in which we established an applicable rate-of-increase percentage to update TEFRA target amounts from FY 2002 to FY 2003 of 3.5 percent (67 FR 50289). This increase was based on our Office of the Actuary's forecasted increase in the excluded hospital market basket for FY 2003, using the best available data at that time. Based on more recent data, our Office of the Actuary now estimates the actual increase in the excluded hospital market based from FY 2002 to FY 2003 is 4.2 percent (as stated above). We believe it is appropriate to use the current estimate of the actual increase in the excluded hospital market basket based from FY 2002 to FY 2003 (4.2 percent) to update LTCHs' FY 2002 costs for inflation to FY 2003 because this reflects the most recent estimate of increases in the prices of goods and services realized by LTCHs when providing inpatient hospital services.

The methodology we are adopting in this final rule to estimate FY 2003 LTCH payments under the TEFRA payment system (which is presented below) is similar in concept to the methodology we used to estimate FY 2003 LTCH total payments under the TEFRA payment system when we determined the initial standard Federal rate in the

August 30, 2002 final rule (67 FR 56030 through 56033). We note that our methodology for estimating FY 2003 LTCH total payments under the TEFRA payment system using FY 2002 cost data for the purposes of the one-time prospective adjustment at § 412.523(d)(3), includes modifications to the methodology we used to estimate FY 2003 LTCH total payments under the TEFRA system when we implemented the LTCH PPS because we used data from a later period (FY 2002 as compared to FYs 1998 and 1999), as discussed in greater detail below. As we proposed, in general, we estimated total LTCH payments under the TEFRA payment system in FY 2003 using the following steps:

• Estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003, including continuous bonus improvement payments (Step 1);

• Estimate each LTCH's payment per discharge for capital-related costs for FY 2003 (Step 2); and

• Sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge (Step 3).

We discuss each of these steps in greater detail below.

Step 1. - Estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003.

Under our methodology, the first step in the process of estimating total FY 2003 payments under the TEFRA payment system is to estimate each LTCH's payment per

discharge for inpatient operating costs under the TEFRA payment system. Until FY 1998, the payment methodology for inpatient operating costs under the TEFRA payment system was a relatively straightforward process. First, we calculated a target amount by dividing the Medicare total allowable inpatient operating costs in a base year by the number of Medicare discharges. The provider's target amount under the TEFRA payment system (referred to as the TEFRA target amount) was then updated by a rate-of-increase percentage (§ 413.40(c)(3) of the regulations to determine the TEFRA target amount for the subsequent cost reporting period (§ 413.40(c)(4)(i) and(ii)). Generally, for any particular cost reporting period, the Medicare payment for inpatient operating costs would be the lesser of the hospital's allowable net inpatient operating costs, or the updated TEFRA target amount multiplied by the number of Medicare discharges during the cost reporting period, that is, the TEFRA ceiling (§ 413.40(a)(3)).

The TEFRA payment system methodology described above, broadly speaking, is the general approach that we used to arrive at an estimate of what Medicare payments for hospital inpatient operating costs would have been in FY 2003 under the TEFRA payment system. That is, under our methodology, each LTCH's FY 2003 TEFRA target amount was calculated by updating its estimated FY 2002 target amount per discharge by the full market basket percentage increase. The sum of all LTCH payments for operating costs (TEFRA target amount multiplied by Medicare discharges), bonus or relief payments, continuous improvement bonus payments, and payments for capital-related costs yields, in general, the estimate of what total Medicare payments to LTCHs would

have been in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented.

However, because sections 4413 through 4419 of the BBA of 1997, section 122 of the BBRA of 1999, and section 307(a)(1) of the BIPA made numerous changes to the TEFRA payment system, our methodology reflects variations in the method described above to arrive at the estimate of FY 2003 payments for the inpatient operating costs of each LTCH under the TEFRA payment system, depending on the participation date of the hospital. Specifically, we made the requisite computations differently for two classes of hospitals, "existing" hospitals and "new" hospitals. (A detailed explanation of the provisions affecting LTCHs, established by each of the amendments, is found in the August 30, 2002 final rule that implemented the LTCH PPS (67 FR 55959).) We discuss below these specific BBA, BBRA, and BIPA changes, and their impact on the calculations of estimated FY 2003 TEFRA payments for "existing" and "new" hospitals under our methodology for estimating total LTCH payments under the TEFRA payment system in FY 2003 for purposes of the one-time prospective adjustment under § 412.523(d)(3). As discussed in greater detail below, we employed two approaches to estimate Medicare payments under the TEFRA payment system to LTCHs in FY 2003, depending on how these changes in calculating TEFRA payments, as established by the amendments, applied to each LTCH. (We note, the discussion below of the specific BBA, BBRA, and BIPA changes and their impact on the calculations of estimated FY 2003 TEFRA payments for "existing" and "new" hospitals under our methodology for estimating total LTCH payments under the TEFRA payment system in FY 2003 for

purposes of the one-time prospective adjustment under § 412.523(d)(3) is the same as the discussion presented in the RY 2009 LTCH PPS proposed rule (73 FR 5356 through 5359).)

The first set of changes that we took into account was included in the BBA. The BBA made significant changes to the TEFRA payment methodology starting with cost reporting periods beginning on or after October 1, 1997. While the changes were applicable to three types of PPS-excluded providers (rehabilitation hospitals and units, psychiatric hospitals and units, and LTCHs), the following discussion will address the provisions of the amendments as they relate to LTCHs.

The first change to consider under the BBA is section 4414 that established caps on the TEFRA target amounts for cost reporting periods beginning on or after October 1, 1997, for LTCHs that were paid as IPPS-excluded providers prior to that date. The cap was determined by taking the 75th percentile of target amounts for cost reporting periods ending in FY 1996 for each class of provider (rehabilitation hospitals and units, psychiatric hospitals and units, and LTCHs), updating that amount by the market basket percentage increases to FY 1998, and applying it to the cost reporting period beginning on or after October 1, 1997 (62 FR 46018). The cap calculated for FY 1998 was updated by the applicable market basket percentages for cost reporting periods beginning during FY 1999 through 2002. Providers subject to the 75th percentile cap were paid the lesser of their inpatient operating costs or the TEFRA target amount, which was limited by the 75th percentile cap amount (67 FR 55959). In addition, section 4411 of the BBA established a formula for calculating the update factor for FY 1999 through FY 2002 that

was dependent on the relationship of a provider's inpatient operating costs to its ceiling amount based on data from the most recently available cost report. Section 121 of the BBRA provided that the 75th percentile cap amount should be wage adjusted, starting with cost reporting periods beginning on or after October 1, 1999, and before October 1, 2002.

The second change that we took into account was section 4415 of the BBA. This provision revised the percentage factors used to determine the amount of bonus and relief payments for LTCHs meeting specific criteria. If a provider's net inpatient operating costs did not exceed the hospital's ceiling, a bonus payment was made to the LTCH (§ 413.40(d)(2) of the regulations). The bonus payment was the lower of 15 percent of the difference between the hospital's inpatient operating costs and the ceiling, or 2 percent of the ceiling. In addition, relief payments were made to providers whose net inpatient operating costs were greater than 110 percent of the ceiling (or adjusted ceiling, if applicable). These relief payments were the lower of 50 percent of the allowable inpatient operating costs in excess of 110 percent of the ceiling (or the adjusted ceiling, if applicable) or 10 percent of the ceiling (or adjusted ceiling, if applicable) (§ 413.40(d)(3)(ii) of the regulations).

The third change that was considered was the additional incentive established by section 4415 of the BBA, the CIB payment for providers meeting certain conditions and that kept their costs below the target amount. Eligibility for the CIB payment required that a provider had three full cost reporting periods as an IPPS-excluded provider prior to the applicable fiscal year (62 FR 46019). To qualify for a CIB payment, a provider's

operating costs per discharge in the current cost reporting period had to be lower than the least of any of the following: its target amount; its expected costs, that is, the lower of its target amount or allowable inpatient operating costs per discharge from the previous cost reporting period, updated by the market basket percent increase for the fiscal year; or, its trended costs, that is, the inpatient operating costs per discharge from its third full cost reporting period, updated by the market basket percentage increase to the applicable fiscal year (62 FR 46019; § 413.40(d)(5)(ii)(B) of the regulations). For providers with their third or subsequent full cost reporting period ending in FY 1996, trended costs are the lower of their allowable inpatient operating costs per discharge or target amount updated forward to the current year (§ 413.40(d)(5)(ii)(A) of the regulations). The CIB payment equals the lesser of 50 percent of the amount by which the operating costs were less than expected costs, or 1 percent of the ceiling(§ 413.40(d)(4) of the regulations). Section 122 of the BBRA increased this percentage for LTCH's for FY 2001 to 1.5 percent of the ceiling, and beginning in FY 2002, to 2 percent of the ceiling (§ 413.40(d)(4)(ii) and (iii) of the regulations). The increase in the CIB payment percentage is not to be accounted for in the development and implementation of the LTCH PPS in accordance with section 307(a)(2) of BIPA.

The fourth change that we took into account was section 4416 of the BBA, which significantly revised the payment methodology for "new" IPPS-excluded providers. This provision applies to three classes of providers – psychiatric hospitals and units, rehabilitation hospitals and units, and LTCHs – that were not paid as excluded hospitals prior to October 1, 1997. The payment amount for a new provider for the first 12-month

cost reporting period is the lower of its Medicare inpatient operating cost per discharge or a limit based on 110 percent of the national median of target amounts for the same class of hospital for cost reporting periods ending in FY 1996, updated by the market basket percentage increases to the applicable period, and wage-adjusted. The payment limit in the second 12-month cost reporting period is the same 110 percent limit as for the first year (§ 413.40(f)(2)(ii)). A new provider's target amount would be established in its third cost reporting period by updating the amount paid in its second cost reporting period by the market basket percentage increase for hospitals and hospital units excluded from the IPPS, applicable to the specific year, as published annually in the **Federal Register**, which then becomes the target amount for its third cost reporting period. The target amount for the fourth and subsequent cost reporting periods is determined by updating the target amount from the previous cost reporting period by the applicable market basket percentage increase.

Finally, two provisions under BIPA specifically related to LTCHs. Section 307(a) of BIPA provided a 2 percent increase to the wage-adjusted 75th percentile cap for existing LTCHs for cost reporting periods beginning in FY 2001, and a 25 percent increase to the target amount for LTCHs, subject to the increased 75th percentile cap. However, it is important to note that in accordance with section 307(a)(2) of BIPA, the 2 percent increase to the 75th percentile cap and the 25 percent increase to the target amount were not to be taken into account in the development and implementation of the LTCH PPS.

In this final rule, under our methodology, in order to determine what a LTCH's estimated payments would be under the TEFRA payment system in FY 2003, we used cost report data for LTCHs from the Hospital Cost Reporting Information System (HCRIS) for FYs 1999 through 2002. In addition, to determine whether a LTCH is "new," the certification date for each LTCH was obtained from the On-line Survey & Certification Automated Reporting (OSCAR) file. Based on the certification date, a LTCH would either be a "new" LTCH, meaning a LTCH that was not paid as an excluded hospital prior to October 1, 1997, or an "existing" LTCH, meaning a LTCH that was paid as an excluded hospital prior to October 1, 1997. This could include a LTCH that was certified as an LTCH on or after October 1, 1997, but was previously paid as another type of IPPS-excluded provider prior to October 1, 1997. Our approach to estimating Medicare payments in FY 2003 under the TEFRA payment system varies somewhat, depending on whether an LTCH was either "existing" or "new" is discussed in greater detail below. Below we discuss our methodology for estimating FY 2003 inpatient operating payments under the TEFRA payment system for "existing" hospitals (Step 1.a.) and "new" hospitals (Step 1.b.), and our methodology for estimating CIB payments under the TEFRA payment system in FY 2003 (under Step 1.c.).

Step 1.a. - Estimate FY 2003 inpatient operating payments under the TEFRA payment system for "existing" LTCHs.

Based on the applicable statutory changes mentioned above, under our methodology, the first step was to estimate FY 2003 inpatient operating payments under the TEFRA payment system for "existing" LTCHs. "Existing" LTCHs are those receiving payment as IPPS-excluded providers in cost reporting periods prior to FY 1998. These LTCHs were subject to the 75th percentile cap on their hospital-specific target amounts. While section 307(a)(1) of BIPA provided for a 2-percent increase to the 75th percentile cap amount for LTCH's for cost reporting periods beginning in FY 2001 and a 25-percent increase to the target amount for cost reporting periods beginning in FY 2001 (subject to the limiting or cap amount determined under section 1886(b)(3)(H) of the Act), section 307(a)(2) of BIPA precluded accounting for these increases in developing the LTCH PPS. In addition, section 122 of the BBRA increased the CIB payment percentage to 1.5 percent for FY 2001 and 2.0 percent for FY 2002 (§ 413.40(d)(4)(ii) and (iii)). But these increases, also, are not to be accounted for the development and implementation of the LTCH PPS in accordance with section 307(a)(2) of BIPA. Therefore, to ensure that these increases would be excluded from the computations, as required by the statute, we estimated an existing LTCH's FY 2003 target amount by starting with the hospital's target amount from the FY 2000 cost report, the year prior to when these increases were effective. Target amounts and payments for FY 2003 were simulated using the FY 2000 target amount in the hospital's cost report and updating the target amount for each subsequent cost reporting period by the applicable rate-of-increase

percentage as described in § 413.40(c)(3)(vii) through FY 2002. The target amount from FY 2002 was updated by the forecasted market basket percentage increase of 3.5 percent to arrive at the FY 2003 target amount (§ 413.40(c)(3)(viii)). (We note that the forecasted increase in the excluded hospital market basket for FY 2003 of 3.5 percent was used to establish the applicable rate-of-increase percentage used to update TEFRA target amounts in accordance with § 413.40(c)(3)(viii) in the FY 2003 IPPS final rule (67 FR 50289)). Based on more recent data, our Office of the Actuary currently estimates an increase of 4.2 percent in the excluded hospital market basket for FY 2003, which we used to update LTCHs' FY 2002 costs to FY 2003, as described below.) In a small number of cases where FY 2002 operating cost data were not available, we used operating cost data from the most recent year available and trended it forward to FY 2003. In addition, we estimated FY 2003 bonus or relief payments without the inclusion of the 2-percent and 25-percent increases to the cap amount and target amount, respectively, and without the 1.5 percent and 2.0 percent increases to the CIB payments, consistent with section 307(a)(2) of BIPA as discussed above.

In addition, because comparisons were made between the target amount and Medicare inpatient operating costs to determine bonus or relief payments, under our methodology, we estimated FY 2003 operating costs for each LTCH by updating its FY 2002 operating costs by the actual percentage increase in operating costs for PPS-excluded hospitals from FY 2002 to FY 2003 (4.2 percent, as determined by our Office of the Actuary) because this is currently our best estimate of actual cost increase from FY 2002 to FY 2003 realized by excluded hospitals, including LTCHs. As discussed

earlier, we estimated the FY 2003 operating costs using FY 2002 costs rather than using the costs reported on the FY 2003 cost report.

The 75th percentile cap for LTCHs for FY 2002, without the 2-percent and 25-percent increases to the cap and target amount, respectively, was $30,783 for the wage-index adjusted labor-related share, and $12,238 for the nonlabor-related share. If a LTCH's costs and hospital-specific target amount were above the 75th percentile cap, Medicare's payment under the TEFRA system would be the wage-index adjusted cap amount. If under our payment model a LTCH's estimated FY 2002 TEFRA payment would have been limited by the wage-adjusted 75th percentile cap in FY 2002, that amount would be updated by the forecasted market basket percentage increase (of 3.5 percent) to FY 2003 to determine the LTCH's FY 2003 target amount that was used to estimate its TEFRA payment system amount for FY 2003 under our methodology.

Step 1.b. - Estimate FY 2003 inpatient operating payments under the TEFRA payment system for "new" LTCHs.

Next, under our methodology, we estimated FY 2003 hospital operating payments under the TEFRA payment system for "new" LTCHs based on the applicable statutory changes discussed above. A "new" LTCH is one that was first paid as an IPPS-excluded hospital on or after October 1, 1997. For a "new" LTCH, payment in the hospital's first 12-month cost reporting period is the lower of its Medicare net inpatient operating costs per discharge or the wage-adjusted 110 percent median amount determined for that particular year (§ 413.40(f)(2)(ii) of the regulations). For the hospital's second 12-month cost reporting period, payment is the lower of their costs, or the same 110 percent median

amount that was used in the first cost reporting period, that is, it is not updated. The hospital's "target amount" is established in the third cost reporting period by updating the per discharge amount that was paid in the prior cost reporting period by the estimated market basket percentage increase for hospitals and hospital units excluded from the IPPS, applicable to the specific year, as published annually in the **Federal Register**. Therefore, if the LTCH was paid its costs in the previous cost reporting period because costs were lower than the 110 percent median amount, the hospital's cost per discharge for the second cost reporting period is updated and becomes the target amount for the hospital's third cost reporting period. Target amounts for subsequent cost reporting periods are determined by updating the previous year's target amount by the applicable market basket percentage increase.

New LTCHs with their first 12-month cost reporting period beginning in FY 1998 would have had a target amount calculated under section 1886(b)(7)(A)(ii) of the Act in FY 2000. Therefore, consistent with our finalized policies concerning "existing" LTCH's (described in Step 1.a. above), in estimating the FY 2003 target amount for "new" LTCHs we used the target amount from the FY 2000 cost report and updated that target amount by the applicable estimated market basket percentage increases as published annually in the **Federal Register** for the IPPS final rule, without the 25-percent increase, to FY 2003. That is, we used 3.4 percent to update from FY 2000 to FY 2001, 3.3 percent to update from FY 2001 to FY 2002, and 3.5 percent to update from FY 2002 to FY 2003. For LTCHs with their first 12-month cost reporting period beginning in FY 1999, we used the lower of their costs or target amount from their FY 2000 cost

report, and updated that amount by the applicable estimated market basket percentage increase to establish the target amount in FY 2001, without the 25-percent increase. Next, we continued to update that target amount by the estimated market basket percentage increases to FY 2003. We believe that it is necessary to compute an estimated target amount for LTCHs that are "new" in FY 1999 under our methodology in order to eliminate the potential inclusion of the increase to the target amounts provided for by section 307(a)(1) of BIPA (consistent with the statute).

The 25-percent increase (under section 307(a) of the BIPA) to the target amount would not be an issue for LTCH's with their first 12-month cost reporting period beginning in FYs 2000, 2001, and 2002 because they would not have a "target amount" based on sections 1886(b)(7)(A)(ii) of the Act, in FY 2001. Rather, for these LTCHs, under our methodology we determined the estimated payment amount for their first 12-month cost reporting period by looking at their certification date from the OSCAR file, the applicable 110 percent median amount (adjusted by their wage-index) and their costs from the applicable cost report, and then proceeded in accordance with the policy in §413.40(f)(2)(ii) of the regulations, to arrive at estimated FY 2003 TEFRA payments.

Step 1c. - Estimate CIB payments that would have been made in FY 2003 under the TEFRA payment system (for both "existing" and "new" LTCHs).

In addition to the TEFRA system payments for operating costs, and any bonus or relief payments made, we also added an amount to account for the estimate of the CIB payments that would have been made in FY 2003 under the TEFRA payment system under § 413.40(d)(4). We estimated what CIB payments would have been in FY 2003 by

using actual CIB payments from the cost reports for FYs 1999 and 2000, as they would not include the statutory increases to the target amount discussed above, and recalculated CIB payments for FYs 2001 and 2002 based on cost report data. Based on these historical CIB payments, we estimated that CIB payments in FY 2003 would have been approximately $10 million. Just as the TEFRA payments and bonus and relief payments had to be recalculated in particular years to eliminate percentage increases that were not to be included in our budget neutrality calculations (as required by the statute), we believe that it is necessary to recalculate the CIB payments in FYs 2001 and 2002 to eliminate the percentage increases to these payments as provided for under section 122 of BBRA, such that they would not be accounted for in the development of the LTCH in accordance with section 307(a)(2) of BIPA. Therefore, under our methodology, we added $10 million as an estimate of the CIB payments that would have been made in FY 2003 under the TEFRA payment system to our estimated FY 2003 TEFRA system payments for operating costs, including any bonus or relief payments.

Step 2. - Estimate each LTCH's payment per discharge for inpatient capital costs under the TEFRA payment system for FY 2003.

As we discussed above, under our methodology, the second step in estimating total payments under the TEFRA payment system was to estimate each LTCH's payment per discharge for capital-related costs for FY 2003. Under the TEFRA payment system, in accordance with the regulations at 42 CFR Part 413, Medicare allowable capital costs are paid on a reasonable cost basis. Therefore, we updated each LTCH's payment for capital-related costs directly from the FY 2002 cost report for inflation using the FY 2003

capital excluded hospital market basket estimate of 0.7 percent, consistent with the methodology used to establish the initial standard Federal rate (67 FR 56031). Thus, we determined capital-related costs per case using capital cost data from Worksheets D, Parts I and II, and total Medicare discharges for the cost reporting period from Worksheet S-3. (We note that because payments for capital-related costs are on a reasonable-cost basis, capital payments were the same for "existing" and "new" LTCHs.)

Step 3. – Sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge.

Under our methodology for estimating FY 2003 LTCH total payments under the TEFRA payment system using FY 2002 cost data for the purposes of the one-time prospective adjustment at § 412.523(d)(3), after estimating payments for inpatient operating costs under the TEFRA payment system for FY 2003 and payments for capital-related costs under the TEFRA payment system for FY 2003, we summed each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge. Therefore, we added the estimate of each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003, including continuous improvement bonus payments (determined under Steps 1.a. through 1.c. above) and the estimate of each LTCH's payment per discharge for capital-related costs for FY 2003 (determined under Step 2 above).

Once we estimated total TEFRA payments as the sum of each LTCH's estimated operating and capital payment per case, under our methodology for evaluating

the one-time prospective adjustment at § 412.523(d)(3), the next step was to estimate FY 2003 payments under the LTCH PPS. As we discussed above, we believe that the best approach was to use FY 2002 LTCH claims data as a proxy for estimating FY 2003 LTCH PPS payments in evaluating the one-time prospective adjustment at § 412.523(d)(3). We note that we used the same FY 2002 LTCH MedPAR data that was used to develop the FY 2004 LTC-DRG relative weights in the FY 2004 IPPS final rule (68 FR 45376), as explained below. As we discussed in that final rule, there is a data problem with the FY 2002 claims data for LTCHs where multiple bills for the stay were submitted. Specifically, given the long stays at LTCHs, some providers had submitted multiple bills for payment under the reasonable cost-based reimbursement system for the same stay. In certain LTCHs, hospital personnel apparently reported a different principal diagnosis on each bill because, under the reasonable cost-based (TEFRA) reimbursement system, payment was not dependent upon principal diagnosis, as it is under a DRG-based PPS system. As a result of this billing practice, we discovered that only data from the final bills were being extracted for the MedPAR file. Therefore, it was possible that the original MedPAR file was not receiving the correct principal diagnosis. In that same IPPS final rule, we discussed how we addressed this problem in the LTCH FY 2002 MedPAR data when we used that data to determine the FY 2004 LTC-DRG relative weights. Therefore, for the evaluation of the one-time prospective adjustment at § 412.523(d)(3)we used the same "corrected" FY 2002 LTCH MedPAR data that was used to develop the FY 2004 LTC-DRG relative weights. For the reader's benefit, we are providing a summary of how we addressed the multiple bill problem in the FY 2002

LTCH MedPAR data below. As we explained in the FY 2004 IPPS final rule (68 FR 45376), we addressed this problem by identifying all LTCH cases in the FY 2002 MedPAR file for which multiple bills were submitted. For each of these cases, beginning with the first bill and moving forward consecutively through subsequent bills for that stay, we recorded the first unique diagnosis codes up to 10 and the first unique procedure codes up to 10. We then used these codes to appropriately group each LTCH case to a LTC-DRG for FY 2004.

For this final rule, as we proposed, we estimated FY 2003 LTCH PPS payments using the same general methodology that we used to estimate FY 2003 payments under the LTCH PPS (without a budget neutrality adjustment) when we determined the initial standard Federal rate in the August 30, 2002 final rule (67 FR 56032). Specifically, we estimated FY 2003 LTCH PPS payments for each LTCH by simulating payments on a case-by-case basis by applying the final FY 2003 payment policies established in the August 30, 2002 final rule that implemented the LTCH PPS (67 FR 55954) based on the LTCH case-specific discharge information from the FY 2002 MedPAR files (as explained above), and we also used LTCH provider-specific data from the FY 2003 Provider-Specific File (PSF), as these were the data used by fiscal intermediaries to make LTCH payments during the first year of the LTCH PPS (FY 2003). Under our methodology, we used the FY 2003 LTC-DRG Grouper (Version 22.0), relative weights, and average length of stay (67 FR 55979 through 55995); we made adjustments for differences in area wage levels established for FY 2003 as set forth at § 412.525(c) using the appropriate phase-in wage index values for FY 2003 (67 FR 56015 through 56020);

we made a cost-of-living adjustment for LTCHs located in Alaska and Hawaii as set forth at § 412.525(b) (67 FR 56022); we made adjustments for SSO cases based on the method for determining payment applicable for discharges occurring during FY 2003 in accordance with § 412.529(c)(1) (67 FR 55975 and 55995 through 56002); and we included additional payments for HCO cases in accordance with former § 412.525(a) for determining payments for discharges occurring in FY 2003 and the FY 2003 fixed-loss amount of $24,450 (67 FR 56023). (We note that correctly billed interrupted stay cases under § 412.531 are single LTCH cases in the MedPAR files; therefore, we estimated a single LTCH PPS payment for those cases.) Under this methodology, for purposes of this calculation we simulated case-by-case payments for each LTCH as if it were paid based on 100 percent of the standard Federal rate in FY 2003 rather than the transition blend methodology set forth at § 412.533. To determine total estimated PPS payments for all LTCHs, we summed the individual estimated LTCH PPS payments for each LTCH. (We note that this is the same methodology we used to estimate FY 2003 payments under the LTCH PPS for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule (73 FR 5359 through 5360).)

In order to determine if there is any difference between estimated total TEFRA payments and estimated LTCH PPS payments in FY 2003 under our methodology for evaluating a possible one-time prospective adjustment under § 412.523(d)(3), we determined a case-weighted average estimated TEFRA payment, consistent with the methodology used when we determined the initial standard Federal rate in the FY 2003

LTCH PPS final rule (68 FR 56032). Under this methodology, each LTCH's estimated total FY 2003 TEFRA payment per discharge was determined by summing its estimated FY 2003 operating and capital payments under the TEFRA payment system based on FY 2002 cost report data (as described in Step 3 above), and dividing that amount by the number of discharges from the FY 2002 cost report data. Next, we determined each LTCH's average estimated TEFRA payment weighted for its number of discharges in the FY 2002 MedPAR file (for the purpose of estimating FY 2003 LTCH PPS payments, as discussed above) by multiplying its average estimated total TEFRA payment per discharge by its number of discharges in the FY 2002 MedPAR file. We then estimated total case-weighted TEFRA payments by summing each LTCH's (MedPAR) case-weighted estimated FY 2003 TEFRA payments. Under our methodology, we compared these estimated FY 2003 total TEFRA payments to estimated FY 2003 total LTCH PPS payments in order to determine whether a one-time prospective adjustment would be appropriate. (As discussed in greater detail above, we determined both estimated total FY 2003 TEFRA payments and estimated total FY 2003 LTCH PPS payments based on FY 2002 cost report and claims data, respectively.) Our policy to adjust our estimate of FY 2003 TEFRA payments for the number of discharges that we used to estimate FY 2003 LTCH PPS payments will ensure that the comparison of estimated aggregate FY 2003 TEFRA payments to estimated aggregate FY 2003 LTCH PPS payments is based on the same number of LTCH discharges.

Using the methodology and data described above, we calculated that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated

payments to the same LTCHs in FY 2003 if the LTCH PPS had not been implemented (that is, estimated total FY 2003 TEFRA payment system payments). Although we project that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated FY 2003 TEFRA payments, as we explained in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28031), reducing the standard Federal rate by 2.5 percent would not "maintain budget neutrality" for FY 2003 (that is, estimated FY 2003 LTCH PPS payments would not be equal to estimated FY 2003 TEFRA payments) because a considerable number of LTCH discharges are projected to have received a LTCH PPS payment in FY 2003 based on the estimated cost of the case (rather than a payment based on the standard Federal rate) under the payment adjustment for SSO cases at § 412.529. (As discussed previously, our payment analysis indicates that nearly 20 percent of estimated FY 2003 LTCH PPS payments are SSO payments that were paid based on estimated cost and not based on the LTCH PPS standard Federal rate. These SSO cases that receive a payment based on the estimated cost of the case are generally unaffected by any changes to the standard Federal rate. If we were to reduce the standard Federal rate by 2.5 percent, estimated total FY 2003 LTCH PPS payments would still be greater than estimated total FY 2003 TEFRA payments (that is, would not be budget neutral), and that difference would be perpetuated in the LTCH PPS payment rates for future years.) Therefore, it is necessary to offset the standard Federal rate by a factor that is larger than 2.5 percent in order to ensure that estimated total FY 2003 LTCH PPS payments would be equal to estimated total FY 2003 TEFRA payments in order to "maintain budget neutrality." To determine the necessary adjustment factor that

would need to be applied to the standard Federal rate in order to "maintain budget neutrality," we simulated FY 2003 LTCH PPS payments using the same payment simulation model discussed above (that we used to estimate FY 2003 LTCH PPS payments without a budget neutrality factor). Using iterative payment simulations using the data from the 250 LTCHs in our database, we determined that we would need to apply a factor of 0.9625 (that is, a reduction of approximately 3.75 percent rather than 2.5 percent) to the standard Federal rate in order to make estimated total FY 2003 LTCH PPS payments equal to estimated total FY 2003 TEFRA payments, consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3) (that is, to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28031), based on the methodology described above, we proposed to revise § 412.523(d)(3) to specify that the standard Federal rate would be permanently reduced by 3.75 percent so that the estimated difference between projected aggregate LTCH PPS payments in FY 2003 and the projected aggregate payments that would have been made in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented. Consistent with current law, we also proposed that this adjustment would not apply to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012. We also proposed to phase-in the 3.75 percent reduction to the standard Federal rate over a 3-year period. We also explained that although the adjustment to the standard Federal rate

provided for under § 412.523(d)(3) is called a ‘‘one-time’’ prospective adjustment, this adjustment will be permanently applied to the standard Federal rate so that the effect of the estimated difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the LTCH prospective payment rates for future years.

Although we did not receive any specific public comments on our proposed revision to § 412.523(d)(3), as we discussed in the comments and responses presented above in this section, in response to the commenter who expressed concern about a potential compounding effect under our proposal to phase-in the one-time prospective adjustment over a 3-year period, we are taking the opportunity in this final rule to clarify in the revisions we are making to § 412.523(d)(3) that the one-time prospective adjustment of 0.9625 will be *permanently* applied to the standard Federal rate so that the effect of the estimated difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the LTCH prospective payment rates for future years.

Therefore, in this final rule, based on the methodology described above, under the broad authority granted to the Secretary under section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are revising § 412.523(d)(3) to specify that the standard Federal rate is permanently adjusted by 3.75 percent (that is, a factor of 0.9625) to reflect the estimated difference between projected aggregate LTCH PPS payments in FY 2003 and the projected aggregate payments that would have been made in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented. Consistent with

current law, this adjustment will not apply to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012. And as we discussed above in this section in our response to public comments, given the magnitude of this adjustment and in acknowledgement of hopeful research outcomes, we are finalizing our proposal to phase-in the one-time prospective adjustment of 3.75 percent (or a factor of 0.9625) to the standard Federal rate over a 3-year period. As noted above, although the adjustment to the standard Federal rate provided for under § 412.523(d)(3) is called a "one-time" prospective adjustment, this adjustment (that is, a factor of 0.9625) will be permanently applied to the standard Federal rate so that the effect of the estimated difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years. During this 3-year period, we intend to further explore potential revisions to certain LTCH PPS payment policies as discussed above in section VII.E.2. of this preamble.

Under the policy we are establishing in this final rule, consistent with the one-time prospective adjustment authorized under § 412.523(d)(3), we are applying a permanent factor of 0.98734 to the standard Federal rate in FY 2013 (which will not apply to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, consistent with current law), FY 2014, and FY 2015 to completely account for our estimate (determined using the methodology described above) that the standard Federal rate must be adjusted 3.75 percent (or a factor of 0.9625) to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total

FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years, consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3). To achieve a permanent adjustment of 0.9625, under the phase-in of this adjustment that we are establishing in this final rule, we will apply a factor of 0.98734 to the standard Federal rate in each year of the 3-year phase-in, that is, in FY 2013 (which will not be applicable to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, consistent with current law), FY 2014, and FY 2015. By applying a permanent factor of 0.98734 to the standard Federal rate in each year for FYs 2013, 2014, and 2015, we will completely account for the entire adjustment by having applied a cumulative factor of 0.9625 (calculated as $0.98734 \times 0.98734 \times 0.98734 = 0.9625$) to the standard Federal rate.

5. Other Comments Received on the Proposed Rule

We note that we received some public comments on the LTCH PPS that were outside of the scope of the FY 2013 IPPS/LTCH PPS proposed rule. These out-of-scope public comments are not addressed with policy responses in this final rule. However, we appreciate these comments and we may consider these public comments in the development of future rulemaking.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

CMS is seeking to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of an increasing number of widely agreed-upon quality measures. CMS has worked with relevant stakeholders to define measures of quality for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

CMS has implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, CMS implemented the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). In addition, CMS has implemented quality reporting programs for hospital outpatient services, the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)), and for physicians and other eligible professionals, the Physician Quality Reporting System (formerly referred to as the Physician Quality Reporting Program Initiative (PQRI)). CMS has also implemented quality reporting programs for inpatient rehabilitation hospitals, hospices, and ambulatory surgical centers, and an end-stage renal disease quality improvement program (76 FR 628 through 646) that links payment to performance.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities

for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, so that the electronic collection of performance information is part of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructural development on the part of hospitals and CMS, and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and burden to hospitals. We believe that automatic collection and reporting of data elements for many measures through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs and that at a future date, such as FY 2015, hospitals will be able to switch primarily to EHR-based reporting of data for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We have also implemented a Hospital Value-Based Purchasing (VBP) Program under section 1886(o) of the Act. In 2011, we issued the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We adopted additional policies for the Hospital VBP Program in section IV.B. of the FY 2012 IPPS/LTCH PPS final rule

(76 FR 51653 through 51660) and in section XVI. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547). Under the Hospital VBP Program, hospitals will receive value-based incentive payments if they meet performance standards with respect to measures for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework of the Hospital VBP Program. Section 1886(o)(2)(B)(i)(I) of the Act states that for FY 2013, the selected measures for the Hospital VBP Program must cover at least the following five specified conditions or procedures: Acute myocardial infarction (AMI), Heart failure (HF), Pneumonia (PN), surgical care, as measured by the Surgical Care Improvement Project (SCIP), and Healthcare-Associated Infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent HAIs (or any successor HHS plan). Section 1886(o)(2)(B)(i)(II) of the Act provides that, for FY 2013, measures selected for the Hospital VBP Program must also be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

The Hospital IQR Program is linked with the Hospital VBP Program because the measures and reporting infrastructure for both programs overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare into an active purchaser of quality healthcare for

its beneficiaries. Value-based purchasing is an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume. As we stated in the Hospital Inpatient VBP Program proposed rule (76 FR 2455), we applied the following principles for the development and use of measures and scoring methodologies:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

- The collection of information should minimize the burden on providers to the extent possible. As part of this effort, we will continuously seek to align our measures with the adoption of e-specified measures, so the electronic collection of performance information is part of care delivery.

- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We also view the Hospital-Acquired Condition (HAC) payment adjustment program authorized by section 3008 of the Affordable Care Act and the Hospital VBP Program as being related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance on a wide variety of measures, while the program established by section 3008 of the Affordable Care Act creates a payment adjustment resulting in payment reductions for the lowest performing hospitals based on their rates of HACs.

Although we intend to monitor the various interactions of programs authorized by the Affordable Care Act and their overall impact on providers and suppliers, we also view programs that could potentially affect a hospital's Medicaid payment as separate from programs that could potentially affect a hospital's Medicare payment.

In this section VIII. of this preamble, we are adopting changes to, or implementing, the following Medicare quality reporting systems:

- In section VIII.A., the Hospital IQR Program.
- In section VIII.B., the Hospital VBP Program.
- In section VIII.C., the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.
- In section VIII.D., the Long-Term Care Hospital Quality Reporting (LTCHQR) Program.

- In section VIII.E., the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

- In section VIII.F., the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of Measures Adopted for the Hospital IQR Program

We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636 through 51637) for the measures we have adopted for the Hospital IQR measure set through FY 2015.

b. Maintenance of Technical Specifications for Quality Measures

The technical specifications for the Hospital IQR Program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission (TJC) Specifications Manual for National Hospital Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at https://www.QualityNet.org. We generally update the Specifications Manual on a semiannual basis and include in the updates detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient

time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS Quality Assurance Guidelines manual, which is available at the HCAHPS On-Line Web site, http://www.hcahpsonline.org. We maintain the HCAHPS technical specifications by updating the HCAHPS Quality Assurance Guidelines manual annually, and include detailed instructions on survey implementation, data collection, data submission and other relevant topics. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF

solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28033), we proposed that if the NQF updates an endorsed measure that we have adopted for the Hospital IQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the QualityNet Web site at https://www.QualityNet.org. We would provide sufficient lead time for hospitals to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to a measure that we consider to substantially change the nature of the measure. We believe that this

proposal adequately balances our need to incorporate NQF updates to NQF–endorsed Hospital IQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invited public comment on this proposal.

Comment: Many commenters supported the proposed subregulatory process to update the measure specifications of adopted NQF-endorsed measures in the Specifications Manual for non-substantive changes that arise from the NQF maintenance review, as well as the continuation of the rulemaking process for substantive changes that arise from NQF review. Several commenters objected to these proposals, and expressed concern that there is no clear definition of non-substantive updates. These commenters felt that changes such as conversion of measures to ICD-10 codes and eMeasures format, and exclusions to the patient population should be considered substantive changes that would warrant rulemaking. Some commenters stated that all changes to measures that are not NQF-endorsed measures should be subject to the rulemaking process.

Response: We thank those commenters that supported our proposal to update NQF-endorsed measures using a subregulatory process. The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate non-substantive updates made by the NQF into the measure specifications we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We also recognize that some changes the NQF might make

to its endorsed measures are substantive in nature and might not be appropriate for adoption using a subregulatory process. Therefore, we are finalizing a policy under which we will use a subregulatory process to make non-substantive updates to NQF-endorsed measures used for the Hospital IQR program. With respect to what constitutes substantive versus non-substantive changes, we expect to make this determination on a case-by-case basis. Examples of non-substantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the Hospital IQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus non-substantive would apply to all measures in the

Hospital IQR Program. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

Comment: A few commenters supported the semiannual updates of the Specifications Manual to provide guidance to hospitals on data collection and submission of the required measures. Commenters urged CMS to provide at least 12 to 18 months' notice before nonsubstantive changes are implemented by vendors and providers.

Response: We thank the commenter for the support for this process, which is consistent across all quality reporting programs. Per our existing policy for specification updates, we will provide at least 6 months lead time for hospitals to implement updates to measures that would require changes to abstraction or data collection systems. This would include non-substantive changes.

Comment: A commenter suggested that CMS must be more transparent about the NQF maintenance review and update process in the Hospital IQR Program proposed rules. Specifically, the commenter urged CMS to describe the NQF status, including the status of maintenance review, of every proposed and previously finalized measure in proposed rules. The commenter believed that the lack of information regarding a measure's NQF status may disadvantage the public in commenting on Hospital IQR Program measures.

Response: We appreciate the suggestion and recognize the commenter's desire to have more information about the measures in the program. This information is currently available and updated frequently on the measures list available on the NQF Web site: http://www.qualityforum.org/Measures_List.aspx. We will strive to provide

additional NQF-related information about the Hospital IQR Program measures in the future.

After consideration of the public comments we received, we are finalizing a policy under which we will use a subregulatory process to make non-substantive updates to measures in the Hospital IQR Program. We will continue to use the rulemaking process to adopt changes to measures that we consider to be substantive.

c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. We will continue our current practice of reporting data from the Hospital IQR Program as soon as it is feasible on CMS Web sites such as the Hospital Compare Web site, http://www.hospitalcompare.hhs.gov, after a 30-day preview period.

The Hospital Compare Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish. The Hospital IQR Program currently includes process of care measures, risk-adjusted outcome measures, the HCAHPS patient experience-of-care survey, structural measures, Emergency Department Throughput timing measures, hospital

acquired condition measures, immunization measures, and hospital acquired infection measures, all of which are featured on the Hospital Compare Web site.

However, information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations for inclusion on Hospital Compare may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as http://www.cms.hhs.gov/HospitalQualityInits/. Publicly reporting the information in this manner, although not on the Hospital Compare Web site, allows CMS to meet the requirement under section 1886(b)(3)(B)(viii)(VII) of the Act for establishing procedures to make information regarding measures submitted under the Hospital IQR Program available to the public following a preview period. In such circumstances, affected parties are notified via CMS listservs, CMS e-mail blasts and memorandums, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than Hospital Compare.

Comment: A commenter recommended that CMS collect and present data on Hospital Compare in a stratified manner in terms of race, language, and gender as the commenter believed all of the above are crucial data to address and reduce health disparities.

Response: We are unable to collect data that is unrelated to quality measures, and therefore, it is not possible for us to stratify measures using demographic data as this commenter suggests.

Comment: A commenter supported display of the Standardized Infection Ratio (SIR) for both CLABSI and CAUTI on Hospital Compare.

Response: We thank the commenter for their support.

Comment: A commenter believed that the public reporting of hospital-specific readmission rates on Hospital Compare needs significant improvement by providing more specific data on actual readmission rates. The commenter pointed out that the current display of readmissions as either "same as the national average," "worse than the national average," or "better than the national average" indicate little variation among hospitals and does not offer to consumers and purchasers meaningful information about how well specific hospitals are performing.

Response: The purpose of the initial display of the readmission measures as "same as the national average," "worse than the national average," or "better than the national average" is to address consumer preferences for the display of information that incorporates confidence intervals or interval estimates for outcome measures such as hospital readmission rates. However, alternative displays that we provide, which can also be accessed through links on the main display at the Hospital Compare Web site, contain both graphical and table displays and provide more information, including the risk-adjusted readmission rates. Additional information is also available in the downloadable file at: http://www.medicare.gov/download/downloaddb.asp that accompanies each Hospital Compare release in order to facilitate customized comparative analyses.

Comment: A commenter requested that CMS notify hospitals of changes to QualityNet Web site reports in a timely manner.

Response: We send out memos in a timely manner to notify hospitals of changes to reports when there is a system release or production fix.

2. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures from the Hospital IQR Program

We generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when they are removed or replaced as indicated. In previous rulemakings, we have referred to the removal of measures from the Hospital IQR Program as "retirement." We have used this term to indicate that Hospital IQR Program measures are no longer included in the Hospital IQR Program measure set for one or more indicated reasons. However, we note that this term may imply that other payers/purchasers/programs should cease using these measures that are no longer required for the Hospital IQR Program. In order to clarify that this is not our intent, beginning with this rulemaking cycle, we will use the term "remove" rather than "retire" to refer to the action of no longer including a measure in the Hospital IQR Program.

As we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), the criteria that we consider when determining whether to remove Hospital IQR Program measures are the following: (1) measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped out" measures); (2) availability of alternative measures with a stronger

relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. These criteria were suggested by commenters during rulemaking, and we agreed that these criteria should be among those considered in evaluating Hospital IQR Program quality measures for removal.

In addition, we take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay for reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

Comment: Several commenters supported the proposals regarding measure removal criteria and the use of "removal" terminology. Some commenters also recommended that CMS provide a list of potential measures for removal from the Hospital IQR Program for MAP review and recommendations.

Response: We thank the commenters for the support of our measure removal criteria and the use of the term "removal." We will consider the recommendation to

provide a list of potential measures for removal from the Hospital IQR Program to MAP for its input.

b. Hospital IQR Program Measures Removed in Previous Rulemakings

In previous rulemakings, we have removed several Hospital IQR Program quality measures, including:

- PN-1: Oxygenation Assessment for Pneumonia, a "topped out" measure, because measures with very high performance among hospitals present little opportunity for improvement and do not provide meaningful distinctions in performance for consumers (73 FR 48604).

- AMI-6: Beta Blocker at Arrival measure from the Hospital IQR Program because it no longer "represent[ed] the best clinical practice," as required under section 1886(b)(3)(B)(viii)(VI) of the Act. We stated that when there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, it is appropriate for CMS to take immediate action to remove a measure from the Hospital IQR Program and not wait for the annual rulemaking cycle. Therefore, we adopted the policy (74 FR 43864 and 43865) that we would promptly remove such a measure, confirm the removal in the next IPPS rulemaking cycle, and notify hospitals and the public of the decision to promptly remove measures through the usual hospital and QIO communication channels used for the Hospital IQR Program. These channels include memos, email notification, and QualityNet Web site postings. To this end, we confirmed the removal of the AMI-6 measure in the FY 2010 IPPS/LTCH

PPS rulemaking cycle after immediate suspension because the measure posed patient safety risks.

- Mortality for Selected Procedures Composite measure because the measure is not considered suitable for purposes of comparative reporting by the measure developer (75 FR 50186).

- Three adult smoking cessation measures: AMI-4: Adult Smoking Cessation Advice/Counselling; HF-4: Adult Smoking Cessation Advice/Counselling; and PN-4: Adult Smoking Cessation Advice/Counselling, because these measures are "topped-out" and no longer NQF-endorsed (76 FR 51611).

- PN-5c: Timing of Receipt of Initial Antibiotic Following Hospital Arrival measure out of concerns that the continued collection of this measure might lead to the unintended consequence of antibiotic overuse (76 FR 51611).

c. Removal of Hospital IQR Program Measures for FY 2015 Payment Determination and Subsequent Years

To accommodate the expansion of the measure set, we have considered the removal of additional Hospital IQR Program measures using our stated measure removal criteria. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28035), based on some of these criteria, we proposed to remove 17 measures from the Hospital IQR Program. One of these 17 measures is chart-abstracted, and the other 16 are claims-based.

(1) Removal of One Chart-Abstracted Measure

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28035), we proposed to remove the SCIP-Venous Thromboembolism (VTE) measure: "SCIP-VTE-1: Surgery

patients with recommended VTE prophylaxis ordered" measure because we believe that the "SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours of pre/post surgery" measure currently used in the Hospital IQR Program assesses practices that are more proximal in time to better surgical outcomes resulting from the use of VTE prophylaxis. We also note that during a recent NQF maintenance review of SCIP-VTE-1, the measure was not recommended for continued endorsement.

Comment: Many commenters strongly agreed with CMS' rationale for proposing the removal of the SCIP-VTE-1 measure and urged its immediate removal from the Hospital IQR Program. One commenter was disappointed that the measure was removed shortly after it was adopted. Commenters requested that CMS clarify whether the end date for data submission of the proposed chart-abstracted measure is effective immediately, or on the effective date of this final rule.

Response: We thank the commenters for the support of the removal of this measure. The removal of this measure is consistent with one of our measure removal criteria of removing a measure when an alternative measure(s) that is either more proximal to or that has a stronger relationship with patient outcomes is available. We are finalizing the removal of this measure from the Hospital IQR Program measure set. The data collection for this chart-abstracted measure will end with December 31, 2012 discharges.

(2) Removal of 16 Claims-Based Measures

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28035), we proposed to remove eight HAC measures, three AHRQ Inpatient Quality Indicator (IQI) measures,

and five AHRQ Patient Safety Indicator (PSI) measures from the Hospital IQR Program measure set.

(A) Removal of Eight Hospital-Acquired Condition (HAC) Measures

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50194 through 50196), for the FY 2012 payment determination, we adopted 8 claims-based HAC measures based on 8 of the 10 conditions applicable under the HAC payment provisions specified in section 1886(d)(4)(D) of the Act. These eight HAC measures are: Air Embolism; Blood Incompatibility; Catheter-Associated Urinary Tract Infection (UTI); Falls and Trauma: (Includes Fracture Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock); Foreign Object Retained After Surgery; Manifestations of Poor Glycemic Control; Pressure Ulcer Stages III or IV; and Vascular Catheter Associated Infections. Six of these HACS were identified by NQF as serious reportable events.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28035), we proposed to remove these eight HAC measures based on several considerations. First, the MAP recommended that we replace the HAC measures in the Hospital IQR Program with NQF-endorsed measures. Second, we seek to reduce redundancy among the measures in the program. Two of the eight HAC measures address HAIs which are addressed by other measures currently in the Hospital IQR Program. These two HAI measures are the NQF-endorsed CAUTI and CLABSI measures collected via the CDC's NHSN system. An additional three of the eight HAC measures address similar topics (pressure ulcers, air embolism, and manifestations of poor glycemic control) to patient safety indicators that are included in the NQF-endorsed AHRQ PSI composite that is also included in the

Hospital IQR Program. Accordingly, because more broadly applicable NQF-endorsed measures are available that address some of the same HAIs and HACs, we believe it is appropriate to remove these measures from the program. We note that section 3008 of the Affordable Care Act will require public reporting of HACs, including those conditions adopted under section 1886(d)(4)(D) of the Act. HACs remain an important aspect of our commitment to patient safety, and the measurement and reduction of patient harm. "Safer care" is one of the six priorities identified to address the three aims established under the National Quality Strategy. We stated our intention to pursue development of an all-cause harm composite measure for potential use in our quality reporting programs.

Comment: The majority of the commenters who commented on the proposed removal of the eight HAC measures supported the MAP recommendation as well as our proposal to remove the eight HAC measures from the Hospital IQR Program. Commenters requested their immediate removal from the Hospital IQR Program as they believed their removal will minimize the potential for hospitals to be penalized twice for these conditions due to the measures' inclusion in the Hospital IQR Program and the HAC payment provisions under section 1886(d)(4)(D) of the Act.

Response: We thank the commenters for their support for the removal of these measures. We are finalizing this proposal, and we do not intend to provide or publicly report new calculations of these individual HACs as part of the Hospital IQR Program after 2012.

Comment: Two commenters supported the removal of the Catheter-Associated Urinary Tract Infection (UTI) and the Vascular Catheter Associated Infections HACs but recommended the retention of rest of the HACs (Air Embolism; Blood Incompatibility; Falls and Trauma: (Includes Fracture Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock); Foreign Object Retained After Surgery; Manifestations of Poor Glycemic Control; and Pressure Ulcer Stages III), and urged us to work with stakeholders to address any coding irregularities that may affect the accuracy of the data used to calculate these six measures. These commenters also suggested continued reporting of these measures on Hospital Compare.

Response: We appreciate the commenters' support of the removal of the Catheter-Associated Urinary Tract Infection (UTI) and the Vascular Catheter Associated Infections HACs. We are not considering the retention of any of the other six non-infection related HACs for the Hospital IQR Program at this time due to the MAP recommendations and our intent to pursue development of an all-cause harm composite measure for potential use in our quality reporting programs.

Comment: One commenter opposed CMS' intention to develop an all-cause harm composite measure, noting that there are too many variables to account for in measuring all-cause harm.

Response: We wish to clarify that our goal of developing an all-cause harm composite measure is to inform the healthcare community and the general public of hospital performance in terms of managing patient safety efficiently and economically. While we agree that HACs often result from multiple factors, some of these conditions

are "never events;" they could cause serious injuries or even death, and should not happen under any circumstances. These never events are foreign objects retained after surgery, air embolism, and blood incompatibility. We are examining risk factors for other HACs. In pursuing this goal, we intend to work with clinical experts in injuries, complications, and infections, and with measure experts with knowledge in composite measures and risk adjustment to develop an all-cause harm measure that can inform clinicians of gaps in their patient safety performance.

(B) Removal of Three AHRQ IQI Measures

In the FY 2009 IPPS final rule (73 FR 48607), we adopted three claims-based AHRQ IQI outcome measures for the FY 2010 payment determination:

(1) IQI-11: Abdominal aortic aneurysm (AAA) repair mortality rate (with or without volume); (2) IQI-19: Hip fracture mortality rate; and (3) IQI-91: Mortality for selected medical conditions (composite).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28035), we proposed to remove these three AHRQ IQI measures from the Hospital IQR Program. In removing measures from the Hospital IQR Program, we seek to eliminate measures that would not be used under the Hospital VBP Program, and to reduce redundancy among the measures in the Hospital IQR Program. Three of the six conditions in the IQI composite measure overlap with 30-day mortality measures that we have in the Hospital IQR Program, and which were recommended by the MAP for use in the Hospital VBP Program. The proposed removal of these AHRQ IQI measures would eliminate unnecessary redundancy in the Hospital IQR Program measure set. We also believe that inclusion of a

large number of in-hospital mortality measures, the performance on which is highly dependent upon hospital discharge patterns, may lead to unintended consequences of patients being discharged sooner than advisable. We invited public comment on this proposal.

Comment: All the commenters who commented on the proposed removal of the AHRQ IQI measures strongly supported and requested the removal of the three proposed AHRQ IQI measures from the Hospital IQR Program.

Response: We thank the commenters for their support.

Based on these comments, we are finalizing the removal of IQI-11, IQI-19, and the IQI-90 composite measures. These measures' calculations will not be refreshed on Hospital Compare after 2012.

(C) Removal of Five AHRQ PSI Measures

In the FY 2009 IPPS final rule (73 FR 48607), we adopted three claims-based PSI outcome measures for the FY 2010 payment determination: (1) PSI-06: Iatrogenic pneumothorax; (2) PSI-14: Postoperative wound dehiscence; and (3) PSI-15: Accidental puncture or laceration. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50194), we adopted two more claims-based PSI outcome measures for the FY 2012 payment determination: PSI-11: Post Operative Respiratory Failure; and PSI 12: Post Operative PE or DVT.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28035), we proposed to remove these five AHRQ PSI measures from the Hospital IQR Program because four of these five individual measures (all but PSI-11) are included in the NQF-endorsed AHRQ

PSI Composite measure that is already included in the Hospital IQR Program. Also, the post-operative ventilator associated events assessed in PSI-11 could be captured more robustly using non-administrative data collected via the NHSN in the near future. Therefore, we proposed to remove these five individual PSIs from the Hospital IQR Program measure set in order to eliminate unnecessary redundancy. We invited public comment on this proposal.

Comment: Almost all of the commenters who commented on the proposed removal of the AHRQ PSI measures supported their removal from the Hospital IQR Program. Commenters stated that these measures, which are based on administrative data, are less sensitive than those measures that utilize chart-abstracted data, and lack the specificity required for use in comparative public reporting programs. One commenter was concerned that the removal of the measures would deprive stakeholders of the opportunity to drill down and access more granular information on the individual measures. The commenter requested assurance that the transparency of information on these safety events is not compromised by the removal of these measures.

Response: We appreciate the supportive comments received for this proposal. Four of the five measures to be removed are part of the PSI Composite that is being retained for the Hospital IQR Program, and we will be able to continue providing this information in "drill down" displays of the PSI Composite because the individual measure information can be made available through links or pop-up windows from the main display of the composite score. We are finalizing the removal of these five PSI measures from the Hospital IQR Program.

Comment: Many commenters strongly supported the proposal to remove the 16 claims-based measures and one chart-abstracted measure as one way to streamline measures in the Hospital IQR Program and make the numbers of Hospital IQR Program measures more manageable. Commenters urged CMS to expedite the proposed removal of the 17 measures sooner than 2015 as proposed and to remove the 17 measures from the Hospital Compare Web site immediately. The commenters recommended that we use the CY 2013 OPPS/ASC proposed rule as a vehicle to propose the removal of these measures from the FY 2013 and 2014 Hospital IQR Program measure set.

Response: We are sensitive to the comments on streamlining measures in the Hospital IQR Program. We thank the commenters for the support. Although we proposed the removal of these measures for the FY 2015 payment determination, the impact from the removal of these measures begins in 2012. In particular, the data collection for the chart-abstracted measure, SCIP-VTE-1: Surgery patients with recommended VTE prophylaxis ordered, will end with December 31, 2012 discharges. New calculations of the 16 individual claims-based measures on the Hospital Compare Web site will not be displayed as distinct measures after July 2012 for purposes of the Hospital IQR Program. However, because the PSI Composite Measure is comprised of individual PSI measures, information on the specific measures that are part of the AHRQ PSI Composite can be provided on Hospital Compare in "drill down" displays from the main composite. Also, some or all of the HAC measures may be reported on Hospital Compare in some manner in the future under the public reporting authority under section 3008 of the Affordable Care Act.

Comment: Two commenters assumed that because CMS proposed the removal of several individual AHRQ PSI measures from the Hospital IQR Program, that we would also remove these indicators from the calculation of the AHRQ PSI-90 composite measure for both Hospital IQR and the Hospital VBP Programs. Furthermore, these commenters believed that the statutory display requirement for the AHRQ PSI-90 composite measure has not been met because CMS did not display data for all eight of the individual AHRQ indicators that are used in the composite.

Response: We wish to clarify that our removal of several individual AHRQ indicators from the Hospital IQR Program does not in any way change the composition of the AHRQ PSI-90 composite measure for either the Hospital IQR or Hospital VBP Programs. No changes have been proposed for the AHRQ PSI-90 composite for the Hospital IQR or Hospital VBP Programs. We adopted and displayed the NQF-endorsed AHRQ PSI-90 composite measure for the Hospital IQR Program (NQF#531) which is comprised of the following individual indicators: PSI-03, PSI-06, PSI-07, PSI-08, PSI-12, PSI-13, PSI-14, and PSI-15. We will continue to use/display this NQF-endorsed version of the PSI composite for the program. Regarding the 1 year display requirement for the PSI-composite for the Hospital VBP Program, we have proposed to use the AHRQ PSI-90 composite calculation in its totality for Hospital VBP Program scoring. We displayed this composite score in its totality on Hospital Compare beginning in October 2011. Therefore, the PSI-90 composite meets the display requirement for use in the Hospital VBP Program regardless of how many individual AHRQ indicators were displayed.

Some commenters also provided suggestions for removal of other measures in the Hospital IQR Program.

Comment: A commenter recommended the removal of the HF-1 (Discharge Instructions) measure because the measure did not receive continued NQF-endorsement and was perceived as a "check-the-box" measure that does not convey meaningful or actionable information about the quality of the discharge process. Another commenter believed that HF-1 should be replaced with a Post-Discharge Appointment for Heart Failure Patients measure.

One commenter proposed the removal of the SCIP Infection-2 (Prophylactic Antibiotic Selection for Surgical Patients) measure because the commenter believed implementation of the Surgical Site Infection measures targeted for FY 2014 will provide more meaningful outcome information than this process measure.

One commenter recommended the removal of all non-NQF-endorsed measures except those measures that are part of TJC's accountability measure set.

One commenter requested the removal of SCIP-INF-10 (Surgery Patients with Perioperative Temperature Management), which the commenter contended is topped out and which is not required for the Hospital VBP Program. One commenter indicated that PN-3b (Blood Culture Performed in the Emergency Department prior to First Antibiotic Received in Hospital) should be removed from the Hospital IQR Program because of the pending removal of its NQF-endorsement status, the consensus among stakeholders, the evidence citing the ineffective and inefficient implementation, and the unintended consequences associated with the measure.

Response: We appreciate the commenters' input on the removal of the measures and we will take this into consideration when we select measures for removal in the future. In our view, currently, these recommended measures for removal still yield valuable information in the improvement of healthcare and we have no plans to remove them unless evidence indicates otherwise. As for the suggested removal of non-NQF-endorsed measures, while we seek to use NQF-endorsed measures where possible, we note that measures that we believe to be important in assessing the quality of hospital care can be adopted for the Hospital IQR Program through our exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act. This section provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

After consideration of the public comments we received on measure removal, we are finalizing our proposal to remove 1 chart-abstracted measure and 16 claims-based measures as set forth in the table below:

Topic	**17 Measures Removed from Hospital IQR Program Measure Set for FY 2015 and Subsequent Payment Determinations**
Surgical Care Improvement Project (SCIP) Measure	
	● SCIP INF -VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures	
	● PSI 06: Iatrogenic pneumothorax, adult

Topic	17 Measures Removed from Hospital IQR Program Measure Set for FY 2015 and Subsequent Payment Determinations
	● PSI 11: Post Operative Respiratory Failure
	● PSI 12: Post Operative PE or DVT
	● PSI 14: Postoperative wound dehiscence
	● PSI 15: Accidental puncture or laceration
	● IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)
	● IQI 19: Hip fracture mortality rate
	● IQI 91: Mortality for selected medical conditions (composite)
Hospital Acquired Condition Measures	
	● Foreign Object Retained After Surgery
	● Air Embolism
	● Blood Incompatibility
	● Pressure Ulcer Stages III & IV
	● Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock)
	● Vascular Catheter-Associated Infection
	● Catheter-Associated Urinary Tract Infection (UTI)
	● Manifestations of Poor Glycemic Control

d. Suspension of Data Collection for the FY 2014 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51611), we suspended data collection for four measures beginning with January 1, 2012 discharges, affecting the FY 2014 payment determination and subsequent years.

Topic	Hospital IQR Program Measures Suspended for FY 2015 Payment Determination and Subsequent Years
Acute Myocardial Infarction (AMI)	
	● AMI-1 Aspirin at arrival
	● AMI-3 ACEI/ARB for left ventricular systolic dysfunction
	● AMI-5 Beta-blocker prescribed at discharge
Surgical Care Improvement Project (SCIP)	

Topic	Hospital IQR Program Measures Suspended for FY 2015 Payment Determination and Subsequent Years
	• SCIP INF-6 Appropriate Hair Removal

We suspended, rather than removed, these measures because although our analysis indicated that these measures are topped-out measures (that is, their performance is uniformly high nationwide, with little variability among hospitals), we recognized some commenters' belief that the processes assessed by the measures were tied to better patient outcomes, and that removal of the measures from the program may result in declines in performance and hence, worse outcomes.

The suspension of data collection for these four measures will be continued unless we have evidence that performance on the measures is in danger of declining. Should we determine that hospital adherence to these practices has unacceptably declined, we would resume data collection using the same form and manner and on the same quarterly schedule that we finalize for these and other chart abstracted measures, providing at least 3 months of notice prior to resuming data collection. Hospitals would be notified of this via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements. In addition, we would comply with any requirements imposed by the Paperwork Reduction Act before resuming data collection of these four measures.

Comment: Many commenters supported CMS' measure suspension policy, which provides a balance between maintaining quality and avoiding unnecessary administrative burden. Several commenters indicated that instead of suspension, these four previously suspended measures should be removed from the Hospital IQR Program permanently.

Response: We thank the commenters for their support of our measure suspension policy. Before we can remove the suspended measures we will need to determine whether the important practices addressed by these suspended measures continue to be routinely practiced.

Comment: A few commenters requested that CMS clarify: (1) the methodology used to determine if the measures are declining in performance; and (2) requirements to resume collection of a suspended measure. The commenters stated that if CMS decides to resume collection of a measure, it should integrate the timeline with the current process for implementation of technical specifications. Commenters offered to collaborate with CMS to identify measures warranting suspension.

Response: We will continue to monitor the measures for evidence of performance slippage by reviewing published literature and examining national performance trends on these measures from data collected by other parties. In the event that data collection on a suspended measure must be resumed, we intend to align with Specifications Manual release and collection cycle timelines in order to provide sufficient notice to hospitals.

3. Measures for the FY 2015 and FY 2016 Hospital IQR Program Payment Determinations

a. Additional Considerations in Expanding and Updating Quality Measures under the Hospital IQR Program

In general, we seek to adopt measures for the Hospital IQR Program that would promote better, safer, more efficient care. We believe it is important to expand the pool of measures to include measures that aim to improve patient safety. This goal is

supported by many reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.[53,54]

In addition to our goals to align measures and support the Hospital VBP Program, we also take into account other considerations in implementing and expanding the Hospital IQR Program:

- Our overarching purpose is to support the National Quality Strategy's (NQS') three-part aim of better health care for individuals, better health for populations, and lower costs for health care. The Hospital IQR Program will help achieve the three-part aim by creating transparency around the quality of care at inpatient hospitals to support patient decision-making and quality improvement. Given the availability of well-validated measures and the need to balance breadth with minimizing burden, measures should take into account and address, as fully as possible, the six domains of measurement that arise from the six NQS priorities: Clinical care; Person- and caregiver-centered experience and outcomes; Safety; Efficiency and cost reduction; Care coordination; and Community/population health. More information regarding the National Quality Strategy can be found at: http://www.hhs.gov/secretary/about/priorities/priorities.html and http://www.ahrq.gov/workingforquality/. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.

[53] OEI–06–09–00090, "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries." Department of Health and Human Services, Office of Inspector General, November 2010.
[54] 2009 National Healthcare Quality Report, pp. 107–122. "Patient Safety," Agency for Healthcare Research and Quality.

- We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. Within the framework of our statutory authority and taking into account programmatic considerations, measures used in the Hospital IQR Program should be harmonized with other Medicare/Medicaid quality reporting programs and incentive programs to promote coordinated efforts to improve quality.

- As part of our burden reduction efforts, we will continuously weigh the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR Program. We seek to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases. In recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources.

- To the extent practicable, measures we use should be nationally endorsed by a multi-stakeholder organization. Section 3001(a)(2) of the Affordable Care Act added new sections 1886(b)(3)(B)(viii)(IX)(aa) and (bb) of the Act. These sections state that ". . . effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a) [of the Act]," and "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the

Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." Accordingly, we attempt to utilize endorsed measures whenever possible.

- Measures should be developed with the input of providers, purchasers/payers, and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.

- Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting quality and efficiency measures that have been endorsed by the entity with a contract under section 1890 of the Act, currently NQF, and measures that have not been endorsed. The MAP is a partnership comprised of multi-stakeholder groups that was convened by NQF to provide input on measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures (http://www.qualityforum.org/map/).

- HHS Strategic Plan and Initiatives. HHS is the U.S. government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The goals of the HHS Strategic Plan for Fiscal Years 2010 through 2015 are: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety,

and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf). HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce HAIs in clinical settings and the Partnership for Patients exemplify these programs.

- CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

- We give priority to measures that assess performance on: (a) conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations in the Medicare population have been reported, despite established clinical guidelines, across populations or geographic areas.

- We will focus on selecting measures that we believe will also meet the Hospital VBP Program measure inclusion criteria and advance the goals of the Hospital VBP Program by targeting hospitals' ability to improve patient care and patient outcomes.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50191 through 502192), we finalized our proposal to adopt measures for the Hospital IQR Program for three consecutive payment determinations. The intent of this policy was to provide greater certainty for hospitals to plan to meet future reporting requirements and implement related quality improvement efforts. In addition to giving hospitals more advance notice in planning quality reporting, this multiyear approach also provides more time for us to prepare, organize and implement the infrastructure needed to collect data on the measures and make payment determinations. However, we indicated that these finalized measure sets for multiple years could still be updated through the rulemaking process should we need to respond to agency and/or legislative changes.

Finally, in section IV.A.5.a.(2) of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219 through 50220), we adopted a proposal to make Hospital IQR Program payment determinations beginning with FY 2013 using one calendar year of data for chart-abstracted measures. We began using this approach, which synchronizes the quarters for which data on these measures must be submitted during each year with the quarters used to make payment determinations with respect to a fiscal year, beginning with January 1, 2011 discharges. However, it will not affect our payment determinations until FY 2013.

Comment: Some commenters complimented CMS for successfully identifying measures that fall into the six NQS domains which can be used to identify measure gaps in domain areas for future measure development. The commenters strongly believed this approach will signal to the private sectors that the public and private sectors are

progressing toward a common path to improve health care quality. However, one commenter noted that it may be premature to utilize the NQS domains for the purposes of payment determination at this time.

Response: We thank the commenters for recognizing our intent for using the NQS as the framework to attain a cohesive public and private national quality strategy to achieve the overarching goal of improving patient care quality across the full healthcare spectrum. We point out that the NQS is intended to be used to identify gap areas in the program, but that individual measures considered for the Hospital IQR Program will continue to be evaluated against the more specific criteria articulated for the Hospital IQR Program.

Comment: Many commenters highly commended CMS for moving the Hospital IQR Program in the right direction by essentially transforming a set of discrete process measures aimed at internal quality improvement to a comprehensive quality reporting program that addresses the needs of consumers and purchasers by including meaningful measures of outcomes, patient experience, and patient safety. The commenters commended CMS' efforts to foster transparency in healthcare quality and believed this approach incentivizes quality improvement and promotes better care, better value, and lower cost. One commenter praised our previous efforts to adopt measures for three consecutive payment determinations.

Response: We are encouraged by the public support of our efforts to promote high-quality care, improve patient outcomes and make quality data publicly available for consumers. We will continue to strive to improve the Hospital IQR Program.

Comment: For program alignment, one commenter suggested CMS should deem a hospital as a meaningful user as required under the HITECH EHR Incentive Program if it participates in the Hospital IQR Program.

Response: It would not be possible to deem Hospital IQR Program participating hospitals as meaningful users under the EHR Incentive Program. We note that aside from quality measure reporting, meaningful users under the HITECH EHR Incentive Program also have other program requirements with which to comply.

Comment: For burden reduction purposes, several commenters recommended that CMS limit data collection for clinical process of care measures to aggregate performance levels only and, in addition, closely monitor the association of process with outcomes, such as mortality and readmission rates.

Response: We thank the commenters for these suggestions. We have found that to fully address the relationship between clinical processes of care and patient outcomes, the analysis of patient level data on processes of care with individual patient level outcomes is necessary. We intend to continue monitoring this association using these data.

Comment: A commenter praised CMS for driving the portfolio of programs administered via the IPPS to be more aligned with what private sector purchasers and payers are doing to improve care and reduce costs. The commenter recommended CMS develop a parsimonious list of high-impact measures suitable for both private purchasers/payers and public purchasers/payers through collaboration with private and state purchasers during pre-rulemaking, using the MAP process. Many commenters

applauded CMS' recognition of recommendations from the MAP in this proposed rule. The commenters noted that the MAP recommends a unified data strategy for public and private sectors, a standardized data platform, approaches to performance-based payment, and use of NQF-endorsed measures.

Response: We thank the commenters for the commendations. We value the recommendations of the MAP and considered these recommendations carefully in determining the measure proposals to include in this year's rulemaking. In adopting many of the MAP's recommendations while giving priority to measures that have high impact in terms of mortality, morbidity, volume and cost, that could be applicable to both the private and public sectors, we feel that we have developed a portfolio of high impact measures that are suitable for use by both private and public purchasers, even though some of the measures in the Hospital IQR Program are not NQF-endorsed. We have adhered to the pre-rulemaking process as required under section and 1890A(a) of the Act in the selection of quality and efficiency measures. As part of this process, we made available to the public a list of the measures described in section 1890(b)(7)(B) of the Act that the Secretary was considering under Title XVIII of the Act.

Comment: For the future growth of the Hospital IQR Program and burden reduction purposes, some commenters recommended that all new measures proposed for the Hospital IQR Program should: (1) align with objectives of the National Priorities Partnership, HHS Strategic Plan and the NQS; (2) align with criteria for meaningful use of EHRs; (3) avoid duplicative reporting via both chart-abstraction and e-reporting; and (4) avoid measures of broad or global facility populations.

Response: We thank the commenters for their valuable suggestions and we will take them into consideration in our future measure proposals.

b. Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

(1) Process for Retention of Hospital IQR Program Measures Adopted in Previous Payment Determinations

We previously finalized 76 measures for the FY 2015 Hospital IQR Program measure set (76 FR 51636 through 51637). We note that this number includes the four measures for which we have suspended data collection.

In past rulemakings, we have proposed to retain previously adopted measures for each payment determination on a year-by-year basis and invited public comment on the proposal to retain such measures for all future payment determinations unless otherwise specified. Specifically, for the purpose of streamlining the rulemaking process, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28038), we proposed that when we adopt measures for the Hospital IQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. We invited public comment on this approach.

Comment: Some commenters supported CMS' proposed policy to automatically retain all previously adopted measures for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. Some commenters opposed the automatic retention of measures because they were concerned that the public may miss an

opportunity to comment on the measures and potential changes to them. These commenters recommended that CMS propose to retain previously adopted measures through rulemaking on a year by year basis.

Response: We thank the commenters for their support of the proposed retention of quality measures from previous payment determinations. Regarding the opportunity for the public to comment on the measures and potential changes to them, automatic retention of measures in the program does not preclude the public from submitting comments on measures in the program, and we post the specifications for the measures used in the program publicly on the QualityNet Web site with updates issued at regular 6-month intervals. Whether NQF-endorsed or not, we consistently maintain the measures used in the program. Should there be changes in scientific evidence or health care delivery models, or if patient safety concerns arise, we will evaluate the adopted measures accordingly. NQF-endorsed measures also undergo a full maintenance review with public comment every three years. The purpose of retaining measures automatically is to streamline the regulation process and make it more efficient.

Comment: A commenter reported significant improvement in the appropriate interventions provided for AMI, HF, PN, and surgical care-hospitalized patients since the initial implementation of the 10 starter measures in 2003 and urged CMS to continue to retain these inpatient measures.

Response: We note that some of the measures in the 10 starter measures were removed for different reasons in previous rulemakings. We thank the commenter for

their support and will consider the suggestion regarding retaining the remaining measures in the 10 starter measures in making future proposals.

Comment: A commenter was concerned about the increasing number of chart-abstracted and structural measures in the Hospital IQR Program. The commenter recommended that CMS exclude the four structural measures as well as the chart-abstracted Stroke and VTE measure sets from the Hospital IQR Program.

Response: We will consider these suggestions for future removal of measures from the program. Our understanding is that, although required collection of the previously adopted Stroke and VTE measures for the Hospital IQR Program will begin with January 1, 2013 discharges, many hospitals already have experience collecting and reporting one or both of these measure sets either to TJC, or to a registry. The structural measures impose minimal burden to hospitals.

We also received some comments on some of the measures that we have previously adopted and proposed to retain.

Comment: A commenter was concerned that in some cases, the ED-1: Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital from the emergency department (ED) measure that was finalized for the FY 2014 payment determination in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50210 through 50211) may be inflated to span days in some cases. The commenter gave an example that a patient may go to the ED, be sent home, return to the ED, and be admitted to the hospital, all over the course of 2 days. The commenter noted that the Medicare billing structure rolls up these 2 ED visits into one single episode of

care and thus the median time from ED to time of departure from the ED would appear to span days.

Response: The commenter is correct that in some instances, the timeframe for ED visits may span 2 calendar days reflecting Medicare billing processes and structures. We are aware of this issue and are working to address these concerns and will review the impact of this situation during upcoming technical expert panel meetings. We are also tracking the frequency in which scenarios like the one described occur in order to determine the impact of this billing process.

Comment: A commenter requested that the ED-1 and ED-2 measures not apply to patients who suffer sexual assault and domestic violence because forensic evidence must be collected from these patients and application of the measures may compromise the time needed to stabilize and treat these patients.

Response: We thank the commenter for the suggestion. However, we believe that all patients, no matter what their situation, should be seen and treated in the ED in a timely manner. The measure does not place time constraints on any type of treatment provided during an ED visitor indicate how much time provision of care in the ED should take. Therefore, we do not agree that patients who are being treated in the ED because they are victims of domestic violence or sexual assault should be excluded from the measure population.

Comment: A commenter recommended the exclusions of various patients from the Influenza Immunization and Pneumococcal Immunization measures that were finalized for the FY 2014 payment determination in the FY 2011 IPPS/LTCH PPS final

rule (75 FR 50210 through 50211) as follows: left against medical advice, transferred to another hospital, discharged to hospice, documentation of comfort measures only.

Response: We agree with the commenter and accordingly, beginning with January 1, 2013 discharges, the Specifications Manual includes exclusions for patients transferring to another acute care facility and patients who leave against medical advice. The manual informing January 1, 2013 discharges was published in July 2012, and includes these changes. Patients who leave against medical advice cannot realistically be given vaccinations if they have already left the facility. Patients transferred to another facility for completion of medical care, vaccinations would be completed by the accepting facility. With these exclusions, the likelihood for double counting a patient is removed, and attribution is correctly achieved for this metric. We do not believe that patients discharged to hospice or those with orders for comfort measures only, should be excluded from the denominator because a secondary infection, potentially resulting from withholding of a vaccination, in this vulnerable population could reduce quality of life.

Comment: A commenter suggested that the measure specification of the SCIP INF-4 (Cardiac surgery patients with controlled 6AM postoperative serum glucose) should be updated to reflect the recent NQF maintenance review updates. The updates would mean changing the 6AM time frame to the currently endorsed time frame of 18 to 24 hours post operative. The commenter also stated that the Specifications Manual should clearly indicate post-operative states.

. Response: We thank the commenter for the suggestion. We will evaluate the nature of this change, as well as the optimal timing for instituting system changes, and

downstream impacts for other programs before determining whether an update can be made to the Specifications Manual.

Comment: One commenter recommended moving the implementation date of the Healthcare Personnel Influenza Vaccination measure from the FY 2015 payment determination to the FY 2014 payment determination. Another commenter recommended delaying the reporting of the measure on Hospital Compare because CDC/NHSN has significantly revised the measure with new data collection protocols, forms, and reports. The commenter noted that hospitals need to gain experience with the data collection process prior to public reporting of the information.

Response: We will continue to require reporting of this measure for the Hospital IQR Program for patients discharged on or after January 1, 2013. In response to the comment regarding the need for experience with the revised CDC/NHSN data collection process prior to public reporting, we will allow the first submission of cases spanning October 1, 2012 to December 31, 2012 to be on a voluntary basis, and we will not publicly report the first submission on Hospital Compare. We will plan to begin public reporting with the second submission of the Healthcare Personnel Influenza Vaccination measure, which would span the complete flu season from October 1, 2013 through March 30, 2014, in December of 2014.

Comment: Two commenters strongly supported the retention of the Stroke measure set even though they may be burdensome because commenters believed these are important for measurement of stroke care.

Response: We thank the commenters for the support of the Stroke measure set. We note that the e-specifications for these 2 measure sets have been completed. We anticipate that once hospitals have acquired the capability to submit data on measures electronically at a future date, such as 2015, the burden will be reduced significantly.

Comment: One commenter noted that the names of the measures in the VTE measure set should be updated to align with TJC's measure names.

Response: We thank the commenter for the input. To maintain alignment between CMS and TJC, we have updated the inpatient Specifications Manual to reflect TJC VTE measure set names.

Comment: One commenter requested delaying the implementation of the MRSA Bacteremia and the C. difficile measures by one year to allow CMS and CDC to collaborate in developing and maintaining a set of technical specifications for the detection and reporting of LabID events from laboratory information systems.

Response: We note that CDC has developed specifications for detecting and reporting LabID events and is prepared to provide the specifications and assistance to implementers. The technical specifications are simply instructions for how to collect and submit the measure using healthcare data that are available in electronic form. However, these detection specifications do not change the measure. Therefore, we believe that there is no need to delay the implementation of these two measures.

After consideration of the public comments we received, we are finalizing the measure retention policy as proposed.

(2) Additional Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636 through 51637), we finalized 17 new measures for the Hospital IQR Program measure set for FY 2015 payment determination: 3 HAI measures collected through the NHSN, (MRSA Bacteremia, C. difficile SIR, and the Healthcare Personnel Influenza Vaccination), the Stroke measure set (8 measures) and the VTE measure set (6 measures).

(A) New Survey-Based Measure Items for Inclusion in the HCAHPS Survey Measure for the FY 2015 Payment Determination and Subsequent Years

For the FY 2015 payment determination and subsequent years, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28038), we proposed to add the NQF-endorsed 3-Item Care Transition Measure (CTM-3) (NQF #0228) to the existing HCAHPS survey. This measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The CTM-3 was developed by the University of Colorado Health Sciences Center for the NQF Endorsement Project entitled "National Voluntary Consensus Standards for Quality of Cancer Care." The MAP supports the immediate inclusion of the CTM-3 within the Hospital IQR Program. The three care transitions items that comprise the CTM-3, which we proposed to add to the HCAHPS survey beginning with January 2013 discharges, are listed below. Detailed information on scoring methodology can be found on the Care Transition Measure Web site: http://www.caretransitions.org/documents/CTM3Specs0807.pdf.

The HCAHPS Survey was designed to accommodate the addition of supplemental items, provided such items adhere to the relevant HCAHPS survey protocols, see HCAHPS Quality Assurance Guidelines V7.0, p. 72: http://www.hcahpsonline.org/files/HCAHPS%20Quality%20Assurance%20Guidelines%20V7.0%20March%202012.pdf. The survey items that comprise the CTM-3 that we propose to add to HCAHPS meet these protocols. The addition of select items to HCAHPS is consistent with the survey's original design, development and NQF endorsement. Further, the CTM-3 was designed by its developers to be consistent and compatible with extant HCAHPS items and HCAHPS sampling and survey administration protocols. The original, NQF-endorsed CTM-3 items and response options are as follows:

- The hospital staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left the hospital.

  □ Strongly Disagree

  □ Disagree

  □ Agree

  □ Strongly Agree

  □ Don't Know/Don't Remember/Not Applicable

- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.

  □ Strongly Disagree

  □ Disagree

□ Agree

□ Strongly Agree

□ Don't Know/Don't Remember/Not Applicable

- When I left the hospital, I clearly understood the purpose for taking each of my medications.

□ Strongly Disagree

□ Disagree

□ Agree

□ Strongly Agree

□ Don't Know/Don't Remember/Not Applicable

In order to make the CTM-3 items more fully consistent and compatible with the original HCAHPS Survey items, we have made a few small modifications. Specifically, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28038), we proposed: (1) to slightly reword the first care transition item by adding the phrase, "During this hospital stay;" (2) to delete the "Don't Know/Don't Remember/Not Applicable" response option from each item; and (3) to add a new response option, "I was not given any medication when I left the hospital," to the third care transition item. These small modifications preserve the integrity and utility of the HCAHPS Survey as it is expanded to encompass a new dimension of patients' experience of hospital care. The developer of the CTM-3 has agreed to these modifications, which we believe are consistent with the NQF endorsement of the original 27-item HCAHPS Survey and the CTM-3.

After incorporating these modifications, the CTM-3 items that we proposed to add to the HCAHPS Survey are as follows:

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.

  □ Strongly disagree

  □ Disagree

  □ Agree

  □ Strongly agree

- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.

  □ Strongly disagree

  □ Disagree

  □ Agree

  □ Strongly agree

- When I left the hospital, I clearly understood the purpose for taking each of my medications.

  □ Strongly disagree

  □ Disagree

  □ Agree

  □ Strongly agree

  □ I was not given any medication when I left the hospital

We also proposed to add two items to the "About You" section of the HCAHPS survey beginning with January 2013 discharges. These two items would not be included in public reporting of the HCAHPS survey but may be employed in the patient-mix adjustment of survey responses.

The two proposed "About You" items are as follows:

- During this hospital stay, were you admitted to this hospital through the Emergency Room?

 Yes

 No

- In general, how would you rate your overall mental or emotional health?

 Excellent

 Very good

 Good

 Fair

 Poor

The two new "About You" items were developed and tested in the Three-State Pilot Study of HCAHPS in 2003. Neither item was adopted in the national implementation of HCAHPS in 2006; however, current circumstances, as explained below, warrant the addition of these items to the HCAHPS survey at this time.

We invited public comment on the three proposed CTM-3 items.

Comment: Commenters expressed support for the CTM-3 items.

Response: We thank the commenters for their support for the CTM-3 items. Inclusion of these tested and well-accepted questions will enable HCAHPS to report on transition of care measures as part of its overall public reporting program.

Comment: One commenter stated that the response options for the CTM-3 items are different from those of existing HCAHPS questions and that this may confuse respondents as well as pose a challenge for hospital public reporting.

Response: The current HCAHPS questionnaire includes a variety of response sets, depending upon the questions being asked. It is standard practice within survey research to use different response sets for different questions within a single questionnaire. Asking respondents to agree or disagree with statements is a common response set option. We have no evidence that a variety of response sets confuses respondents or poses a significant challenge for hospital public reporting.

Comment: Some commenters stated that some of the CTM-3 items appear to be redundant with items already on the HCAHPS survey and are not distinct enough to warrant inclusion.

Response: Similar items do exist in the current survey, but they are asked in contexts other than care transitions. For example, current HCAHPS questions about medications are asked in the context of the hospital environment, rather than care transitions. Accordingly, we believe the CTM-3 is appropriate for inclusion in the HCAHPS survey.

Comment: One commenter believed that the CTM-3 item on medications will not be answered accurately or will confuse patients and should be limited to new medications.

Response: Testing has not revealed any issues with this item. In addition, the wording of the item reflects a wide variety of scenarios, including situations in which patients were handed prescriptions, or actual medications, when they left the hospital. The item is intended to measure the degree to which patients feel they understand the purpose for all of their medications as they transition to another care location. It is not intended to focus solely on new medications that may have been prescribed at the hospital.

Comment: Commenters expressed their belief that the CTM-3 item regarding "care needs" is really about patient preferences, not care transitions.

Response: The CTM-3 item regarding "care needs" asks patients about an issue that patients have identified in qualitative studies as critically important to care coordination when leaving the hospital.

Comment: Comments suggested that the CTM-3 items be reworded for clarity, to make them easier to read, to avoid questions that ask patients about both their own preferences and those of the patient's family or caregiver, and to make the response items more similar to other response items already included in the HCAHPS survey.

Response: We carefully reviewed the CTM-3 items for both content and style before proposing their inclusion in the HCAHPS Survey and found no reason to make substantial changes. In terms of content, the CTM-3 was developed to be compatible

with HCAHPS Survey. While the style of the CTM-3 items differs slightly from existing HCAHPS Survey items, our testing indicates this not a problem for patients. In addition, hospitals that currently use the CTM-3 have not reported problems with item wording or confusion with questions that ask patients about their preferences and those of their family or caregiver (which are considered a unit). Finally, the CTM-3 items have been tested by their developer and are NQF-endorsed. While we made some minor modifications to the CTM-3 items and their response options to make them more compatible with other items on the HCAHPS Survey, we are not free to substantially alter either the wording of NQF-endorsed items or to change their response sets without re-submitting them for endorsement.

Until 2010, "emergency room admission" as a point of origin for hospital patients was an administrative code provided by hospitals and was used as a patient-mix adjustment for HCAHPS scores. However, since July 2010, the "Point of Origin for Admission or Visit" code for Emergency Room has been discontinued for use by Medicare payment systems and, thus became unavailable for HCAHPS patient-mix adjustment. In the original HCAHPS mode experiment, we determined empirically that emergency room admission status both vary across hospitals and have an important bearing on patient experience of care: http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf. The inclusion of a new patient-reported survey item will allow us to again use emergency room admission as a patient-mix adjustment variable.

We have received numerous inquiries and requests from hospitals and researchers to add a survey item concerning the patient's overall mental health. The survey item we proposed to add, which is very similar in structure to the existing "overall health" item, will allow us to introduce a patient-mix adjustment for this characteristic in the future. Although we chose not to add a survey item about patient's overall mental health status in the national implementation of HCAHPS in 2006, we continue to receive inquiries and requests from hospitals and researchers on this topic. Some researchers claim that mental health status is an important factor in how patients respond to HCAHPS survey items. The continuing interest in this topic, coupled with the direct impact of HCAHPS performance on hospital payments beginning in October 2012, led to the decision to add an overall mental health item to the HCAHPS survey. The overall mental health survey item we have chosen very closely resembles the Overall General Health item in the HCAHPS Survey, has been extensively tested, and is currently included in several other CAHPS surveys.

We proposed to add these two "About You" items to the existing HCAHPS survey, with required collection beginning January 1, 2013. More detail regarding HCAHPS requirements is included in the Form, Manner and Timing section of this preamble for this program. We invited public comment on the proposed addition of these items for the FY 2015 payment determination.

Comment: Commenters on the mental/emotional health status rating question believed that the item is too sensitive and that it constitutes a self-diagnosis of psychiatric conditions. Commenters also asked whether the item has been tested and how it will be

used in case-mix adjustment and expressed concern that responses to this question might put the hospital in the position of having information that might or might not be in the medical record.

Response: Cognitive testing across a variety of populations, including commercial, Medicare and Medicaid populations, has revealed no respondent hesitancy to answer this question. This item does not request self-diagnoses, but merely a rating of perceived mental or emotional health status. There is a body of literature to indicate that single-item health perception measures (overall ratings) are substantially correlated with long-form (multi-item) measures of physical and emotional health. This is a well-established approach to capturing general health perceptions. The mental/emotional health item is one of the oldest and best-validated items in patient surveys; it has been successfully fielded on Medicare CAHPS surveys since 2002. The HCAHPS project team has received many requests to adjust HCAHPS scores for perceived mental/emotional health status. We will be looking at the feasibility of making patient mix adjustments using this item. Asking patients for a self-assessment of their mental and/or physical health is a well-established survey item that has been successfully used in many contexts, including other CAHPS surveys. Patient responses to this and other HCAHPS items are collected after discharge, and thus, are not in hospitals' possession during the hospitalization or part of the patient medical record. Finally, responses to this item do not constitute a clinical assessment of the patient's mental or emotional health, nor do they constitute a self-diagnosis. They relate to the patient's perception of his or her mental or emotional health.

Comment: Commenters on the question about being admitted through the hospital ED believed that patients may not be able to accurately report whether they were admitted through the ED and that administrative data are preferable to self-reports as a source of this information. One commenter said the item has the potential to decrease the confidence of their patients because the patients may perceive that the hospital should already know this information. A commenter asked whether the validity of the item had been tested.

Response: The ''Point of Origin for Admission or Visit'' code for Emergency Room was discontinued for use by Medicare payment systems in July 2010 and became unavailable for HCAHPS patient-mix adjustment. The inclusion of a new patient-reported survey item will allow us to again use emergency room admission as a patient mix adjustment variable if it is shown to influence response tendencies. The emergency room admission self-report question was included in the original HCAHPS three-State pilot study in 2003. In that study we were able to compare patient self-reports with administrative data and found that the patient self-report is a valid indicator of whether the patient had been admitted through the ED. Prior testing did not reveal a pattern of decreased patient confidence resulting from this item. Patients who are unsure about their admission origin may leave this question unanswered.

Comment: Commenters suggested that the addition of the CTM-3 and two About You items will increase the survey's length, resulting in a reduced response rate, more administrative difficulties, and higher costs for hospitals. Commenters suggested that we

develop a core set of items, plus a rotating set of items in order to keep the survey short, but allow for the inclusion of new topics.

Response: We have not found issues with survey administration of instruments that are more than twice as long as Hospital CAHPS. Many vendors currently add questions to the HCAHPS questionnaire. As many as 25 additional items are now being successfully fielded as part of the HCAHPS survey. We believe that adding five items is unlikely to substantially impact either the cost or the difficulty of administering the survey. We are, however, concerned that using a set of rotating questions would unnecessarily increase the complexity, cost, and difficulty of survey administration for both hospitals and vendors.

After consideration of the public comments we received, we are adopting the proposed changes as final.

(B) New Claims-Based Measures for the FY 2015 Payment Determination and Subsequent Years

(i) Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1550)

The THA and TKA are commonly performed procedures for the Medicare population to improve quality of life. In 2003, there were 202,500 THAs and 402,100 TKAs performed,[55] and the number of procedures performed annually has increased steadily over the past decades. Annual hospital charges are projected to increase by 340

[55] Kurtz S, Ong K, Lau E, Mowat F, Halpern M., Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780-785.

percent to $17.4 billion for THA and by 450 percent to $40.8 billion for TKA by 2015.[56] The post-operation complications of these procedures are high considering these are selective procedures and usually the complications are devastating to patients. For example, rates for periprosthetic joint infection, a rare but devastating complication, have been reported at 2.3 percent for THA/TKA patients with rheumatoid arthritis,[57] and 1.6 percent in primary elective TKA patients after 1 and 2 years of follow up, respectively.[58] Two studies reported 90-day death rates following THA at 0.7 percent[59] and 2.7 percent.[60] Reported rates for pulmonary embolism following TKA range from 0.5 percent to 0.9 percent. [61,62,63,64] Reported rates for septicemia range from 0.1 percent, during the index admission[65] to 0.3 percent, 90 days following discharge for primary TKA.[66] Rates for bleeding and hematoma following TKA have been reported at 0.94

---

[56] Kurtz SM, Ong KL, Schmier J, et al., Future clinical and economic impact of revision total hip and knee arthroplasty. J Bone Joint Surg Am. Oct 2007;89 Suppl 3:144-151.
[57] Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713-1720.
[58] Kurtz S,Ong K,Lau E,Bozic K,Berry D,Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.
[59] Cram P,Vaughan-Sarrazin MS,Wolf B,Katz JN,Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675-1684.
[60] Soohoo NF,Farng E,Lieberman JR,Chambers L,Zingmond DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363-2371.
[61] Cram P,Vaughan-Sarrazin MS,Wolf B,Katz JN,Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675-1684.
[62] Mahomed NN,Barrett JA,Katz JN, et al. Rates and outcomes of primary and revision total hip replacement in the United States medicare population. *J Bone Joint Surg Am.* Jan 2003;85-A(1):27-32.
[63] Khatod M,Inacio M,Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812-819.
[64] Solomon DH,Chibnik LB,Losina E, et al. Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536-1542.
[65] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152-156.
[66] Cram P,Vaughan-Sarrazin MS,Wolf B,Katz JN,Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675-1684.

percent[67] to 1.7 percent.[68] In 2005, annual hospital charges totaled $3.95 billion and $7.42 billion for primary THA and TKA, respectively.[69] Combined, THA and TKA procedures account for the largest payments for procedures under Medicare.[70]

Both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, and the volume and cost associated with these procedures are very high. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

The Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure (NQF # 1550) is an outcome measure. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28039), we proposed this measure for the Hospital IQR Program because outcome measures are priority areas for the Hospital IQR Program. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures and publicly report the hospital rates for consumer choice of care.

The proposed measure assesses complications occurring after THA and TKA surgery from the date of the index admission to 90 days post date of the index admission. The outcome is one or more of the following complications: acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding,

---

[67] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152-156.
[68] Huddleston JI,Maloney WJ,Wang Y,Verzier N,Hunt DR,Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1):95-100.
[69] Kurtz S, Ong K, Lau E, Mowat F, Halpern M., Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780-785.
[70] Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008;23(6 Suppl 1):133-138.

pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. The data indicated that the median hospital-level risk-standardized complication rate for 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals. The variation in complication rates suggest that there are important differences in the quality of care delivered across hospitals, and that there is room for quality improvement.

In 2010, we developed a hospital-level risk-standardized complication rate (RSCR) following elective primary THA and TKA surgery. NQF endorsed this THA and TKA complication measure in February 2012 (NQF #1550). In its Pre-Rulemaking Report for 2012, the MAP also recommended the inclusion of this measure in the Hospital IQR Program. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28040), we proposed to adopt the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure for the Hospital IQR Program for the FY 2015 payment determination and subsequent years. This measure is NQF-endorsed (NQF #1550); therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure specifications can be found at: http://www.qualityforum.org/Projects/Surgery_Maintenance.aspx#t=2&s=&p=.

The proposed measure uses the same hierarchical logistic modeling (HLM) methodology that is specified for other NQF-endorsed CMS inpatient outcome measures previously adopted for this program, including AMI, HF, and PN readmission and mortality measures because this modeling has already been subjected to NQF review, and

has been determined to appropriately account for the types of patients a hospital treats, the number of patients it treats, and the quality of care it provides. The HLM model estimates risk-standardized complications rates. Medicare Part A and Part B (FFS) claims are the data source we used to develop the measure and that we proposed to use to calculate the measure if finalized. Index admission diagnoses and in-hospital comorbidities would be assessed using Medicare Part A claims. Additional comorbidities prior to the index admission would be assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment and post-discharge mortality status would be obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

The proposed Total Hip and Total Knee Arthroplasty Complication measure includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-Federal acute care hospitals for THA or TKA. The measure methodology identifies eligible index admissions, using the following ICD-9-CM procedure codes: 81.51 Total Hip Arthroplasty; and 81.54 Total Knee Arthroplasty in Medicare Part A inpatient claims data. The measure specifications will be updated yearly and will be specified using ICD-10.

In addition, the proposed measure includes patients who have had continuous enrollment in Medicare FFS for one year prior to the date of index admission to ensure full data availability for risk adjustment. We restrict the sample to admissions of patients enrolled in Medicare FFS coverage in the 12 months prior to and including the time of

their index admission to a non-Federal acute care hospital because of the availability of complete administrative data for most Medicare FFS patients.

The proposed measure does not include beneficiaries enrolled in Medicare Managed Care ("Medicare Advantage") plans because only partial administrative data are reported to CMS. We would not have complete data on these Medicare Advantage enrollees. Patients under age 65 (the qualifying age for Medicare coverage for those not considered disabled or with end-stage renal disease) or for whom we otherwise have incomplete information—for example, those enrolled in a Medicare Advantage plan during any part of the relevant time period— will also be excluded to ensure data comparability. These restrictions on the data also allow for an appropriately comprehensive risk-adjustment for patient case-mix and comorbidity that would not be possible without access to data available to this population.

The proposed measure excludes patients with hip fractures (patients with hip fractures have higher mortality, complication rates and the procedure (THA) is not elective); patients undergoing revision procedures (may be performed at a disproportionately small number of hospitals and are associated with higher mortality, complication and readmission rates); patients undergoing partial hip arthroplasty (primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions); patients undergoing resurfacing procedures (different type of procedure which is typically performed on younger, healthier patients); patients who are transferred to the index hospital (it is likely that the procedure is not elective); patients who leave the hospital against medical advice (it is

likely that the procedure is not elective); patients with more than two THA/TKA procedure codes during the index hospitalization (unlikely that patients would receive more than two THA/TKA procedures in one hospitalization, and this pattern may reflect coding errors); and patients with multiple admissions for THA/TKA in the 12 months studies.

Consistent with the requirements in section 1886(b)(3)(B)(viii)(VIII) of the Act, the proposed measure is risk-adjusted. It takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the Hierarchical Condition Categories (CC), which are clinically relevant diagnostic groups of ICD-9-CM codes.[71] The CCs used in the risk adjustment model for this measure, are provided at: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1182785083979. The proposed measure meets the statutory requirement because it adjusted for hospital patient mix including age and comorbidities to ensure that hospitals that care for a less healthy patient population are not penalized unfairly. The measure methodology defines "complications" as Acute myocardial infarction; Pneumonia; Sepsis/septicemia; Pulmonary embolism; Surgical site bleeding; Death; Wound infection; Periprosthetic joint infection; and Mechanical complication within 30 to 90 days post the index date of admission, depending on the complication. The decision on the appropriate follow-up period was based on our analysis of 90-day trends in complication rates using the 2008 Medicare FFS Part A Inpatient Data. We found that rates for mechanical complications are elevated until 90 days post the date of

[71] Pope G, Ellis R, Ash A, et al., Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

index admission. We found that the rates for four other complications – death, surgical site bleeding, wound infection, and pulmonary embolism – are elevated for 30 days, and that AMI, pneumonia, and sepsis/septicemia level off 7 days post date of index admission. The following table presents the follow-up period for each complication.

Complication Follow-up Periods	
Complication	**Follow-up Period**
Death	30 days
Mechanical complications	90 days
Periprosthetic joint infection (PJI)	90 days
Surgical site bleeding	30 days
Wound infection	30 days
Pulmonary embolism	30 days
AMI	7 days
Pneumonia	7 days
Sepsis/septicemia	7 days

We proposed to calculate the hospital risk-standardized complication rate by producing a ratio of the number of "predicted" complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of "expected" complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw complication rate.

We invited public comment on the proposed inclusion of the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty measure in the Hospital IQR Program for the FY 2015 payment determination and future years.

Comment: Many commenters strongly supported this NQF-endorsed and MAP-recommended hip/knee complication measure, stated that the measure will provide valuable data for improvement and enhance patient care, and commended CMS for considering the measure for patients undergoing inpatient joint procedures. Commenters stated that this measure is important in capturing patient outcomes during the post-discharge period, and provides hospitals access to data to which they may not have access otherwise, including a limited set of complications that occur after the patient has left the hospital. A commenter stated that hip and knee replacements are often non-emergent procedures, therefore information on outcomes will give consumers an opportunity to research the quality of care provided in their local hospitals.

Several commenters also supported our exclusion criteria for the hip/knee complication measure, the hierarchical logistic modeling for risk-adjustment, and the inclusion of major bleeds in the list of complications.

Response: We thank the commenters for the support and recognizing the significance of this measure.

Comment: Several commenters did not support this claims-based measure and asserted that the infection data obtained from claims significantly differs from post-operative infection data recorded in medical records and reported to NHSN, which is a better indicator of surgical site infections.

Response: The claims-based hip/knee complications measure underwent a medical record validation process. We found a high level of consistency between the complications found in claims with those found in the medical records. Using the current

specifications, 99 percent of patients were found to have a complication in the claims as well as in the medical records.

Comment: A few commenters noted this measure does not have adequate adjustment for socioeconomic status (SES) and psycho-social support, and recommended such adjustments be made prior to implementation.

Response: The measure does not adjust for SES or other patient factors such as psycho-social support because we do not want to hold hospitals to different standards of patient care simply because they treat a large number of low SES patients. Moreover, we do not want mask potential disparities in care or minimize incentives to improve the outcomes of care for disadvantaged populations. This is also consistent with the NQF's position regarding risk adjustment, which is that risk-adjusted measures should not include variables such as SES and race that would adjust away disparities in care.

During development and review of the hip/knee measures some stakeholders and experts expressed concerns regarding the influence of patient SES on hip/knee readmission and complication rates. We conducted preliminary analyses to explore disparities by SES (http://www.nysna.org/images/pdfs/practice/nqf_ana_outcomes_draft10.pdf) focusing on the readmission measure where concerns were greatest. We used Medicaid eligibility status identified in the Medicare claims enrollment database (EDB) as a proxy for SES. Patients were categorized into two groups, based on their eligibility status for Medicaid (yes/no). The Medicaid eligible population represents lower SES status. We then estimated the odds ratio for this SES variable by adding it to the hip/knee risk-adjustment

model. The results showed that although SES was an independent predictor of readmission risk (odds ratio of 1.2), adding the variable to the model did not improve the model's overall ability to predict patient readmission risk. When the SES variable was added, the strength of clinical variables in the model was attenuated and the model c-statistic was essentially unchanged. This analysis suggested that the clinical variables in the model are adequately accounting for differences in patients' risk of readmission. The results were presented to the national Technical Expert Panel for the hip/knee measures. Based on these analyses, we did not include SES as a risk-adjuster in either of the hip/knee measures.

However, we are committed to tracking this issue and will continue to evaluate disparities in care and the impact of the hospital risk- standardized complication rates on providers of vulnerable populations.

Comment: One commenter was concerned about the unintended consequence of the Hip/Knee Complications measure for rheumatoid arthritis patients who are at high risk for infection. In particular, the commenter was concerned that this measure could cause hospitals to hesitate to perform the total hip/knee arthroplasty procedure on patients with rheumatoid arthritis.

Response: The hip/knee measures include risk-adjustment in order to level the playing field and account for differences in the risk between the case-mix at different hospitals. Rheumatoid arthritis is one of the risk-adjustment variables, so any increased risk associated with patients that have rheumatoid arthritis will be accounted for by the measure.

Comment: A few commenters requested clarifications regarding several aspects of the proposed measure: complications attributable to the process of care, unrelated complications, POA complications, and the measurement period. Another commenter was concerned that data analysis of this measure is challenging and difficult for consumers to interpret. The commenter inquired about the level of data that will be made available to providers and suggested that providing detailed information regarding the count by complication and cohort would help quality improvement efforts.

Response: The commenter appears to be asking for clarification about why complications attributable to the processes of care and unrelated complications are included. The hip/knee complications measure is designed to capture complications related to both the surgical and medical care provided for elective hip/knee procedures. The outcome, therefore, includes both medical and surgical complications. The timeframe for each was chosen based on the typical window in which each of these complications occurs. Specifically, the measure counts in the outcome: AMI, pneumonia, or sepsis/septicemia during the admission or within 7 days of the admission date; surgical site bleeding, pulmonary embolism or death during the admission or within 30 days of admission; or mechanical complications or PJI or wound infection during the admission or within 90 days of admission. We included these outcomes because they are clinically related to care provided as documented in the literature and informed by extensive expert input. The measure is structured so that it does not count complications that are present on admission. For example, patients with mechanical complications on admission are excluded from the measure. To help hospitals with their quality

improvement effort, we will provide hospitals with their hospital-specific report with detailed information about the patients included in the measure. We will share with hospitals this report prior to posting of the measures on the Hospital Compare Web site during the 30-day preview period for the Hospital IQR Program. We welcome specific suggestions on additional data that would be helpful for hospital quality improvement.

Comment: A commenter requested the publication of the ICD-10-CM/PCS versions of the measure specifications in the final rule.

Response: We are working on specifying the measures using the ICD-10-CM/PCS and will make the specifications available to the public as soon as possible.

After consideration of the public comments we received, we are finalizing the proposed Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure for the FY 2015 payment determination and subsequent years as proposed.

(ii) Hip/Knee Readmission: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1551)

As previously stated, outcome measures such as complications and readmissions are the priority areas for the Hospital IQR Program. The THA and TKA are commonly performed procedures that improve quality of life. The complications are usually devastating to the patient and costly to the Medicare program. Furthermore, we believe

that there is an opportunity for quality improvement by hospitals to improve quality of life for the patient. The 2008 Medicare FFS claims data indicate that 30-day hospital-level risk-standardized readmission rates ranged from 3.06 percent to 50.94 percent among hospitals with a median rate of 6.06 percent. The mean risk-standardized readmission rate was 6.3 percent. This variation suggests there are important differences in the quality of care received across hospitals, and that there is room for improvement. Given the high volume and high cost associated with these hip and knee procedures (relative to other elective procedures performed in the Medicare population), we believe that it is imperative to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures. A measure that addresses readmission rates following THA and TKA provides an opportunity to provide targets for efforts to improve the quality of care and reduce costs for patients undergoing these elective procedures. The measure also increases transparency for consumers and provides patients with information that could guide their choices. Finally, it has the potential to lower health care costs associated with readmissions. The development of risk-adjusted measures of patient readmission outcomes can provide a critical perspective on the provision of care, and support improvements in care for the Medicare patient population following THA/TKA hospitalization.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28041), we proposed to adopt the Hip/Knee Readmission: Hospital 30-Day All-Cause Readmission Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure for the Hospital IQR Program for the FY 2015 payment determination and subsequent years.

This measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure specification for this measure can be found on the Web site at: http://www.qualityforum.org/Projects/Surgery_Maintenance.aspx#t=2&s=&p= In its Pre-Rulemaking Report, the MAP recommended the inclusion of this measure in the Hospital IQR Program. The objective of this proposed measure is to assess readmission from any cause within 30 days of the initial total hip arthroplasty and total knee arthroplasty admissions for patients discharged from the hospital following elective primary THA and TKA.

The proposed measure uses the same HLM methodology that is specified for the NQF-endorsed AMI, HF, and PN 30-day risk-adjusted all-cause readmission measures in the Hospital IQR Program because it has already been subjected to NQF review and has been determined to appropriately account for the types of patients the hospital treats, the number of patients it treats, and the quality of care it provides. The HLM model estimates risk-standardized readmission rates. The data source we used to develop the measure and that we would use to calculate the measure if finalized is Medicare Part A (FFS) claims. Index admission diagnoses and in-hospital comorbidity data would be assessed using Medicare Part A claims. Additional comorbidities prior to the index admission would be assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment status would be obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

The proposed measure includes admissions for patients who were Medicare FFS beneficiaries, aged 65 years or older, admitted to non-Federal acute care hospitals with an ICD-9-CM code for THA or TKA. Eligible index admissions would be identified using the following ICD-9-CM procedure codes: 81.51 (Total hip arthroplasty); and 81.54 (Total knee arthroplasty) in Medicare Part A inpatient claims data.

In addition, patients must have had continuous enrollment in Medicare FFS for one year prior to the date of index admission to ensure full data availability for risk adjustment. We restrict the included cases to admissions of patients enrolled in Medicare FFS coverage in the 12 months prior to and including the time of their index admission to a non-Federal acute care hospital because of the availability of complete administrative data for most Medicare FFS patients.

We proposed not to include beneficiaries enrolled in Medicare Managed Care ("Medicare Advantage") plans because only partial administrative data are reported to CMS. We would not have complete data on these Medicare Advantage enrollees. Patients under age 65 (the qualifying age for Medicare coverage for those not considered disabled or with end-stage renal disease) or for whom we otherwise have incomplete information—for example, those enrolled in a Medicare Managed Care plan during any part of the relevant time period— will also be excluded to ensure data comparability.

We proposed to exclude patients with hip fractures (patients with hip fractures have higher mortality, complication and readmission rates and the procedure (THA) is generally not elective) patients undergoing revision procedures (may be performed at a disproportionately small number of hospitals and are associated with higher readmission

rates); patients undergoing partial hip arthroplasty (partial arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions); patients undergoing resurfacing procedures (resurfacing procedures are a different type of procedure which are typically performed on younger, healthier patients); patients who are transferred into the index hospital (it is likely that the procedure is not elective); patients who are admitted for the index procedure and subsequently transferred to another acute care facility (attribution of readmission to the index hospital would not be possible in these cases); patients who leave the hospital against medical advice (providers do not have the opportunity to provide the highest quality care for these patients); patients with more than two THA/TKA procedure codes during the index hospitalization (unlikely that patients would receive more than two THA/TKA procedures in one hospitalization and this may reflect a coding error); patients without at least 30-days post-discharge enrollment in Medicare FFS (the 30-day readmission outcome cannot be assessed for the standardized time period); and patients who die during the index admission (patients who die during the initial hospitalization are not eligible for readmission).

The proposed measure methodology does not count readmissions that are associated with a subsequent "planned" THA/TKA procedure within 30-days of discharge from index hospitalization. Some patients may elect to stage their orthopedic replacement procedures across hospitalizations (for example, a patient may have the left and right knees replaced within one or two weeks of each other, potentially across multiple hospitalizations). The planned readmissions are defined as a second admission

with a procedure code for THA or TKA AND a primary discharge diagnosis of osteoarthritis, rheumatoid arthritis, osteonecrosis, or arthropathy (excluding septic arthropathy).

Consistent with the requirements in section 1886(b)(3)(B)(viii)(VIII) of the Act, the proposed measure is risk-adjusted. It takes into account patient age and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for readmission using diagnosis codes collected from all patient claims one year prior to patient index hospitalization for THA and TKA. The patient diagnosis codes are grouped using Hierarchical Condition Categories (CCs), which are clinically relevant diagnostic groups of ICD-9-CM codes.[72]

The CCs used in the risk adjustment model for this measure, are provided at: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694. Patient risk factors are used to determine how sick the patients are on admission (that is, patient comorbidities). The hospital measure rates are calculated taking into account how sick their patients are. In summary, age and comorbidities present at the time of admission would be adjusted for differences in hospital case mix (patient risk factors).

The proposed measure uses the HLM methodology for risk adjustment. As we do for all the other 30-day readmission measures adopted for the Hospital IQR Program, we would calculate (using the HLM) the hospital risk-standardized readmission rate by producing a ratio of the number of "predicted" readmissions (that is, the adjusted number

[72] Pope G, Ellis R, Ash A, et al., Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

of readmissions at a specific hospital) to the number of "expected" readmissions (that is, the number of readmissions if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw readmission rate.

While the hip and knee complications measure will inform quality improvement efforts targeted toward minimizing medical and surgical complications during surgery and in the recovery phase, the hip and knee readmission measure portrays a broader range of medical and surgical outcomes affected by in-hospital care and the transition to post-acute care. This measure was endorsed by the NQF (#1551) and recommended by the MAP for the Hospital IQR Program in its Pre-Rulemaking report for 2012.

We proposed to include the Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure in the Hospital IQR Program for the FY 2015 payment determination and future years. We invited public comment on this proposal.

Comment: Many commenters supported this measure because elective total hip and knee procedures are on the rise on Medicare beneficiaries; also, the measure is NQF-endorsed and is recommended by the MAP. The commenters believed that hip and knee arthroplasty readmissions are an important measure of patient outcomes and that the measure would positively reduce patient readmissions overall. Another commenter stated that hip and knee replacements are often non-emergent procedures, therefore information on outcomes will give consumers an opportunity to research the quality of care provided in their local hospitals to select where to have these procedures performed.

Response: We thank the commenters for the support and sharing our goal to focus on improving patient outcomes in hip/knee surgical procedures.

Comment: A few commenters supported our exclusion criteria for the hip/knee complication measure and the hierarchical logistic modeling for risk-adjustment. Nonetheless, several commenters argued that there are flaws in its methodology because it does not: differentiate between planned and unplanned readmissions or between related and unrelated readmissions; exclude extreme circumstances (transplant, ESRD, burn, trauma, psychosis, and substance abuse); or adjust for patient characteristics (dual eligible status, race/ethnicity, and SES). Commenters noted that this measure would require extensive measure specification revisions should CMS adopt it for the Hospital Readmissions Reduction Program.

Response: We thank the commenters that supported the risk-adjustment model and the exclusion criteria of this measure. We disagree with commenters that the measure does not differentiate between planned and unplanned readmissions. The measure does identify and not count certain planned readmissions. For example, some patients are admitted within 30 days of the index hospitalization to undergo another elective primary THA/TKA procedure. If a patient undergoes a second elective primary THA/TKA within 30 days of the discharge date for the index admission, and the admission is associated with a primary discharge diagnosis of osteoarthritis, rheumatoid arthritis, osteonecrosis, or arthropathy (excluding septic arthropathy), the readmission is considered "planned" and is not counted as a readmission in the measure.

We used all-cause readmission, rather than narrowly related readmission, to assess performance for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care after an acute hospitalization. Second, readmissions not directly related to hip/knee replacement may still be a result of the care received during hospitalization for the procedure. For example, a patient hospitalized for a hip/knee replacement who developed renal failure may ultimately be readmitted for care. It would be inappropriate to treat this readmission as unrelated to the care the patient received during the index hospitalization. Furthermore, the range of potentially avoidable readmissions also includes those not directly related to the initial hospitalization, such as those resulting from poor communication at discharge or inadequate follow-up. In addition, readmissions for rare reasons completely unrelated to hospital care, such as car accidents involving the patient as a passenger, are likely to be distributed randomly across hospitals and are not expected to introduce any bias into the measure results. We appreciate the concern expressed by the commenters that patients of these "extreme circumstances" clinically could be sicker and likely to be readmitted. The measures address clinical differences in hospitals' case-mix through risk adjustment rather than through excluding patients from the measure as suggested by the commenter. The goal in developing outcomes measures is to create a clinically cohesive cohort that includes as many patients as possible admitted with the given condition. Greatly expanding our list of exclusions would result in a measure that was less useful and meaningful because it would reflect the care of fewer patients. In addition, we believe that by excluding patients with significant comorbidities, the

measure would not assess of the quality of care for those patients. To fairly profile hospitals' performance, it is critical to place hospitals on a level playing field and account for their differences in the patients that present for care. This is accomplished through adequate risk-adjustment for patients' clinical presentation rather than exclusion of patients.

Consistent with NQF guidelines, this measure does not risk-adjust for SES factors, such as race or dual eligibility, because we do not want to hold hospitals to different standards for the outcomes of their low SES patients. We do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations by adjusting for these factors. The findings from our analyses of disparities by SES in the past (discussed in our responses to comments on the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1550)) indicated that although SES is a significant predictor of readmission at the patient level, it does not affect overall hospital performance in the risk-adjusted readmission model. We are committed to tracking SES issues and will continue to evaluate disparities in care and the impact of the hospital risk standardized readmission rates on providers of vulnerable populations.

With respect the commenters' concern that this measure would require extensive measure specification revisions should we adopt it for the Hospital Readmissions Reduction Program, in the FY2013 IPPS/LTCH PPS proposed rule, we proposed use of the measure only for the Hospital IQR Program and not for Hospital Readmissions

Reduction Program. We will propose additional readmission measures for Hospital Readmissions Reduction program through future rulemaking.

Comment: A commenter requested the post-discharge time period be shortened to 7 days.

Response: The measure uses 30 day time frame versus 7 days as suggested by the commenter because it is a clinically meaningful and sufficient time period for hospitals to show the result of their efforts to reduce readmissions. These efforts include ensuring that patients are clinically ready at discharge, reducing risk of infection, reconciling medications, improving communication with community providers participating in transitions of care, educating patients adequately upon discharge, and assuring patients understand follow-up care upon discharge. Furthermore, our analyses show that risk of readmission is highest within the first two weeks post discharge of the index admission. The rate plateaus between 30 and 45 days post discharge, suggesting that a 30-day window would capture the period of highest risk of readmission. In addition, the 30-day timeframe is consistent with the other CMS readmissions measures that are NQF-endorsed and publicly reported by CMS.

Comment: A commenter was uncertain of the impact of the 3-day waiver policy on readmission rates, and cautioned there may be potential negative implications of the waiver policy on this measure. The commenter encouraged CMS to adopt a time period that will ensure sufficient data and rates that are statistically significant and also requested clarification regarding the measurement period for this measure.

Response: We appreciate the commenter's concern and suggestions. It appears that the issue that the commenter is concerned about is whether implementation of the measure would have an impact on use of outpatient services, such as use of ED or observation services 3 days prior to hospitalization. It is our intent to track use of these services as unintended consequences. We plan to use 3 years of data to calculate the hospital rates. We believe this time period would ensure sufficient data for meaningful statistical analysis.

Comment: A commenter requested that CMS clarify whether a single year of data or three years of data will be used for display on Hospital Compare in the future. The commenter believed that three years of data yields more robust and reliable results.

Response: We agree with the commenter that 3 years of data will yield more robust and reliable results. We plan to use 3 years of data to calculate the measure for display on Hospital Compare.

Comment: A few commenters requested the publication of the ICD-10-CM/PCS versions of the measure specifications in the final rule.

Response: We are working on specifying the measures using the ICD-10-CM/PCS and will make the specifications available to the public as soon as possible.

Comment: A commenter opposed the proposed adoption of this measure as the commenter believed readmission rates are more closely related to patient expectations, community standards, health literacy, and other unknown factors during hospitalization, which are not accounted for in the risk models articulated in the rule. The commenter

suggested that there is little correlation between quality of care provided and overall readmission rates.

Response: We believe that readmissions are related to quality of care provided by hospitals during hospitalization as well as transition from inpatient to outpatient settings. We chose to measure readmission within 30 days of discharge because during this period, readmission can be strongly influenced by hospital care and the early transition to the outpatient setting. The timeframe of 30 days is a clinically meaningful period for hospitals to collaborate with their communities in an effort to reduce readmissions. Such efforts may include ensuring patients are clinically ready at discharge, reducing risk of infection, reconciling medications, improving communication with community providers participating in transitions of care, educating patients adequately upon discharge, and assuring patients understand follow-up care upon discharge. The commenter suggested that patient factors such as patient expectations and health literacy are closely related to readmissions. The CMS measure takes into account patient health/clinical factors at the time of admission but not patient's SES factors. One reason is that we want to encourage hospitals to work with their communities to help patients with low SES (for example, low health literacy) transition to post-acute care. The other reason is that risk adjusting for patient SES, we would adjust away potential disparities of care by hospitals.

After consideration of the public comments we received, we are finalizing the proposed Hip/Knee Readmission: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty measure for the FY 2015 payment determination and subsequent years as proposed.

(iii) Hospital-Wide Readmission (tentative NQF #1789)

During 2003 and 2004, over 2.3 million Medicare patients (almost one fifth of all Medicare beneficiaries) were rehospitalized within 30 days of discharge from an acute care hospital, and it was estimated that readmissions within 30 days of discharge cost Medicare more than $17 billion annually.[73] In its 2007 Report to the Congress, MedPAC estimated that in 2005, 17.6 percent of hospital patients were readmitted within 30 days of discharge.[74] MedPAC estimated that the average payment for a "potentially preventable" readmission was approximately $7,200. A 2006 Commonwealth Fund Report estimated that if national readmission rates were lowered to the levels achieved by the top performing regions, Medicare would save $1.9 billion annually.[75] We believe that reducing preventable readmissions will bring down healthcare costs.

Since 2009, we have publicly reported risk-standardized readmission rates (RSRRs) for three conditions: heart failure (HF), pneumonia (PN) and acute myocardial infarction (AMI) on Hospital Compare (http://www.hospitalcompare.hhs.gov/), as part of the efforts to improve quality of care and lower health care costs. However, these three conditions account for only a relatively small proportion of total hospital readmissions. High RSRRs and substantial variations in hospital RSRRs were found. The median 30-day RSRRs across hospitals is 19.9 percent for AMI (range from 15.3 percent to

---

[73] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. Apr 2 2009;360(14):1418-1428.
[74] Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Promoting Greater Efficiency in Medicare. 2007.
[75] The Commonwealth Fund, Why Not the Best? Results from a National Scorecard on U.S. Health System Performance. 2006: Harrisburg, PA.

26.8 percent); 24.8 percent for HF (range from 17.0 percent to 33.0 percent); and 18.4 percent for PN (range from 13.8 percent to 26.4 percent).[76]

A hospital's readmission rate is affected by complex and critical aspects of care such as communication between providers or between providers and patients; prevention of, and response to, complications; patient safety; and coordinated transitions to the outpatient environment. While disease-specific measures of readmission are useful in identifying deficiencies in care for specific groups of patients, they account for only a small minority of total readmissions.[77] By contrast, a hospital-wide, all-condition readmission measure could portray a broader sense of the quality of care in hospitals. Consequently, hospital-wide, all-condition readmission measures can promote hospital quality improvement and better inform consumers about care quality.

Studies have estimated the rate of preventable readmissions to be as low as 12 percent and as high as 76 percent.[78,79] Some readmissions are unavoidable, for example, those that result from inevitable progression of disease or worsening of chronic conditions. However, readmissions may also result from poor quality of care or inadequate transitional care. Randomized controlled trials have shown that improvement in the following areas can directly reduce hospital readmission rates: quality of care during the initial admission; improvement in communication with patients, their

---

[76] Bernheim S, Wang Y, Grady J, et al. Measures Maintenance Technical Report: Acute Myocardial Infarction. Heart Failure, and Pneumonia 30-day Risk Standardized Mortality Measures. 2011; Available at: http://www.qualitynet.org/.

[77] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. Apr 2 2009;360(14):1418-1428.

[78] Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Inter Med 2000;160(8):1074-81.

[79] Medicare Payment Advisory Commission (U.S.). Report to the Congress promoting greater efficiency in Medicare. Washington, DC: Medicare Payment Advisory Commission, 2007.

caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Successful randomized trials have reduced 30-day readmission rates by 20-40 percent.[80,81,82,83,84,85,86] Evidence that hospitals have been able to reduce readmission rates through these quality-of-care initiatives illustrates the degree to which hospital best practices can affect readmission rates.

Our Quality Improvement Organizations (QIOs) began projects to improve care transitions during the 9th Statement of Work in 14 communities by applying successful interventions learned from clinical trials, such as medication reconciliation, increased patient education, follow up after discharge, and post-discharge instructions for patients.[87] Important interventions to integrate care for populations and communities now continue among all 53 QIOs on a national scale in the QIO 10th Statement of Work which began August 2011.

---

[80] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009;150(3):178-87.

[81] Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc 2004;52(11):1817-25

[82] Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. J Am Geriatr Soc 2009;57(3):395-402.

[83] Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomised controlled trial. BMC Public Health 2007;7:68.

[84] Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. J Hosp Med 2009;4(4):211-218.

[85] Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Ann Intern Med 1994;120(12):999-1006.

[86] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. Jama 1999;281(7):613-20.

[87] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009;150(3):178-87.

Because many studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, we believe that it is appropriate to include an all-condition readmission rate as a quality measure in the Hospital IQR Program. Promoting quality improvements leading to successful transition of care for patients from acute care to outpatient setting, and reducing short term, preventable hospital-wide readmission rates are CMS' priority objectives.

To provide a broader assessment of the quality of care at hospitals, especially for hospitals with too few AMI/HF/PN readmissions to count separately, we have developed a Hospital-Wide Readmission (HWR) measure using 2008 Medicare FFS data. Detailed information and specifications for this measure can be found on the NQF Web site at: http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&s=&p=7%7C6%7C5%7C4%7C. The objective of the proposed HWR measure is to assess the hospital-level, risk-standardized rate of unplanned, all-cause readmissions after admissions for any eligible condition within 30 days of hospital discharge. The proposed measure comprises a single summary score, derived from the results of five different models, one for each of the following specialty cohorts (groups of discharge condition categories or procedure categories): medicine, surgery/gynecology; cardiorespiratory; cardiovascular; and neurology.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28043), we proposed to use one year of data to calculate the measure rate for the HWR measure, which we believe is sufficient to calculate this measure in a statistically reliable manner. This is because t he reliability of a hospital's measure rate is related to its sample size. For its

rate to be calculated reliably statistically, a hospital needs to have a sufficient number of patient cases to which the measure applies. Because the proposed HWR measure addresses over 90 percent of Medicare FFS hospitalizations for patients aged 65 and older (a much larger number of patients than the condition-specific measures for AMI, Heart Failure, Pneumonia, and Total Hip/Knee procedures), we believe one year of data would yield a sufficient number of cases to assess hospital performance in a statistically reliable manner. In contrast, for the condition-specific readmission measures for AMI, Heart Failure and Pneumonia, each of which address a smaller proportion of Medicare FFS Hospitalizations than the HWR measure, we must use three years of data to have a enough patient cases to calculate the rates for these measures. We also believe that use of one year of data for the HWR measure is appropriate because it allows us to calculate up-to-date hospital performance for the most recent year, rather than calculating hospital performance over the course of three years, as we must do for the AMI, HF, and PN readmission measures. The proposed measure methodology is described in greater detail below.

The proposed measure uses 30 days following the index admission as the timeframe for assessing hospital performance because within this timeframe, readmissions are more likely attributable to care received during the index hospitalization and during the transition to the outpatient setting. For example, hospitals, in collaboration with their medical communities take actions to reduce readmission, such as ensuring patients are clinically ready at discharge, reducing risk of infection, reconciling medications, improving communications among providers involved in management

principles, and educating patients about symptoms to monitor, whom to contact with questions, and where and when to seek follow-up care. Furthermore our "time-to-event curve" analyses showed a readmission curve with rapid early accrual of readmissions with a stable and consistent readmission rate thereafter; the curve typically stabilized within 30-days of discharge. Finally, the proposed 30-day timeframe is consistent with the other publicly reported CMS readmission measures endorsed by the NQF.

The proposed HWR measure defines the outcome as "all-cause" unplanned readmissions. Unplanned readmissions are acute clinical events experienced by a patient that require urgent hospital admission. Higher than expected unplanned readmission rates suggest lower quality of care and are the focus of quality measurement as part of quality improvement efforts. Because planned readmissions are not a signal of quality of care, we chose to exclude planned readmissions from being considered as an outcome for this measure. The proposed measure includes hospitalizations of patients who were age 65 or older (at the time of admission) who were in Medicare Fee-for-Service (FFS) for 12 months prior to the index admission, and who remained in Medicare FFS for at least 30-days post-discharge. The measure excludes patients who died during the index admission; patients who were transferred to another acute care hospital; patients who were discharged against medical advice; and patients who died within the 30-day post-discharge period. The measure also excludes admissions for medical treatment of cancer; for primary psychiatric disease (patients admitted for psychiatric treatment are typically cared for in separate psychiatric or rehabilitation centers which are not comparable to acute care hospitals); or for physical rehabilitation and prosthetic services.

The proposed measure excludes patients undergoing medical treatment for their cancer as their primary procedure because we concluded that readmission may not be a good quality indicator for this cohort of patients compared to other cohorts. For example, the cancer cohort had more than twice the post-discharge mortality of any other cohort. It also has a planned readmission rate six times that of any other cohort – 41 percent of readmissions in this cohort were considered planned. This indicates that readmission in this population is a different phenomenon than for other cohorts. Most importantly, this cohort's risk standardized readmission ratio (SRR) was poorly correlated with the composite hospital-wide SRR of all other cohorts. Statistically this implies that readmission for the cancer cohort is likely measuring an aspect of quality very different from that for other cohorts. Consequently, we elected to exclude this subset of cancer patients from the measure.

For this measure, a patient is considered to have been readmitted if they experience one or more inpatient admissions within the 30 days after being discharged from an initial inpatient admission, whether the patient was readmitted to the same hospital or another. The proposed measure identifies "planned readmissions" in claims data that will not count as readmissions in the measure using an algorithm that identifies readmissions that are likely to be planned as opposed to readmissions due to probable complications. The algorithm was based on two main principles:

- The "planned" readmissions are those in which one of a pre-specified list of procedures took place (we refer readers to the measure methodology documentation on the NQF Web site at:

http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&p=2|3|&s for the list), or those for maintenance chemotherapy or rehabilitation. Maintenance chemotherapy and rehabilitation are common planned readmissions that are reliably distinguishable in the data even though they are not accompanied by procedures.

- Admissions for acute illness or for complications of care are likely not "planned." Clinically, any procedure completed during an admission for an acute illness is not likely to have been planned, even if that procedure is usually planned in other non-acute cases.

Therefore, the proposed measure uses procedure codes and discharge diagnosis categories for each readmission to identify planned readmissions. Readmissions that occur for planned procedures (we refer readers to the measure methodology report on the NQF Web site at: http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&p=2|3|&s for the list) and which are not for acute diagnoses or complications of care (listed below) are identified as planned.

For example, some patients have their gallbladders removed after having been identified as having symptomatic gallstones. Usually this is a surgery that is planned in advance and scheduled. However, occasionally a patient becomes acutely ill or has sudden inflammation or infection that requires a gallbladder surgery that was not planned in advance. The measure uses the patients' principal discharge diagnosis to differentiate between patients coming in for gallbladder removal with chronic gallstones (biliary

disease) and patients acutely ill with inflamed gallbladders (cholecystitis) who are having an unplanned gallbladder removal.

Therefore, the proposed HWR measure defines planned readmissions which are excluded from the measure as any readmission:

- In which any of these procedures set out in the table below are performed if the discharge condition category is not acute or a complication of care, as discussed below; or
- For maintenance chemotherapy.

All other readmissions are considered unplanned and are counted as readmissions in the measure.

The following is the list of planned procedures based on the full AHRQ Clinical Classification Software (CCS) procedure category list.

Procedure Categories Considered Planned Depending on the Discharge Condition	
	Description
45	Percutaneous transluminal coronary angioplasty (PTCA)
	Rehabilitation (condition CCS 254)
84	Cholecystectomy and common duct exploration
157	Amputation of lower extremity
44	Coronary artery bypass graft (CABG)
78	Colorectal resection
51	Endarterectomy; vessel of head and neck
113	Transurethral resection of prostate (TURP)
99	Other OR gastrointestinal therapeutic procedures
48	Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator
	Maintenance Chemotherapy (condition CCS 45)
211	Therapeutic radiology for cancer treatment

Procedure Categories Considered Planned Depending on the Discharge Condition	
	Description
3	Laminectomy; excision intervertebral disc
43	Heart valve procedures
152	Arthroplasty knee
158	Spinal fusion
55	Peripheral vascular bypass
52	Aortic resection; replacement or anastomosis
36	Lobectomy or pneumonectomy
153	Hip replacement; total and partial
60	Embolectomy and endarterectomy of lower limbs
85	Inguinal and femoral hernia repair
104	Nephrectomy; partial or complete
1	Incision and excision of CNS
124	Hysterectomy; abdominal and vaginal
167	Mastectomy
10	Thyroidectomy; partial or complete
114	Open prostatectomy
74	Gastrectomy; partial and total
119	Oophorectomy; unilateral and bilateral
154	Arthroplasty other than hip or knee
	Radical laryngectomy, revision of tracheostomy, scarification of pleura (ICD-9 codes 30.4, 31.74, 34.6)
166	Lumpectomy; quadrantectomy of breast
64	Bone marrow transplant
105	Kidney transplant
176	Other organ transplantation
	Electroshock therapy (ICD-9 codes 94.26, 94.27)

The algorithm is designed to identify admissions for acute illness or complication of care as “unplanned” readmissions. The acute and complication discharge condition categories for unplanned readmissions are listed below.

Discharge Condition Categories Considered Acute or Complications of Care	
AHRQ CCS	**Description**
237	Complication of device; implant or graft
106	Cardiac dysrhythmias
	Fracture (condition CCS 207, 225, 226, 227, 229, 230, 231, 232)
100	Acute myocardial infarction
238	Complications of surgical procedures or medical care
108	Congestive heart failure; nonhypertensive
2	Septicemia (except in labor)
146	Diverticulosis and diverticulitis
105	Conduction disorders
109	Acute cerebrovascular disease
145	Intestinal obstruction without hernia
233	Intracranial injury
116	Aortic and peripheral arterial embolism or thrombosis
122	Pneumonia (except that caused by TB or sexually transmitted disease)
131	Respiratory failure; insufficiency; arrest (adult)
157	Acute and unspecified renal failure
201	Infective arthritis and osteomyelitis (except that caused by TB or sexually transmitted disease)
153	Gastrointestinal hemorrhage
130	Pleurisy; pneumothorax; pulmonary collapse
97	Peri-; endo-; and myocarditis; cardiomyopathy
127	Chronic obstructive pulmonary disease and bronchiectasis
55	Fluid and electrolyte disorders
159	Urinary tract infections
245	Syncope
139	Gastroduodenal ulcer (except hemorrhage)
160	Calculus of urinary tract
112	Transient cerebral ischemia
	All condition categories

To compare readmission performance across hospitals, the proposed measure accounts for differences in patient characteristics (patient case mix) as well as differences in mixes of services and procedures offered by hospitals (hospital service-mix). The proposed measure includes 93.4 percent of Medicare FFS hospitalizations occurring in 2008, and includes 92.1 percent of readmissions following those hospitalizations.

The proposed measure uses the conditions and procedures defined by the AHRQ CCS, which is a widely used and accepted method of grouping patients into diagnostic categories. The AHRQ CCS collapsed the more than 17,000 different ICD-9-CM diagnosis and procedure codes into 285 clinically-coherent, mutually-exclusive condition categories and 231 mutually-exclusive procedure categories. We created five major specialty cohorts based on organization of care (medical, surgery/gynecology, cardiorespiratory, cardiovascular, and neurology), and assigned each condition category to a cohort. Admissions that included major surgical procedures (regardless of condition category) were assigned to the surgery/gynecology cohort. We estimated separate adjustment coefficients for each cohort using a single set of risk factors. We used hierarchical logistic regression to adjust for differences in hospital case mix and to account for the clustering of patients within a hospital. We adjusted for case mix differences among hospitals by risk-adjusting for patients' comorbid conditions identified in inpatient episodes of care for the 12 months prior to the index admission as well as those present at admission. We did not risk adjust for diagnoses that may have been a complication of care during the index admission. We used CMS Condition Category groups (CMS-CCs) to define the comorbid risk adjusters and used a fixed set of comorbid

risk variables across models. We risk adjusted for service mix differences among hospitals within each major cohort by including indicator variables for discharge condition categories (as defined by AHRQ CCS) in each model.

Finally, we used each of the five cohort models to calculate predicted and expected numbers of readmissions for each hospital in each cohort. We then derived a single summary score from the results of the five models by calculating the volume-weighted log average of the predicted over expected ratios from each model and multiplying the resulting ratio by the average national readmission rate. This approach allowed us to take into account the variation in hospital specialty cohort mix.

The proposed HWR measure was recommended to the NQF board of directors for endorsement in March 2012 by the NQF Consensus Standards Approval Committee (CSAC). The MAP supported selection of the HWR measure for the Hospital IQR Program contingent on NQF endorsement. This measure is in the final stages of the NQF measure endorsement process, and we expect its endorsement to be finalized in the coming months.

We proposed to adopt this measure in the Hospital IQR Program for the FY 2015 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act. This section provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus

organization identified by the Secretary. We reviewed the NQF-endorsed measures, and we were unable to identify any other NQF-endorsed measures that assess hospital-wide readmissions. We also are not aware of any other hospital-wide readmission measures that have been endorsed or adopted by a consensus organization other than NQF. The one other hospital-wide readmissions measure of which we are aware is the Risk-Adjusted 30-Day All-Cause Readmission Rate measure (formerly NQF # 0329). This measure was endorsed by NQF, but NQF removed the measure's endorsement during a recent consensus development project that recommended endorsement of the HWR measure. Accordingly, we proposed to adopt the HWR measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act. We invited public comment on this proposal.

Comment: Two commenters supported the proposed measure and added that avoidable readmission can result from poor quality of care or inadequate transitional care. The commenters anticipate that the HWR measure will be a robust measure to identify deficiencies in communication and gaps in care as it would enable hospitals to examine all facets of their hospital operations.

Response: We thank the commenters for their support.

Comment: Many commenters appreciated CMS' newly added exclusion criteria (such as medical treatment of cancer, transplants and primary psychiatric diagnoses) for certain planned readmissions for this measure and recommended that for harmonization efforts, CMS should harmonize measure exclusions for the condition-specific

readmission measures in the Hospital IQR Program and the Hospital Readmissions Reduction Program.

Response: We are currently updating the planned readmissions for other CMS condition-specific readmission measures using the newly added criteria in the HWR measure and will submit the updated measures to the NQF for re-endorsement.

Comment: Many commenters did not support the inclusion of this measure in the Hospital IQR Program because it was not targeted to a specific condition. Commenters attributed success from the implementation of the AMI, HF and PN readmission measures to the condition-specific nature of these measures which allow hospitals to target their intervention efforts on specific causes of readmissions for each condition. The commenters stated that, in contrast, the proposed hospital-wide, all-cause, all-condition readmission measure does not highlight any specific condition and, therefore, it will only serve to detract away from successful condition-specific strategies.

Response: We agree that it is helpful to assess readmission rates and hence target quality improvement for specific groups for patients with specific conditions, as indicated by the commenters. However, we are mindful that these conditions account for only a small proportion of total hospital readmissions. That is the reason for our proposal of the hospital-wide readmission measure, which would provide a broader assessment of the quality of care provided to hospital patients who have medical conditions other than AMI, HF, and PN. The hospital-wide measure will allow for a more comprehensive evaluation of a hospital's quality. The hospital-wide measure is designed with five distinct cohorts, which allow for quality improvement efforts within

particular service lines. Overall the hospital-wide measure and condition-specific measures should be complementary in allowing both for profiling overall hospital quality and promoting quality improvement.

Comment: Some commenters specifically opposed our proposal to account for the variations in hospital specialty cohort mix with a single summary score obtained from calculating the volume-weighted log average of the predicted over expected ratios from each of the five models and multiplying the resulting ratio by the average national readmission rate.

Response: The commenters opposed, but did not provide the rationale for opposing, using a single summary score obtained from 5 models for the measure. We explain our rationale for using it here. The measure approach allows us to take into account the variation in hospital specialty cohort mix. In particular, we wanted to be careful to fully account for the differences in readmission risk between surgical and non-surgical patients. Our analyses found that even within the same discharge condition, patient risk for readmission was strongly affected by whether a surgical procedure was performed during hospitalization. Patients undergoing surgical procedures typically had better outcomes than patients who did not undergo a procedure but were admitted with the same discharge condition. In short, using five models rather than a single model improves model performance and patient-level discrimination, and will significantly improve the usability of the measure.

Comment: Some commenters were concerned that hospitals might have difficulties in using the measure which is based on the AHRQ Clinical Classification

Software (CCS) for acute and complication discharge condition categories for unplanned readmissions, whereas hospitals use the ICD-9 DRGs for claims purposes. The CCS codes do not match the Medicare Severity Diagnosis related groups-driven claim data that the hospitals are using. Therefore, the commenters recommended organizing readmissions in a manner consistent with current hospital claim data such as specific ICD-9 codes and future ICD-10 codes.

Response: Although hospitals are paid by DRG, the claims that hospitals submitted to CMS contain diagnoses (the primary and secondary diagnoses) in the ICD-9 format. The AHRQ software groups patients into CCS using the ICD-9 codes. Hospitals should have no problems crosswalk between the AHRQ CCS (maintained for both ICD-9 and ICD-10 codes) and the diagnosis on hospital claims.

Comment: Many commenters did not support this measure and perceived the measure as lacking in: (1) differentiation between related and unrelated readmissions; and identification of all planned readmissions; (2) sufficient risk-adjustments for patient characteristics (dual eligible status, race/ethnicity, and SES factors); and (3) exclusions for extreme circumstances (transplant, end-stage renal disease burn, trauma, psychosis, and substance abuse). Commenters were particularly concerned that the lack of adjustments for SES factors will have unintended consequences of unfairly penalizing hospitals treating disadvantaged patients as well as impairing patients, access to hospitals.

Response: The measure does not differentiate between related and unrelated readmission for a number of reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care after an acute hospitalization.

Second, readmissions not directly related to the index hospitalization may still be a result of the care received during hospitalization. For example, a patient hospitalized COPD who develops a hospital-acquired infection may ultimately be readmitted for sepsis. It would be inappropriate to treat this readmission as unrelated to the care the patient received during the index hospitalization. Furthermore, the range of potentially avoidable readmissions also includes those not directly related to the initial hospitalization, such as those resulting from poor communication at discharge or inadequate follow-up. In addition, readmissions for rare reasons completely unrelated to hospital care, such as car accidents involving the patient as a passenger, are likely to be distributed randomly across hospitals and are not expected to introduce any bias into the measure results. Thus, the goal of this measure is not to reduce readmissions to zero, but to instead assess hospital performance relative to what is expected given the performance of other hospitals with similar case mixes.

We appreciate the concern expressed by the commenters that patients of these "extreme circumstances" clinically could be sicker and likely to be readmitted. The measure addresses clinical differences in hospitals' case-mix through risk adjustment rather than through excluding patients from the measure as suggested by the commenter. The goal in developing outcomes measures is to create a clinically cohesive cohort that includes as many patients as possible admitted with the given condition. Greatly expanding our list of exclusions would result in a measure that was less useful and meaningful, because it would reflect the care of fewer patients. In addition, we believe that by excluding patients with significant comorbidities, the measure would not assess of

the quality of care for those patients. To fairly profile hospitals' performance, it is critical to place hospitals on a level playing field and account for their differences in the patients that present for care. This is accomplished through adequate risk-adjustment for patients' clinical presentation rather than exclusion of patients.

Comment: A few commenters opposed the proposed adoption of this measure as the commenters believed readmission rates are more closely related to patient expectations, community standards, health literacy, and other unknown factors during hospitalization which are not accounted for in the risk models articulated in the rule. The commenters suggested that there is little correlation between quality of care provided and overall readmission rates.

Response: Risk-standardized readmission rates provide an important quality signal. Readmission of patients who were recently discharged after hospitalization with AMI, HF, or pneumonia represents an important, expensive, and often modifiable adverse outcome. The risk of readmission can be modified by the quality and type of care provided to these patients. There is ample evidence that hospitals can reduce their readmission rates through such efforts as: ensuring patients are clinically ready at discharge, reducing risk of infection, reconciling medications, improving communication with community providers participating in transitions of care, educating patients adequately upon discharge, and assuring patients understand follow-up care upon discharge.

Comment: A commenter raised some methodological questions on the HWR measure. First, the commenter noted that the HWR model was originally estimated using

2008 data and the commenter asked for the anticipated lag between finalization and when the measure is implemented for FY 2015 payment determination. Second, the commenter asked whether it was methodologically appropriate to view statistical power as additive between the five individual models for the five specialty cohorts identified by the model developers. Finally, the commenter asked for the sample size of the five cohort models in the 2008 data.

Response: For 2013 public reporting, we plan to use one year of data to calculate the measure. We note that all of the patients in the five models contribute to the statistical power of the measure. The measure is divided into five specialty cohorts in order to enable hospitals to focus improvement efforts within clinically coherent specialties. CMS evaluated the appropriateness of combining the 5 specialty cohort scores into a single score by looking at the correlation among the specialty cohort scores and calculating Cronbach's alpha, a statistic that measures the internal consistency of a composite. The correlations among the coefficients ranged from 0.35 to 0.65, and the Cronbach alpha result was 0.83, indicating good internal consistency. Both of these analyses confirmed the appropriateness of combining the 5 scores into a composite score. These findings were included in the technical report submitted to the National Quality Forum. Finally, the sample size of the five cohort models in the 2008 data for the Medicine group is 3,086,792, Surgery/gynecology 2,163,279, Cardiorespiratory 1,405,267, Cardiovascular 843,373, and Neurology 7,957,901.

Comment: A commenter asked if the new proposed readmission exclusion criteria would be applied to the existing condition-specific measures before the October implementation of the Hospital Readmissions Reduction Program.

Response: In the FY 2013 IPPS/LTCH PPS proposed rule, we proposed to use the current NQF-endorsed AMI, HF, and pneumonia condition-specific measure specifications for the Hospital Readmissions Reduction Program. However, in response to stakeholder input, we will update the condition-specific measures to include more planned readmissions which would not be counted as readmissions. The updated measures will be submitted to NQF for approval. Should NQF approve these changes to the measures, because we have already adopted these NQF endorsed measures in the IQR and Hospital Readmission Reduction, we would adopt these updates to the measures for future use in these programs through the subregulatory process we are finalizing in this rule.

Comment: Many commenters believed it is premature to include the 30-day all-cause hospital-wide readmission measure at this time. The commenters indicated several reasons for not supporting this measure. The commenters stated that the measure is still under appellate review by the NQF and endorsement is still pending. The commenters believed that CMS is risking the disengagement of the provider community by proposing a non-NQF-endorsed measure.

Some commenters were concerned over the suitability of this measure for public reporting and future ties to payment policy because the claims data used is between 18 to 30 months old. The commenters contended that older data does not afford hospitals the

opportunity for meaningful feedback needed for immediate improvement opportunities. Commenters inquired if hospitals will have the opportunity to verify and/or appeal their HWR discrepancies. The commenters recommended that CMS provide calculated actionable data results on a quarterly basis, rather than the annual posting currently used for the conditions-specific measures.

Finally, the commenters believed the measure creates potential for significant and harmful unintended consequences by resulting in more ED visits or more repeated observation stays during the 30-day period. The commenters also cautioned that publicly reporting readmission rates without monitoring potentially adverse unintended consequences as stated in the comment could undermine patient-centered care.

Response: We note that NQF endorsed the Hospital-Wide Readmission (tentative NQF #1789) measure in the summer of 2012. Therefore the measure we proposed is an NQF-endorsed measure. For public reporting of this measure, we intend to use one year of data. This would allow the measures to be calculated using the most recent data. There will be one year lag when the data are finally posted on Hospital Compare. It is because we need to build in sufficient time for data production and data display and for hospitals to preview their data before they are posted on Hospital Compare. We appreciate the commenters' request for timely, quarterly data and we are considering options for providing hospitals with unadjusted all-hospital readmission data on a more frequent basis to assist hospitals in their quality improvement efforts.

We want to assure the commenters that we have a solid review, correction and payment process in place that would appropriately link submitted data to payment. The

hospital-wide readmission measures are calculated based on the claims that hospitals submitted to and were paid by CMS. We will share with hospitals their measure data using the same "preview" process that we have been implementing for the Hospital IQR Program. We will transmit to hospitals through QualityNet their hospital-specific reports containing their individual patient data and their measure rates 30 days prior to posting their measures on Hospital Compare Web site. Hospitals are encouraged to verify their data during this 30-day preview period. If hospitals find errors in the claims they submitted to CMS for calculating the measure, they can submit the corrections in accordance with the normal claims adjustment and timely filing rules specified in the Medicare Claims Processing Manual Pub. 100-04, Chapter 1. During the preview period, hospitals' hospital-specific reports we will include data to track where their patients were readmitted in their hospital-specific report, which should help hospitals with their quality improvement efforts. Regarding the concern whether we are applying the exclusion criteria of the measure methodology correctly, the preview process can be helpful. Hospitals will have the opportunity to verify and monitor the cases being included in the measures.

We appreciate the commenter's suggestion to monitor for unintended consequences such as more ED visits and observations services and CMS plans to conduct analyses to monitor these consequences.

Comment: A few commenters recommended that with the implementation of the 30-day all-cause hospital-wide readmission, the 30-day risk-standardized readmission

measures for AMI, HF, and PN should be removed from the Hospital IQR Program measure set so that these three conditions would not be counted twice.

Response: We appreciate the comment, however, we see value in reporting both the condition-specific measures and the hospital-wide measure. The condition-specific measures give hospitals detailed information and results on well-defined clinical groups of patients that account for a disproportionate number of hospital readmissions, and we expect that these results can provide important benchmarks for hospitals and inform quality improvement. In contrast, the hospital-wide measure will provide hospitals with information on how it compares to other hospitals with similar patients hospital-wide and inform strategies for lowering readmission risk across the board for all patients.
CMS intends to publicly report both the hospital-wide and condition-specific readmission measures as we believe both measures help present a more comprehensive picture of the quality of care in hospitals.

Comment: A commenter encouraged CMS to recognize a patient's responsibility regarding hospital readmissions as hospitals should not be held accountable for patient behavior.

Response: We recognize the role of patient compliance and the role of primary care and post acute care providers in preventing readmissions. However, currently approximately one out of five admissions resulted in readmission. We believe that this rate is too high. We recognize that reducing readmission is a multi-facet effort that requires collaboration among different stakeholders in the communities. However there is ample evidence that hospitals can reduce their readmission rates through such efforts

as: ensuring patients are clinically ready at discharge, reducing risk of infection; reconciling medications; improving communication with community providers participating in transitions of care; educating patients adequately upon discharge; and assuring patients understand follow-up care upon discharge. The measure encourages hospitals to improve patient care transitions and collaborate with the providers and other resources in their communities to reduce readmissions.

After consideration of the public comments we received, we are finalizing the HWR measure for the FY 2015 payment determination and subsequent years as proposed.

(C) New Chart-Abstracted Measure: Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (NQF #0469)

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28046), we proposed for the FY 2015 payment determination and subsequent years to add a chart-abstracted measure, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. In launching the Strong Start Initiative (http://www.innovation.cms.gov/initiatives/strong-start/) to help reduce preterm births, the HHS Secretary indicated in a press release that more than half a million infants are born prematurely in America each year, and that this trend has increased 36 percent over the last 20 years. Preterm births may require additional medical attention and early intervention services. Some recent research indicates that elective deliveries before 39 weeks increase the risk of significant complications for

mother and baby, as well as long-term health problems. [88] [89] [90] [91] Preterm births are a growing public health problem that has significant consequences for families well into a child's life.

As a public campaign to reduce preterm births, the Strong Start Initiative's objective is to test ways to reverse this trend by helping provide expectant mothers with the care they need for a healthy delivery and a healthy baby, and by focusing on reducing early elective deliveries, which can lead to a variety of health problems for mothers and infants.

The Strong Start Initiative cuts across many agencies within HHS and involves external organizations including the March of Dimes, and the American College of Obstetricians and Gynecologists (ACOG). We believe that a reduction in the number of nonmedically indicated elective deliveries at >=37 to <39 weeks gestation will result in a substantial decrease in neonatal morbidity and mortality, as well as a significant savings in healthcare costs. In addition, the rate of cesarean sections should decrease with fewer elective inductions resulting in decreased length of stay and healthcare costs. The proposed measure would assist hospitals in tracking nonmedically indicated early term elective deliveries and reduce the occurrence of such deliveries. This measure would assess patients with elective vaginal deliveries or elective cesarean sections at >=37 and <39 weeks of gestation completed. The numerator for this measure is the number of

---

[88] Glantz, J. (Apr.2005). Elective induction vs. spontaneous labor associations and outcomes. *J Reprod Med*. 50(4):235-40.

[89] Vardo, J., Thornburg, L., Glantz J., (2011). Maternal and neonatal morbidity among nulliparous women undergoing elective induction of labor. J. report med. 56(1-2): 25-30.

[90] Tita, A., Landon, M., Spong, C., Lai, Y., Leveno, K., Varner, M, et al. (2009). Timing of elective repeat cesarean delivery at term and neonatal outcomes. [Electronic Version]. *NEJM*. 360:2, 111-120.

[91] Clark, S., Miller, D., Belfort, M., Dildy, G., Frye, D., & Meyers, J. (2009). Neonatal and maternal outcomes associated with elective delivery. [Electronic Version]. *Am J Obstet Gynecol*. 200:156.e1-156.e4.

patients with elective deliveries with principal or other procedure codes for one or more of the following: Medical induction of labor, and Cesarean section while not in active labor or experiencing spontaneous rupture of membranes. Exclusions are: Less than 8 years of age; Greater than or equal to 65 years of age; Length of Stay >120 days; and enrolled in clinical trials.

We proposed to adopt this measure for the Hospital IQR Program because we believe this measure furthers the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and low costs for health care. In addition, we have determined that the measure is relevant to the nearly 2 million Medicare beneficiaries who are aged 44 and under, most of whom are dual eligible beneficiaries, who have the potential to be impacted by pre-term births. This is evidenced by the fact that, in 2011, Medicare paid for roughly 14,000 births. The measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure is currently under NQF maintenance review. In its Pre-Rulemaking report for 2012, the MAP also recommended the inclusion of this measure in the Hospital IQR Program. TJC is the measure steward of this measure and the detailed measure specification can be found on the TJC Web site at: http://manual.jointcommission.org/releases/TJC2012A/MIF0166.html.

We proposed to add this measure to the Hospital IQR Program for the FY 2015 payment determination, with collection beginning with January 1, 2013 discharges. Although this measure is chart-abstracted, we proposed that this measure would be collected in aggregated numerator, denominator, and exclusion counts per hospital via a

Web-based tool (as opposed to collecting patient-level data from hospitals). Specific details regarding this proposed approach to data collection are included in section VIII.A.5. of this preamble on the form, manner, and timing of quality data submission for the Hospital IQR Program. We anticipate that the e-specifications of this measure will be completed in the summer of 2012. We intend to move to EHR-based collection of this and other measures once the necessary infrastructure to do so is in place. We invited public comment on our proposal to adopt this measure.

Comment: A commenter suggested that preterm delivery is better defined as delivery "prior to 37 completed weeks of gestation" rather than "prior to 39 completed weeks of gestation" as indicated in the proposed measure.

Response: After reviewing the comment, we recognize that in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28046), we incorrectly used the term "pre-term births" to describe the measure, which refers to early elective deliveries occurring ≥ 37 weeks and < 39 weeks. The commenter is correct that preterm delivery is better defined as delivery prior to 37 weeks of gestation. However, for this measure, we clarify that we are not referring to deliveries prior to 37 weeks gestation.

Comment: Many commenters supported this proposed measure for inclusion in the Hospital IQR Program, but did not believe it is appropriate for the Hospital VBP Program in future years. Instead, the commenters suggested that a measure focusing on obstetrical delivery of babies would be more appropriate for potential inclusion in a Medicaid VBP Program or for use by other purchasers for whom this constitutes a substantial proportion of hospitalized patients.

Four commenters supported this proposed NQF-endorsed and MAP-recommended measure for inclusion in the Hospital IQR Program, and they believed the measure will encourage providers to reduce the number of non-medically indicated elective deliveries, which could result in a substantial decrease in neonatal morbidity and mortality. Two commenters stated that the measure sends a clear signal that CMS recognizes the importance of using measures that go beyond the Medicare population and reflects the quality concerns of the private purchasers as well as states that are facing extreme financial challenges related to Medicaid. One commenter noted that this measure will be enormously meaningful to women, a large and important group of health care consumers, who can then make informed decisions about non-medically indicated elective delivery.

Response: We thank the commenters for their support and note that regardless of the source of health benefits for women of childbearing age, the ACOG and AAP standard of requiring 39 weeks gestation prior to elective delivery should be adhered to. Therefore, we believe that whether a woman of childbearing age is provided healthcare benefits under Medicare, Medicaid or both should not determine which CMS program this measure is implemented in. We have not yet evaluated this measure in terms of its suitability for the Hospital VBP Program, but we believe that patient safety in general is a topic that should be addressed in the Hospital VBP Program.

Comment: A few commenters noted that Medicare paid for only about 14,000 deliveries in 2011 out of approximately 4 million babies born in the U.S. each year. The commenters asked for clarification on whether a hospital is

expected to report the early-term elective delivery rate for all obstetric patients or only for the tiny fraction of Medicare patients with elective deliveries. Commenters assumed that CMS proposed this measure for all patients given that individual hospitals would likely lack enough data for Medicare-only deliveries to produce meaningful rates of early-term elective deliveries. One commenter stated that the inclusion of such a measure that only applies to a small number of hospitals is not appropriate to expand the Hospital IQR Program. A commenter requested clarification whether the measure applies to all patients or just Medicare patients.

Response: We appreciate the opportunity to clarify the population in which the measure will be used. We intend to apply the measure to all births, not just births to Medicare patients in order to identify the percentage that is occurring ≥ 37 weeks and < 39 weeks. The applicable patients are all patients that are > 8 years of age. We are not restricting the population to Medicare patients for this or any other chart abstracted measures used in the Hospital IQR Program.

Comment: Two commenters suggested induction should be defined as when cervical drugs are administered, outpatient cervical ripening occurs, or cervical ripening occurs in non-delivery admissions when patients are sent home and admitted later for delivery. The commenters also suggested that gestational age should be defined as cervical ripening, AROM, or oxytocin started. One commenter believed the current definition of gestational age used by CMS is inadequate, and recommends that CMS amend the acceptable sources for determination of gestational age.

Commenters recommended risk-adjustment as well as the inclusion of membrane stripping and cervical ripening agents in this measure as an induction. Commenters preferred data collection from registries rather than a Web-based tool. For the future, one commenter recommended including patients within a medical necessity category that may benefit from a gestation period greater than 39 weeks.

Response: Regarding the definition of induction and gestational age, data collection for measure calculation from registry data and refining the measure inclusion criteria, we will take these recommendations into consideration and collaborate with the steward of the measure to address these concerns. We note that the measure is endorsed with the current methodology. Should the measure steward change the current measure methodology by the addition of risk adjustment and/or make changes to induction definitions or inclusion criteria, the measure could change substantially and place the measure at risk for losing its endorsement status. We will take these definitions and recommendations into consideration prior to the next measure maintenance review.

Comment: One commenter requested clarification regarding the definition of elective and recommends CMS exclude cases of prior cesarean or myomectomy.

Response: In the context of this measure and as defined by the measure steward, elective deliveries are those that occur without medical indication. In the context of this measure and as defined by the measure steward, elective deliveries are those that occur without medical indication. For those situations in which a history of prior myomectomy or cesarean section are clear medical indications for delivery prior to 39 weeks, the measure allows for the abstractors to indicate that delivery was medically indicated. We

will also convey the recommended exclusions of cases with a history of medical indication of prior cesarean or myomectomy to the measure steward for consideration.

Comment: A commenter pointed out that this measure is part of the required clinical quality measures proposed for Stage 2 meaningful use of certified EHR technology. The commenter recommended that CMS defer the implementation of this measure until the measure can be reported as an eMeasure.

Response: Because we believe that the data reporting based on the current measure specification is not burdensome, we do not see a need to delay the implementation of this measure in the Hospital IQR Program. Once e-specification of the measure is completed, we will consider the option of e-reporting.

Comment: A few commenters supported the proposed aggregate data reporting but were unclear how would this data collection method would alleviate burden on hospitals.

One commenter requested that CMS clarify the frequency of data reporting as well as how the data would be displayed accurately without validation. The commenter was encouraged that TJC is working on the e-specification of this measure and the commenter requested CMS to consult with TJC for any recent changes in the measure.

Response: We appreciate the importance of having adequate resources when performing quality health assessments. We believe that methods of collecting data for this measure should minimize additional hospital burden because the measure data are submitted for the hospital's aggregate numerator, denominator and exclusions through a Web-based entry tool rather than submitting data on each of the hospital's individual

patient cases. Display of measure results on Hospital Compare is required as part of the Hospital IQR Program, and we note that not all measure results on Hospital Compare are validated, but that hospitals are responsible for ensuring completeness and accuracy of the data regardless of whether CMS independently validates that data. We will work closely with TJC to implement the measure. The frequency of reporting this measure is addressed in the Form, Manner and Timing section of this program.

Comment: A commenter urged CMS to allow hospitals to authorize an ORYX vendor to submit the same data that the vendor is submitting to TJC.

Response: We will consider this suggestion for future implementation.

Based on the public comments we received, we are finalizing the Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation measure for FY 2015 payment determination and subsequent years as proposed. The data collection requirements for this measure are detailed in the "Form, Manner, and Timing of Quality Data Submission" section of this preamble.

In summary, we are adopting all the Hospital IQR Program measures adopted in previous payment determinations, with the exception of the 17 measures (1 chart-abstracted measure and 16 claims-based measures) that we are removing. We are finalizing new survey-based measure items for inclusion in the HCAHPS survey measure, 3 claims-based measures, and 1 chart-abstracted measure, for a total of 59 measures for the FY 2015 payment determination and subsequent years. These 59 measures are listed below.

Topic	Hospital IQR Program Measures for FY 2015 Payment Determination and Subsequent Years
Acute Myocardial Infarction (AMI) Measures	
	● AMI-2 Aspirin prescribed at discharge
	● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
	● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)
	● AMI-10 Statin Prescribed at Discharge
Heart Failure (HF) Measures	
	● HF-1 Discharge instructions
	● HF-2 Evaluation of left ventricular systolic function
	● HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction
Stroke (STK) Measure Set	
	● STK-1 VTE prophylaxis
	● STK-2 Antithrombotic therapy for ischemic stroke
	● STK-3 Anticoagulation therapy for Afib/flutter
	● STK-4 Thrombolytic therapy for acute ischemic stroke
	● STK-5 Antithrombotic therapy by the end of hospital day 2
	● STK-6 Discharged on Statin
	● STK-8 Stroke education
	● STK-10 Assessed for rehab
VTE Measure Set	
	● VTE-1 VTE prophylaxis
	● VTE-2 ICU VTE prophylaxis
	● VTE-3 VTE patients with anticoagulation overlap therapy
	● VTE-4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol
	● VTE-5 VTE discharge instructions
	● VTE-6 Incidence of potentially preventable VTE
Pneumonia (PN) Measures	
	● PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital
	● PN-6 Appropriate initial antibiotic selection
Surgical Care Improvement Project (SCIP) Measures	
	● SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision
	● SCIP INF-2: Prophylactic antibiotic selection for surgical patients
	● SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours

Topic	Hospital IQR Program Measures for FY 2015 Payment Determination and Subsequent Years
	after surgery end time (48 hours for cardiac surgery)
	● SCIP INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose
	● SCIP INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero
	● SCIP INF-10: Surgery patients with perioperative temperature management
	● SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period
	● SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Mortality Measures (Medicare Patients)	
	● Acute Myocardial Infarction (AMI) 30-day mortality rate
	● Heart Failure (HF) 30-day mortality rate
	● Pneumonia (PN) 30-day mortality rate
Patients' Experience of Care Measures	
	● HCAHPS survey (expanded to include one 3-item care transition set* and two new "About You" items)
Readmission Measures (Medicare Patients)	
	● Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure
	● Heart Failure 30-day Risk Standardized Readmission Measure
	● Pneumonia 30-day Risk Standardized Readmission Measure
	● 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty*
	● Hospital-Wide All-Cause Unplanned Readmission (HWR)*
AHRQ Patient Safety Indicators (PSIs) Composite Measures	
	● Complication/patient safety for selected indicators (composite)
AHRQ PSI and Nursing Sensitive Care	
● PSI-4 Death among surgical inpatients with serious treatable complications	
Structural Measures	
	● Participation in a Systematic Database for Cardiac Surgery
	● Participation in a Systematic Clinical Database Registry for Stroke Care
	● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care
	● Participation in a Systematic Clinical Database Registry for General Surgery
Healthcare-Associated Infections Measures	
	● Central Line Associated Bloodstream Infection
	● Surgical Site Infection

Topic	Hospital IQR Program Measures for FY 2015 Payment Determination and Subsequent Years
	● Catheter-Associated Urinary Tract Infection
	● MRSA Bacteremia
	● Clostridium Difficile (C.Diff)
	● Healthcare Personnel Influenza Vaccination
Surgical Complications	
	● Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty*
Emergency Department (ED)Throughput Measures	
	● ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital
	● ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status
Prevention: Global Immunization (IMM) Measures	
	● Immunization for Influenza
	● Immunization for Pneumonia
Cost Efficiency	
	● Medicare Spending per Beneficiary
Perinatal Care	
	● Elective delivery prior to 39 completed weeks of gestation*

* New measures/items for the FY 2015 payment determination and subsequent years.

(D) Clarifications Regarding Existing Hospital IQR Program Measures that Have Undergone Changes during NQF Measure Maintenance Processes

As discussed previously, once adopted, we retain measures in the Hospital IQR Program unless specifically stated otherwise. Recently the CLABSI and CAUTI measures were expanded to pertain to non-ICU locations in hospitals and to other types of care settings as part of NQF maintenance review. These measures retained their original NQF numbers as these changes were not considered substantive by NQF. However, we will continue to require hospitals to submit data for these two measures on

ICU locations only for the Hospital IQR Program. We sought comment from hospitals on the feasibility and timing of expanding collection of these measures to include non-ICU locations in hospitals. We address these comments below in the VIII.A.4., Possible New Quality Measures and Measure Topics for Future Years section.

NQF, in addition to expanding the care settings to which the CLABSI and CAUTI measures could apply, also changed how these measures are calculated. The original endorsed versions of the measures calculated an infection rate per 1,000 central line days for CLABSI and for 1,000 urinary catheter days for CAUTI. In the course of its maintenance review, NQF changed the way the measures are calculated from an infection rate per 1,000 days to a standardized infection ratio ("SIR"), which is comprised of the actual rate of infection over the expected rate of infection. We note that although the previously endorsed versions of the CAUTI and CLABSI measures did not include the SIR calculation, we have reported the CDC-calculated SIR for both measures on the Hospital Compare Web site. While use of this calculation is different from the original NQF-endorsed measure output, we believe the SIR is a more accurate way to calculate the CLABSI and CAUTI measures for comparative purposes rather than the rate per 1,000 infection days because it takes into account hospitals' case mix. We will continue to report SIRs for both measures because this calculation is now consistent with NQF's endorsement of the measures. We also note that use of the SIR calculation does not change the type of data that hospitals submit on the CLABSI and CAUTI measures.

c. Hospital IQR Program Quality Measures for the FY 2016 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74466), we adopted the Safe Surgery Checklist Use measure for the Hospital OQR Program for the CY 2014 payment determination. In the same rule, we adopted this measure for the ASCQR Program for the CY 2015 payment determination (76 FR 74507). This structural measure assesses whether a hospital outpatient department utilizes a Safe Surgery checklist that assesses whether effective communication and safe practices are performed during three distinct perioperative periods: (1) the period prior to the administration of anesthesia; (2) the period prior to skin incision; and (3) the period of closure of incision and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications and post-surgical mortality.[92] Like hospital outpatient settings and ambulatory surgical centers, acute care hospitals also perform many surgical procedures. Therefore, we believe this measure is also applicable for hospital inpatient settings in strengthening patient safety precautions in hospitals and in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28048), we proposed to adopt this measure for the Hospital IQR Program for FY 2016 payment determination and subsequent years.

For this proposed structural measure, a hospital inpatient department would indicate whether or not it uses a safe surgery checklist for its surgical procedures that includes safe surgery practices during each of the three critical perioperative periods

[92] Haynes, A.B.; Weiser, T.G.; Berry, W.G. et. al (2009). "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population." New England Journal of Medicine. 360: 491-499.

discussed above. The measure would not require a hospital to report whether it uses a checklist in connection with each individual inpatient procedure. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74505 through 74506) for a detailed discussion of the Safe Surgery Checklist Use measure.

We proposed to adopt this Safe Surgery Checklist structural measure, which is not NQF-endorsed, under the exception authority provided in section 1886(b)(3)(B)(IX)(bb) of the Act. This section provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed the NQF-endorsed measures, and we were unable to identify any NQF-endorsed measures that assess use of safe surgery checklists. We also are not aware of any other safe surgery checklist use measures that have been endorsed or adopted by a consensus organization other than NQF. Accordingly, we propose to adopt the Safe Surgery Checklist measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act.

This measure was included on the pre-rulemaking list for consideration by the MAP, and this multi-stakeholder organization comprised of affected parties supported the direction of this measure pending availability of specifications. These specifications will be made available in an upcoming manual release for the ASCQR Program which will be available on Quality Net Web site at http://www.qualitynet.gov. The proposed safe

surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federation of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety, which is comprised of the American Association of Nurse Anesthetists, the American College of Surgeons, the American Association of Surgical Physician Assistants, the American Society of Anesthesiologists, the American Society of PeriAnesthesia Nurses, the AORN, and the Association of Surgical Technologists. Two State agencies (Oregon and South Carolina), the Veterans Health Administration,[93] numerous hospital systems, State hospital associations (such as California and South Carolina), national accrediting organizations, and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[94,95] Although there is not currently an NQF endorsed measure for safe surgery checklist use, because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist use reflects consensus among affected parties. We also note that TJC included safe surgery checklist practices among those to be used to achieve National Patient Safety Goals (NPSGs) adopted for 2011 for surgeries performed in ambulatory settings and hospitals.

---

[93] Neily, J; Mills, PD, Young-Xu, Y. (2010). "Association between implementation of a Medical Team Training Program and Surgical Mortality." JAMA. 304 (15): 1693-1700.
[94] Haynes, AB; Weiser, TG; Berry, WR et al (2009) "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population." NEJM. 360:491-499.
[95] Birkmeyer, JD (2010) "Strategies for Improving Surgical Quality – Checklists and Beyond." NEJM. 363: 1963-1965.

Given that this measure is pivotal in preventing human errors in surgical operations which are commonly performed by acute care hospitals, we proposed to adopt this measure for the Hospital IQR Program for the FY 2016 payment determination and subsequent years. This proposal would achieve our goal to align measures across settings.

Comment: Many commenters supported the proposed measure if a specific checklist is not mandated.

Response: We appreciate the support for the measure, which was designed to assess the adoption of a best practice for surgical care to reduce preventable medical errors and mortality while giving hospitals the flexibility to develop their own checklist that meets their needs. We chose not to finalize any specific checklist but will consider providing links to specific examples of Surgical Safety Checklists as an Appendix in the Specification Manual.

Comment: Many commenters did not support the Safe Surgery Checklist measure, and believed that the proposed measure is merely a concept and not a fully developed measure. Some commenters noted that CMS should first seek NQF endorsement for the measure. Commenters also stated that the MAP only supports the general concept and direction of the measure but did not recommend the measure for inclusion in the Hospital IQR Program.

A commenter stated that managing the processes involved in surgical care is what improves quality of care, not the mere use of a checklist.

Response: We agree that good management of processes around surgical care is critical to high quality surgical care, however, we also believe that the use of a surgical checklist facilitates management and communication of these processes. In addition, the MAP 2012 Pre-Rulemaking Report indicated that the MAP supported the direction of this measure pending further specification. We have since specified this measure for implementation in the Hospital OQR Program and the ASCQR Program, and specifications are available on the QualityNet Web site in the Specifications Manuals for these two programs at: https://www.qualitynet.org/. We also note that non-endorsed measures that we believe to be important in assessing the quality of hospital care can be adopted for the Hospital IQR Program through our exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act. This section provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We believe the Safe Surgery Checklist complements the management of surgical care processes and ultimately contributes to better patient outcomes by increasing safe surgery practices, reducing preventable human error, and minimizing complications and post-surgical mortality. To that end, we believe it warrants inclusion in the Hospital IQR Program.

Comment: A commenter provided examples of other safeguards that are already in place to address safe surgeries. The commenter also noted that the introduction of this

measure would create an undue burden on hospitals because the Medicare National Coverage Determinations already specify no Medicare reimbursement for any adverse event from any aspects of a surgery. The commenter presumed that this is a strong incentive for hospitals to take steps to ensure safe surgeries. Furthermore, the commenter noted that TJC surveys all accredited institutions for surgery checklists as part of its patient safety requirements. Therefore, the commenter concluded that there is already adequate use of the safe surgery checklist among hospitals performing surgeries.

Response: In our view, the widespread use of safe surgery checklists affirms our view regarding the significance of this structural measure. We believe that reporting information about the implementation of these safeguards to consumers is important for transparency and awareness. This is why this measure has been adopted for the Hospital OQR and ASCQR Programs as well. Public reporting of this measure is not occurring; therefore, we believe that including this measure in the Hospital IQR Program and publicly reporting the measure data is not redundant. This measure imposes a minimal reporting burden on hospitals.

Comment: One commenter requested that CMS provide sources of surgical safety checklists, which include safe surgery practices during each of the three critical perioperative periods. A few commenters stated that the WHO Safe Surgery Checklist Implementation Manual described one time pause, and not three as stated in the proposed rule. Commenters agreed that the pauses are important but a series of three time outs are disruptive and impracticable. Commenters recommended CMS clarifies and ensures that

surgeons can implement and modified CMS' sample Safe surgery Checklist and are not mandated to incorporate the three "pauses."

Response: We did not propose to require the use of any particular checklist for this measure. In the discussion of the Safe Surgery Checklist Use measure in the proposed rule we referred readers to the discussion of this measure in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74464 through 74466). In that final rule with comment period, we presented examples of typical safe surgery practices corresponding to three critical preoperative periods. Although the discussion in the CY 2012 OPPS/ASC final rule with comment period noted that the WHO Surgical Safety Checklist "lists safe surgery practices during each of these three perioperative periods," we agree with the commenters that the WHO Safe Surgery Checklist Implementation Manual only specifies a single pause. However, we did not propose to adopt the WHO checklist and, under our proposal, hospitals have the flexibility to determine the use of a safe surgery checklist with the number of pauses they feel are necessary to elicit the safest surgical practices. The measure does not assess the process or content of their safe surgery checklists, nor does the Safe Surgery Checklist Use measure finalized for the Hospital OQR Program or ASCQR Program. The measure does not prescribe for facilities the processes for completion of (for example, number of pauses) or content of a safe surgery checklist (for example, which items to check on). Instead, the measure just requires hospitals to report whether or not they use a safe surgery checklist.

Comment: A commenter recommended that after implementation, CMS should evaluate the appropriate implementation and utilization of the use of the safe surgery

checklist by providers as indicated in this measure. Commenters were concerned that the use of a surgical checklist may result in a "check the box" process which does not result in the improved delivery of care for which the checklist is intended. A commenter suggested focusing on specifying standardized criteria to be followed in using the safe surgery checklist instead of whether the checklist is in place.

Response: We agree with the commenters that the use of a safe surgery checklist as indicated in this measure should be implemented appropriately to achieve improved delivery rather than just creating an additional documentation requirement. The use of a checklist is intended to help prevent serious medical errors involving surgical care such as anesthesia dosing errors and allergic reactions, wrong site surgery, wrong procedure or wrong patient surgery, and the retention of foreign objects in the body. During our measure maintenance process, we will review the improvement potential for this measure, like all the measures we adopted for the Hospital IQR Program, for indication of best practices, among other review criteria.

Comment: A commenter was skeptical that the proposed Safe Surgery Checklist attestation could be validated by CMS and therefore, does not warrant consideration as a structural measure.

Response: At this time we have not proposed to validate this measure or other structural measures previously adopted in the Hospital IQR Program.

After consideration of public comments we received, we are finalizing the Safe Surgery Checklist use measure as proposed for a total of 60 measures for the FY 2016 payment determination and subsequent years. The data collection requirements for this

measure are detailed in the "Form, Manner, and Timing of Quality Data Submission" section of this preamble. The 60 measures for the FY 2016 payment determination and subsequent years are listed below.

Topic	Hospital IQR Program Measures for FY 2016 Payment Determination and Subsequent Years
Acute Myocardial Infarction (AMI) Measures	
	● AMI-2 Aspirin prescribed at discharge
	● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
	● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)
	● AMI-10 Statin Prescribed at Discharge
Heart Failure (HF) Measures	
	● HF-1 Discharge instructions
	● HF-2 Evaluation of left ventricular systolic function
	● HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction
Stroke Measure (STK) Set	
	● STK-1 VTE prophylaxis
	● STK-2 Antithrombotic therapy for ischemic stroke
	● STK-3 Anticoagulation therapy for Afib/flutter
	● STK-4 Thrombolytic therapy for acute ischemic stroke
	● STK-5 Antithrombotic therapy by the end of hospital day 2
	● STK-6 Discharged on Statin
	● STK-8 Stroke education
	● STK-10 Assessed for rehab
VTE Measure Set	
	● VTE-1 VTE prophylaxis
	● VTE-2 ICU VTE prophylaxis
	● VTE-3 VTE patients with anticoagulation overlap therapy
	● VTE-4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol
	● VTE-5 VTE discharge instructions
	● VTE-6 Incidence of potentially preventable VTE
Pneumonia (PN) Measures	
	● PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital
	● PN-6 Appropriate initial antibiotic selection

Topic	Hospital IQR Program Measures for FY 2016 Payment Determination and Subsequent Years
Surgical Care Improvement Project (SCIP) Measures	
	● SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision
	● SCIP INF-2: Prophylactic antibiotic selection for surgical patients
	● SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
	● SCIP INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose
	● SCIP INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero
	● SCIP INF-10: Surgery patients with perioperative temperature management
	● SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period
	● SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Mortality Measures (Medicare Patients)	
	● Acute Myocardial Infarction (AMI) 30-day mortality rate
	● Heart Failure (HF) 30-day mortality rate
	● Pneumonia (PN) 30-day mortality rate
Patients' Experience of Care Measures	
	● HCAHPS survey (expanded to include one 3-item care transition set* and two new "About You" items)
Readmission Measures (Medicare Patients)	
	● Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure
	● Heart Failure 30-day Risk Standardized Readmission Measure
	● Pneumonia 30-day Risk Standardized Readmission Measure
	● 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty*
	● Hospital-Wide All-Cause Unplanned Readmission (HWR)*
AHRQ Patient Safety Indicators (PSIs) Composite Measures	
	● Complication/patient safety for selected indicators (composite)
AHRQ PSI and Nursing Sensitive Care	
● PSI-4 Death among surgical inpatients with serious treatable complications	
Structural Measures	
	● Participation in a Systematic Database for Cardiac Surgery
	● Participation in a Systematic Clinical Database Registry for Stroke Care
	● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care

Topic	Hospital IQR Program Measures for FY 2016 Payment Determination and Subsequent Years
	● Participation in a Systematic Clinical Database Registry for General Surgery
	● Safe Surgery Checklist Use **
Healthcare-Associated Infections Measures	
	● Central Line Associated Bloodstream Infection
	● Surgical Site Infection
	● Catheter-Associated Urinary Tract Infection
	● MRSA Bacteremia
	● Clostridium Difficile (C.Diff)
	● Healthcare Personnel Influenza Vaccination
Surgical Complications	
	● Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty*
Emergency Department (ED) Throughput Measures	
	● ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital
	● ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status
Prevention: Global Immunization (IMM) Measures	
	● Immunization for Influenza
	● Immunization for Pneumonia
Cost Efficiency	
	● Medicare Spending per Beneficiary
Perinatal Care	
	● Elective delivery prior to 39 completed weeks of gestation*

* New measures/items for FY 2015 payment determination and subsequent years
** New measures for FY 2016 payment determination and subsequent years

4. Possible New Quality Measures and Measure Topics for Future Years

We anticipate that, as EHR technology evolves and more infrastructure is put in place, we will have the capacity to accept electronic reporting of many of the clinical chart-abstracted measures that are currently part of the Hospital IQR Program or have been proposed for adoption into the program. We intend for this future progress to

significantly reduce the administrative burden on hospitals under the Hospital IQR Program. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures that we proposed. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into EHR technology to capture and calculate the results, and implementing the systems. We believe that at a future date, such as 2015, CMS and hospitals will be able to use EHR-based reporting for many chart-abstracted measures for the Hospital IQR Program, and we intend to work diligently toward this goal. We believe this will simplify measure collection and submission for the Hospital IQR Program, and will reduce the burden on hospitals to report chart-abstracted measures.

Once the e-specifications and the EHR-based collection mechanism are available for the smoking and alcohol cessations measures developed by TJC, we intend to propose two TJC smoking and alcohol cessation measure sets for inclusion in the Hospital IQR Program. Each of these TJC sets consists of four measures:

- Smoking Cessation Set – (1) TAM-1 Tobacco Use Screening; (2) TAM-2 Tobacco Use Treatment Provided or Offered; (3) TAM-3 Tobacco Use Treatment Management at Discharge; and (4) TAM-4 Assessing Status after Discharge, and
- Alcohol Cessation Set – (1) TAM-5 Alcohol Use Screening; (2) TAM-6 Alcohol Use Brief Intervention Provided or Offered; (3) TAM-7 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge; and (4) TAM-8 Substance Use: Assessing Status after Discharge.

These measure sets were recommended by the MAP for inclusion in the Hospital IQR Program, provided they complete the NQF endorsement process prior to inclusion. We invited public comment on our intention to propose these measure sets.

Comment: Roughly equal numbers of commenters supported and opposed the two TJC smoking and alcohol cessation measure sets for inclusion in the Hospital IQR Program. A commenter did not support the TAM-4 Assessing Status after Discharge and TAM-8 Substance Use: Assessing Status after Discharge measures as data collection after discharge was perceived to be very labor intensive. A commenter urged CMS to align the Smoking and Alcohol Cessation measure names with TJC's measure names should CMS propose the measures in the future.

A few commenters highlighted some limitations of e-specifications and EHR-based collection and added that a high validation rates such as 95 percent, across electronic data capture method and manual chart-abstraction is crucial.

Response: We thank the commenters for their input on the prospective TJC alcohol and smoking cessation measure sets. We will take this input into consideration in future rulemakings.

We intend to propose the following measure domains in the Hospital IQR Program measure set in future measurement proposals for the Hospital IQR Program: clinical quality (for example, the AMI, HF, PN, STK, and VTE measures), care coordination (for example, the mortality measures), patient safety (for example, the SCIP and HAI measures), patient and caregiver experience of care (for example, the HCAHPS measure), population/community health (for example, the global immunization

measures), and efficiency (for example, the Medicare Spending per Beneficiary measure). This approach will enhance better patient care while bringing the Hospital IQR Program in line with our other established quality reporting and pay-for-performance programs.

Comment: We received many suggestions for future measure domains or measure topics including:

- HAIs measures collected via NHSN
- Risk-adjusted, rate-based HAC measures
- Beta blockers prescribed to HF patients
- Beta blocker therapy for left ventricular systolic dysfunction
- Post-discharge appointment for HF patients
- AAA mortality measures
- Cardiac Rehabilitation Referral
- Discharge appointment measure for heart failure patients
- Coronary artery and heart disease
- Medication safety
- Surgical outcome measures
- Sepsis and septic shock
- Registry-based CABG composite score
- Potentially avoidable complication
- A comprehensive COPD measure set
- Pain assessment

- Alzheimer's disease/cognitive impairment quality measures
- Efficiency, resource use, and appropriateness of care measures
- Malnutrition
- Patient-reported outcomes and engagement
- Pediatric care

In addition, some commenters opposed the future inclusion of measures that require a global population. A commenter requested CMS to provide a detailed list of measures under consideration in the proposed rulemakings.

Response: We thank the commenters for their valuable input for the suggestions regarding future measures and will take them into consideration for future rulemakings. We also noted that consistent with the updated NQF endorsements of the CLABSI (NQF #139) and CAUTI (NQF #138) measures, we intend to propose to collect data for non-ICU patients as well for these two measures when feasible at a future time, and we sought public comment on the feasibility and timing of expanding data collection to non-ICU locations for acute care hospitals.

Comment: A few commenters highlighted the prevalence of CLABSI in ICUs in hospitals and noted that the morbidity and mortality from these types of infections are preventable. The commenters strongly encouraged CMS to move forward with data collection from non-ICU locations as soon as possible.

Response: We thank the commenter for the encouragement to advance our goal to reduce central line associated blood-stream infections.

Comment: Many commenters stated that expansion of the CLABSI and CAUTI measures into the non-ICU locations in hospitals is a good long-term goal. However, commenters requested delaying the proposal to expand these two measures to include non-ICU locations until hospitals have gained several years of experience with data collection and validation in ICUs. Two commenters perceived the expansion of data collection to non-ICU locations as burdensome and strongly urged CMS not to expand data collection beyond ICU units. A commenter questioned the capability of the NHSN to handle the influx of data from the expansion of the CLABSI measures into non-ICU locations.

Response: We will take these comments into consideration in determining an appropriate time to propose to expand collection of these measures in non-ICU locations. As more and more acute care hospitals reduce CLABSI and CAUTI incidence in ICU locations and prioritize reductions of CLABSI and CAUTI incidence in other hospital locations, extending CLABSI and CAUTI reporting to those locations will yield benefits for prevention and quality improvement and will justify extending the scope of CLABSI and CAUTI reporting to non-ICU locations. We anticipate that NHSN infrastructure would be enhanced as needed to handle any expansion of CLABSI and CAUTI reporting requirements.

Comment: A commenter strongly supported using the NHSN as the core component of HAI data reporting. Another commenter expressed concerns that the functionality of the NHSN database as is not user-friendly. According to this commenter, there are significant limitations for uploading data. For example, a hospital may have an

incomplete data set to upload into the surgical site infection application for colon and hysterectomy patients, but the data cannot be saved in a temporary file until it is complete. In addition, the database does not accept simple spreadsheets to be uploaded. The commenter urged CMS to collaborate with the CDC to improve the usability of the NHSN database.

Response: We thank the commenter for the support of using NHSN as the mechanism to collect HAI measure data. We understand that CDC continues to use input from users and systematic field studies of its own to improve the usability of NHSN's Web interface. CDC requires healthcare facilities to submit complete healthcare-associated infection data records via the NHSN system, to avoid storing volumes of incomplete records while substantial back-and-forth communication between CDC and the reporting facility is pending during close out for the facility's reporting for a specified reporting interval. The importance of requiring complete records is heightened by the use of NHSN for mandatory healthcare-associated infection reporting in 29 states (including Washington, DC) and use of NHSN for CMS quality reporting programs. CDC informed us that NHSN accepts comma separated value (CSV) files for importation of patient demographic data, procedure data, and surgeon data. These CSV files can be readily created from spreadsheets and uploaded into NHSN, eliminating the need for manual data entry of patient demographic data, procedure data, and surgeon data.

We thank the commenters for their input on the feasibility and timing of expanding collection of these measures to include non-ICU locations in hospitals. We will take them into consideration in future rulemakings.

5. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (II) of the Act state that the applicable percentage increase, for FY 2007 and each subsequent fiscal year, shall be reduced by 2.0 percentage points (or, beginning with FY 2015, by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act)) for any subsection (d) hospital that does not submit quality data in a form and manner, and at a time, specified by the Secretary. CMS requires that hospitals submit data in accordance with the specifications for the appropriate discharge periods. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: http://www.QualityNet.org/. Hospitals submit quality data through the secure portion of the QualityNet (formerly known as QualityNet Exchange) Web site (https://www.QualityNet.org). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements for security of protected health information.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural requirements. Hospitals choosing to participate in the Hospital IQR Program must also meet specific data collection, submission, and validation requirements.

b. Procedural Requirements for the FY 2015 Payment Determination and Subsequent Years

The Hospital IQR Program procedural requirements are now codified in regulation at 42 CFR 412.140. Hospitals should refer to the regulation for participation

requirements. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28051), for the FY 2015 payment determination and future years, we proposed to modify the following procedural requirements and the corresponding regulation text.

- In order to ensure that hospitals that participate in the Hospital IQR Program are submitting data for a full year, we proposed that hospitals that would like to participate in the Hospital IQR Program for the first time, or that previously withdrew from the Program and would like to participate again, must submit to CMS a completed Notice of Participation by December 31 of the calendar year preceding the first quarter of the calendar year in which the chart-abstracted Hospital IQR data submission is required for any given fiscal year. For example, if a hospital wishes to participate in FY 2015, it must submit a pledge by December 31, 2012, and submit data beginning with January 1, 2013 discharges. We also proposed to modify our regulations at 42 CFR 412.140(a)(3)(i) to reflect this proposed requirement.

- Currently, CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made. In order to decrease the time between final submission of Hospital IQR data and Hospital IQR payment determination notification for the hospitals, we proposed that a subsection (d) hospital may withdraw from the Hospital IQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital must submit the withdrawal form by May 15 prior to the start of the payment year affected. For example, if a hospital seeks to withdraw from the FY 2015 payment determination, the hospital

must submit the withdrawal form to CMS by May 15, 2014. If a hospital withdraws from the Program, it will receive a reduction until such time as it meets the participation requirements. This proposal will also align with the final abstraction data submission deadline, which will eliminate the burden of one extra deadline for providers and vendors. We also proposed to modify our regulations at 42 CFR 412.140(b) to reflect this proposed requirement.

Comment: A few commenters supported the proposed changes in the data submission requirements regarding the timing of notifications for participating in and withdrawing from the Hospital IQR Program.

Response: We would like to thank the commenters for their support.

After consideration of the public comments we received, we are finalizing these participation changes and modifying the associated regulation text at 42 CFR 412.140(a)(3)(i) and 42 CFR 412.140(b).

c. Data Submission Requirements for Chart-Abstracted Measures

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28051), for FY 2015 and subsequent years, we proposed to retain the 4½ months quarterly submission deadline for chart-abstracted quality measures. We also proposed to retain the aggregate population and sampling deadline of 4 months. Hospitals would continue to be required to submit aggregate population and sample size counts to CMS on a quarterly basis for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (76 FR 51640 through 51641). We proposed the same 14-day period after the aggregate population and sample size count deadline to submit the required patient-level

records. For the FY 2015 payment determination and subsequent years, hospitals must submit data for four consecutive calendar year discharge quarters. For example, for FY 2015, the submission quarters are as follows: 1Q CY 2013, 2Q CY 2013, 3Q CY 2013 and 4Q CY 2013.

We received no comments on this proposal; therefore, we are finalizing our proposal to retain the 4½ months quarterly submission deadline for chart-abstracted quality measures and the aggregate population and sampling deadline of 4 months for the FY 2015 payment determination and subsequent years.

We proposed to collect a new chart-abstracted measure for FY 2015, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. Although this is a chart-abstracted measure, we proposed that this measure would be collected in aggregated numerator, denominator, exclusion counts and total population per hospital via a Web-Based Measure Tool. The complete data submission requirements, submission deadlines, and data submission mechanism, known as the Web-Based Measure Tool, will be posted on the QualityNet Web site at: http://www.qualitynet.org/. The Web-Based Measure Tool will be an Internet database for hospitals to submit their aggregate data. We proposed that hospitals submit data in accordance with the specifications for the appropriate reporting periods to the Web-Based Measure Tool that will be found in the hospital section on the QualityNet Web site (http://www.qualitynet.org/).

Comment: One commenter opposed the use of aggregate reporting because many hospitals already report this measure to TJC in a patient-level format.

Response: We thank the commenter for the input and appreciate that hospitals that submit to TJC will need to submit their aggregate totals to the Web tool. However, we believe this aggregate submission will be less burdensome for hospitals that do not already collect this measure.

Comment: Several commenters supported the aggregate collection of the data for the Elective Delivery Prior to 39 Completed Weeks Gestation measure.

Response: We thank the commenters for their support.

Comment: Several commenters support the aggregate collection of the measure but wanted more details on the submission deadlines and requirements.

Response: We thank the commenters for their input and reiterate our statement from the proposed rule that we consider the Elective Delivery Prior to 39 Completed Weeks Gestation measure to be a chart-abstracted measure. Accordingly, we are clarifying that the deadlines that we are finalizing for submission of patient-level data for all of the chart-abstracted measures also apply to submission of aggregate numerator, denominator, exclusion counts and total population and sample size for this measure. The only difference between the submission requirements for this measure and the other chart-abstracted measures is that the method hospitals will follow will vary somewhat, while the actual deadlines will not.

In particular, we provide hospitals with the opportunity to begin submitting patient-level charts for the other chart-abstracted measures as candidate cases occur during the quarter at issue. It is not necessary for us to provide this same mechanism for the Elective Delivery Prior to 39 Completed Weeks Gestation measure because hospitals

will not know their aggregate counts for a particular quarter until the quarter has ended. In addition, hospitals should need less time to submit data for this measure because, unlike the other chart-abstracted measures, hospitals are only required to submit several aggregate counts instead of potentially numerous patient-level charts. We note that submission of this measure places less burden on hospitals than the other chart-abstracted measures because of the ease with which hospitals can simply submit their aggregate counts using our Web-Based Measure Tool through the QualityNet Web site.

In summary, the data submission deadline for all of the chart-abstracted measures, including the Elective Delivery Prior to 39 Completed Weeks Gestation measure, is 4 ½ months after the end of the discharge quarter. For example, the deadline for submission of data for all chart-abstracted measures for the first calendar quarter of 2013 is August 15, 2013. The only difference in timing for submission of data for the Elective Delivery Prior to 39 Completed Weeks Gestation measure and the other chart-abstracted measures is the duration of the submission periods. For the Elective Delivery Prior to 39 Completed Weeks Gestation measure the submission period for the first quarter of 2013 will be July 1st, 2013- August 15th, 2013and for the other chart-abstracted measures the submission period is for the first quarter of 2013 will be January 1, 2013- August 15, 2013. While the submission periods differ, the deadlines for each quarter will be the same for all chart-abstracted measures, including the Elective Delivery Prior to 39 Completed Weeks Gestation measure.

Comment: Several commenters were concerned about including this measure in the Hospital VBP Program because it is would be difficult to validate since there are no underlying patient records from which to pull the data.

Response: We thank the commenters for their input. We point out that the measure was not proposed for the Hospital VBP Program at this time. We also have not proposed to validate this measure.

After consideration of the public comments we received, we are finalizing the aggregate data collection and submission requirements for the Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation measure.

d. Sampling and Case Thresholds Beginning with the FY 2015 Payment Determination

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), we continued, for the FY 2015 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) regarding hospital submission of population and sampling data. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28051), we did not propose any changes to these requirements.

We strongly recommend that hospitals review the QIO Clinical Warehouse Feedback Reports and the Hospital IQR Program Provider Participation Reports that are available after patient-level data are submitted to the QIO Clinical Warehouse. We generally update these reports on a daily basis to provide accurate information to hospitals about their submissions. These reports enable hospitals to ensure that their data were submitted on time and accepted into the QIO Clinical Warehouse.

Comment: Several commenters expressed concern about changes to QualityNet feedback reports. In addition, several commenters expressed concern that QualityNet's role in validation is being expanded at a time when the system is not functioning properly.

Response: We thank the commenters for their concerns. The QualityNet reporting system recently underwent significant changes as a result of a Hospital IQR Program and Hospital OQR Program system alignment and re-design. The format of standard QualityNet reports should be consistent at this time, with changes being applied only to accommodate changes in data collection, updates necessary to support changes in program requirements. We believe QualityNet is reliable and that the system will continue to be capable of supporting the uploads necessary for validation.

Comment: One commenter expressed concern that electronic medical records owners be given assistance from vendors or have access to programming to assure correct documentation and obstetric reporting.

Response: We thank the commenter and encourage submitters to work with their vendors to assure correct documentation and obstetric reporting.

e. HCAHPS Requirements for the FY 2014, FY 2015, and FY 2016 Payment Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), beginning with discharges occurring in third quarter CY 2011, we established that hospitals will have about 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse.

Other than this change, we did not make any other changes to the HCAHPS requirements for the FY 2013 and FY 2014 Hospital IQR Program payment determinations, which were adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28051), for the FY 2016 Hospital IQR payment determinations, we proposed to continue these HCAHPS requirements. Under these requirements, a hospital must continuously collect and submit HCAHPS data in accordance with the current HCAHPS Quality Assurance Guidelines and the quarterly data submission deadlines, both of which are posted at http://www.hcahpsonline.org. In order for a hospital to participate in the collection of HCAHPS data, a hospital must either: (1) contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the hospital's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a survey vendor provided that the hospital attends HCAHPS training and meets Minimum Survey Requirements as specified on the HCAHPS Web site at: http://www.hcahpsonline.org. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site. For the FY 2016 Hospital IQR Program, we proposed that the HCAHPS data would be based on discharges from January 1, 2014 through December 31, 2014.

Every hospital choosing to contract with a survey vendor must provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the Quality Assurance Guidelines located at

http://www.hcahpsonline.org for details about HCAHPS survey administration.) Hospitals are strongly encouraged to submit their entire patient discharge list, excluding patients who had requested "no publicity" status or who are excluded because of State regulations, in a timely manner to their survey vendor to allow adequate time for sample creation, sampling, and survey administration. We emphasize that hospitals must also provide the administrative data that is required for HCAHPS in a timely manner to their survey vendor. This includes the patient MS-DRG at discharge, or alternative information that can be used to determine the patient's service line, in accordance with the survey protocols in the most recent HCAHPS Quality Assurance Guidelines.

We note that the HCAHPS Quality Assurance Guidelines require that hospitals maintain complete discharge lists that indicate which patients were eligible for the HCAHPS survey, which patients were not eligible, and which patients were excluded, and the reason(s) for ineligibility and exclusion. (We refer readers to the Quality Assurance Guidelines located at http://www.hcahpsonline.org for details about HCAHPS eligibility and sample frame creation.) In addition, the hospital must authorize the survey vendor to submit data via My QualityNet, the secure part of the QualityNet Web site, on the hospital's behalf.

Hospitals must obtain and submit at least 300 completed HCAHPS surveys in a rolling four-quarter period unless the hospital is too small to obtain 300 completed surveys. We wish to emphasize that the absence of a sufficient number of HCAHPS eligible discharges is the only acceptable reason for obtaining and submitting fewer than 300 completed HCAHPS surveys in a rolling four quarter period. If a hospital obtains

fewer than 100 completed surveys, the hospital's HCAHPS scores will be accompanied by an appropriate footnote on the Hospital Compare Web site alerting the Web site users that the scores should be reviewed with caution, as the number of surveys may be too low to reliably assess hospital performance.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that hospitals employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) and the HCAHPS Review and Correction Report that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time, the data has been accepted into the QIO Clinical Warehouse, and the data accepted into the QIO Clinical Warehouse are complete and accurate.

In order to ensure compliance with HCAHPS survey and administration protocols, hospitals and survey vendors must participate in all oversight activities. As part of the oversight process, during the onsite visits or conference calls, the HCAHPS Project Team will review the hospital's or survey vendor's survey systems and assess protocols based upon the most recent HCAHPS Quality Assurance Guidelines. All materials relevant to survey administration will be subject to review. The systems and program review includes, but is not limited to: (a) survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone and Interactive Voice Response (IVR) materials and facilities; (d) data receipt, entry and storage facilities; and (e) written documentation of survey processes. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. We point out that the

HCAHPS Quality Assurance Guidelines state that hospitals should refrain from activities that explicitly influence how patients respond on the HCAHPS survey. If we determine that a hospital is not compliant with HCAHPS program requirements, we may determine that the hospital is not submitting HCAHPS data that meet the requirements of the Hospital IQR Program.

We continue to strongly recommend that each new hospital participate in an HCAHPS dry run, if feasible, prior to beginning to collect HCAHPS data on an ongoing basis to meet Hospital IQR Program requirements. New hospitals can conduct a dry run in the last month of a calendar quarter. The dry run will give newly participating hospitals the opportunity to gain first-hand experience collecting and transmitting HCAHPS data without the public reporting of results. Using the official survey instrument and the approved modes of administration and data collection protocols, hospitals/survey vendors will collect HCAHPS dry-run data and submit the data to My QualityNet, the secure portion of QualityNet.

We again are encouraging hospitals to regularly check the HCAHPS Web site at http://www.hcahpsonline.org for program updates and information. We invited public comment on our proposal to continue using these HCAHPS requirements for the FY 2016 payment determination.

We did not receive any public comments and we are adopting the HCAHPS requirements for the FY 2014, FY 2015, and FY 2016 payment determinations, as proposed.

f. Data Submission Requirements for Structural Measures

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644), beginning with FY 2013, we finalized the period of data collection for which hospitals will submit the required registry participation information once annually for the structural measures via a Web-Based Measure Tool. We finalized our proposal for FY 2014 for submission of structural measures between April 1, 2013 and May 15, 2013 with respect to the time period of January 1, 2012 through December 31, 2012. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28052), we proposed to continue this policy for FY 2015 and subsequent years. For the FY 2015 payment determination, the period of data collection for which hospitals will submit the required registry participation information for the structural measures via a Web-Based Measure Tool will be between April 1, 2014 and May 15, 2014, with respect to the time period of January 1, 2013 through December 31, 2013. We invited public comment on this proposal.

Comment: One commenter supported the timing of collection for structural measures for FY 2015 and subsequent years.

Response: We thank the commenter for the support.

After consideration of the public comment we received, we are finalizing our proposal to align the structural measure submission with the final submission quarter for each fiscal year for FY 2015 and subsequent years.

g. Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51644 through 51645), we adopted the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of the HAI measures to NHSN. The existing data collection and submission timeframes for the HAI measures for the FY 2014 payment determination align with the submission timeframes for chart abstracted measures. The data submission deadlines are posted on the QualityNet Web site at: http://www.QualityNet.org/.

Hospitals will have until the Hospital IQR Program final submission deadline to submit their quarterly data to NHSN. After the final Hospital IQR Program submission deadline has occurred for each calendar quarter of CY 2013, for FY 2015 quarters, CMS will obtain the hospital-specific calculations that have been generated by the NHSN for the Hospital IQR Program.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28052), we proposed to continue this policy, with the two exceptions discussed below, for the FY 2015 payment determination and subsequent years.

The HAI measures that will be included in the FY 2015 payment determination are included in the following chart:

Topic	FY 2015 Payment Determination: Hospital Associated Infection Measures (CDC/NHSN)
	Central Line Associated Blood Stream Infection
	Surgical Site Infection
	Catheter Associated Urinary Tract Infection
	MRSA Bacterimia
	Clostridium difficile
	Healthcare Provider Influenza Vaccination

We realize that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting, for example, when a hospital has no ICUs. We proposed to provide an exception for the CLABSI and CAUTI measures for hospitals that do not have an ICU, reducing the burden associated with reporting to NHSN. In addition, we recognize that some facilities may perform so few procedures requiring surveillance under the Surgical Site Infection (SSI) measure that the data may not be meaningful for Hospital Compare or sufficiently reliable to be utilized for payment determination.

We proposed to provide an exception for these hospitals from the reporting requirement in any given year if the hospital performed fewer than a combined total of 10 colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year. For example, a hospital that performed only 2 colon surgeries and 4 abdominal hysterectomies in 2012 would not be required to report the SSI measure in 2014. We proposed to provide hospitals with a single HAI exception form, to be used for seeking an exception for any of the CLABSI, CAUTI and SSI measures, which will be available on QualityNet. We invited public comment on this proposal.

Comment: Several commenters supported the CMS proposal to provide an exception from NHSN reporting for hospitals without ICU locations or that perform a combined total of 10 or fewer colon and abdominal hysterectomy procedures.

Response: We thank these commenters for their support.

Comment: One commenter suggested that a combined total of 25 colon and abdominal hysterectomy procedures may be more appropriate.

Response: We proposed to exempt hospitals performing 10 or fewer colon or abdominal hysterectomy procedures because we believe that facilities performing this number of procedures may not have data for the Surgical Site Infection (SSI) measure that is sufficiently meaningful for a measure score to be displayed on Hospital Compare for this measure. However, we believe that setting the minimum number of procedures as low as ~~is~~ possible for SSI is essential to ensuring the availability of the most data possible for Hospital Compare reporting for this critical HAI measure. We thank the commenter for the suggestion and will re-evaluate this policy when more data are available.

After consideration of the public comments we received, we are finalizing the proposed exception process to provide hospitals with a single HAI exception form, to be used for seeking an exception for any of the CLABSI, CAUTI and SSI measures as defined above.

6. Supplements to the Chart Validation Process for the Hospital IQR Program for the FY 2015 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28053 through 28059), for the FY 2015 payment determination and subsequent years, we proposed to continue using, with some modifications, the validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229) and the FY 2012

IPPS/LTCH PPS final rule (76 FR 51645 through 51648). The modifications we proposed, explained in detail below, are as follows: (a) Using separate validation approaches for chart-abstracted clinical process of care and HAI measures; (b) changing the number of hospitals included in the base annual validation random sample; and (c) using targeted selection of supplemental hospitals to be added to the base sample. As described below, these proposals are intended to strengthen the Hospital IQR Program by validating a larger set of measures, increasing opportunities to detect poor reporting through different approaches to targeting and scoring, and increasing the rigor associated with our validation process, all while ensuring that the wider scope and greater rigor only modestly increases the burden of validation activities on hospitals relative to prior years. We invited public comment on each of these proposals.

a. Separate Validation Approaches for Chart-Abstracted Clinical Process of Care and Healthcare Associated Infection (HAI) Measures

(1) Background and Rationale

We finalized reporting to the Hospital IQR Program of 25 chart-abstracted measures in 7 topic areas: acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); surgical care improvement project (SCIP); emergency department throughput (ED); immunization (IMM); and HAIs for the FY 2014 payment determination and subsequent years in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51628 through 51629). In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28053), for the FY 2015 payment determination and subsequent years, we proposed to continue validating the chart-abstracted clinical process of care measures

with the exception of the SCP–VTE–1 measure, which we proposed for removal from the Hospital IQR Program starting with the FY 2015 payment determination. We also proposed to continue validating the one HAI measure—CLABSI—that we finalized for validation in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51646). We also proposed to validate two additional HAI measures, catheter-associated urinary tract infection (CAUTI) and surgical site infection (SSI), which were finalized for inclusion in the Hospital IQR Program for the FY 2014 payment determination and subsequent years in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51628 through 61629). We proposed to add these two measures to those we validate so that we can ensure data reliability on all chart-abstracted measures on which hospitals will have been reporting data under the Hospital IQR Program for at least one year prior to the FY 2015 payment determination.

The inclusion of the three chart-abstracted HAI measures—CLABSI, CAUTI, and SSI—in the Hospital IQR Program reflects HHS' priority to increase patient safety by preventing HAIs. As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51645), the mechanism for reporting HAI measures is different from the mechanism for reporting on the chart-abstracted clinical process of care measure sets (AMI, ED, IMM, HF, PN, SCIP). In addition, the infection events for which hospitals would report on the HAI measures occur rarely relative to the events for which hospitals would report on the clinical process of care measure sets. We cannot report a single number describing the national incidence for these three HAIs collectively or individually because infection rates vary by the type of hospital, their patient populations, device

utilization rates, and performance of different types of surgeries.[96] However, we know that these events are sufficiently rare that if we did not find a way to target records with a higher probability of including an HAI, many hospitals would have to submit virtually all records per quarter to effectively validate the HAI measure set. For these reasons, we proposed, and we describe below in section VIII.A.6.a.(3) of this preamble to separate the approaches for targeting and sampling of records for HAI validation from the approaches finalized for validation of the chart-abstracted clinical process of care measure sets in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51647 through 51648), and summarized in VIII.A.6.a.(2) of this preamble, and we proposed to calculate separate scores for the group of clinical process of care measure sets and the HAI measure set as described in VIII.A.6.a.(4) of this preamble.

Comment: Several commenters expressed general support for the validation proposal. Many commenters acknowledged that validation of the chart-abstracted clinical process of care and HAI measures should be separated. In fact, many commenters suggested that CDC should manage HAI validation efforts because of its responsibility for defining and maintaining the NHSN system. Others encouraged CMS "to work closely with NHSN in its validation development."

Response: We appreciate these comments, and agree that CDC is responsible for defining and maintaining the NHSN system and is an important partner in validating HAI measures. However, we wish to clarify that validation of Hospital IQR Program data is

[96] Dudeck MA, Horan TC, Peterson KD, *et al.* National Healthcare Safety Network (NHSN) Report, data summary for 2010, device-associated module. Am J Infect Control. 2011 Dec;39(10):798–816. Edwards JR, Peterson KD, Mu Y, *et al.* National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December 2009. Am J Infect Control 2009 Dec; 37:783–805.

our responsibility because the authority to perform this function is vested in us by statute. We also wish to clarify that QIO contractor regulatory authority (42 CFR 476.78(c)) is used to require hospitals to provide copies of medical record documentation. This regulatory authority is critical to ensuring complete submission of hospital documentation for validated hospitals. CDC is unable to use this same regulatory authority to gain access to records. Moreover, by retaining control over the HAI validation process, we are also able to reduce burden on hospitals by only requesting a record once in the event that a record is sampled for validation of both clinical process of care and HAI measure sets. We administer the Hospital IQR clinical process of care measure collection and validation without any CDC direct role, so CDC does not have any access to clinical process of care measure records submitted for validation. Accordingly, if CDC had sole responsibility for validating HAI measures, hospitals could potentially have to submit the same records twice for both clinical process of care and HAI measures. For all of these reasons, we do not agree that CDC should manage the Hospital IQR Program HAI validation process.

We emphasize that we have collaborated closely with CDC on all aspects of HAI reporting, including last year's final rule for CLABSI validation, the positive blood culture template distributed on QualityNet at: http://www.qualitynet.org, the instructions for CDAC abstractors performing validation, and this year's proposal for HAI validation.

In recognition that the HAI and clinical process of care measures are collected through different data collection systems, and after consideration of the public comments we received, we are finalizing our proposal for the FY 2015 payment determination and

subsequent years to separate the approaches for HAI validation from the approaches finalized for validation of the chart-abstracted clinical process of care measure sets, with one exception. We will not require hospitals to receive separate passing scores on both clinical process of care and HAI measures. This policy is described further in response to comments in section VIII.A.6.a.(4) of this preamble.

(2) Selection and Sampling of Clinical Process of Care Measures for Validation.

The approach to selection and sampling of clinical process of care measure sets for validation was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) for the 2014 payment determination and subsequent years. These measures and measure sets are shown in the table below.

Hospital Inpatient Quality Reporting (IQR) Program Chart-Abstracted Clinical Process of Care Measures to be Validated for the FY 2014 Payment Determination and Subsequent Years	
Topic	**Measures**
Acute Myocardial Infarction (AMI) Measures	● AMI-2 Aspirin prescribed at discharge ● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival ● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) ● AMI-10 Statin Prescribed at Discharge
Heart Failure (HF) Measures	● HF-1 Discharge instructions ● HF-2 Evaluation of left ventricular systolic function ● HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction
Pneumonia (PN) Measures	● PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital ● PN-6 Appropriate initial antibiotic selection
Surgical Care Improvement Project (SCIP) Measures	● SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision ● SCIP INF-2: Prophylactic antibiotic selection for surgical patients ● SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours

Hospital Inpatient Quality Reporting (IQR) Program Chart-Abstracted Clinical Process of Care Measures to be Validated for the FY 2014 Payment Determination and Subsequent Years	
	after surgery end time (48 hours for cardiac surgery) ● SCIP INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose ● SCIP INF-9: Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero ● SCIP INF-10: Surgery patients with perioperative temperature management ● SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period ● SCIP INF -VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered* ● SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Emergency Department Throughput (ED) Measures	● ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital ● ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status
Prevention: Global Immunization (IMM) Measures	● Immunization for Influenza ● Immunization for Pneumonia

*We are removing this measure from the Hospital IQR Program starting with the FY 2015 payment determination.

We describe the validation approach for these measures, which was finalized in FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648), for informational purposes only. A total of 15 records will be selected per quarter for the chart-abstracted clinical process of care measures. Three records per quarter will be sampled from among all records submitted to the Warehouse in each of four groups defined as part of the AMI, HF, PN, and SCIP measure sets. In addition, three records per quarter will be sampled from among the remaining submissions to the Warehouse and will be validated for the

ED and IMM measure sets. CMS will also abstract data regarding the ED and IMM measure sets from records submitted for the AMI, HF, PN, and SCIP measure sets.

We finalized our proposal in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51648) to abstract ED and IMM data from all cases selected from other measure sets (AMI, HF, PN, SCIP, and CLABSI). In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28054), for the FY 2015 payment determination and subsequent years, we proposed to discontinue abstracting ED and IMM data from cases selected for the CLABSI measure. We proposed this change in order to be consistent with the policy described in section VIII.A.6.a.(1) of this preamble to calculate separate scores for HAI and chart-abstracted clinical process of care measure sets.

Comment: One commenter requested clarification as to whether a hospital is required to submit ED/IMM data on all AMI, HF, PN, and SCIP cases submitted to the warehouse to support the process wherein CDAC will abstract ED and IMM measures from all AMI, HF, PN, and SCIP cases selected for validation. The commenter further stated that "the sampling methodology described in the specifications manual does not work if a hospital does 100 percent review of AMI, HF, PN, and SCIP cases on a weekly basis, but samples the global population at the end of the month, when all possible cases in the population are available for sampling."

Response: We welcome the opportunity to clarify the sampling process for ED/IMM. The CDAC process to abstract ED and IMM data from all cases sampled for AMI, HF, PN, and SCIP validation does not necessitate that hospitals themselves submit ED and IMM data from all of their AMI, HF, PN, and SCIP cases in the Hospital IQR

Program, only a sample of them. Operational guidance on how to sample records for submission of Hospital IQR data is provided in our Hospital IQR Program Specifications Manual on QualityNet at http://www.qualitynet.org. The Specifications Manual calls for a representative random sample of the global population; the AMI, HF, PN, and SCIP populations are subsets of this global population. Therefore, using random sampling methodology to identify the global population sample will also randomly sample AMI, HF, PN, and SCIP cases for which hospitals will provide ED and IMM data. The validation sample of AMI, HF, PN, and SCIP cases will not perfectly overlap with those AMI, HF, PN, and SCIP cases for which ED and IMM data are submitted. However, the ED/IMM data submitted and validated will be representative of the underlying global population, which is what matters for the global measures (ED/IMM). We anticipate that the validation approach will support adequate reliability assessment of the global measures. We intend to provide additional training on monthly sampling during 2012.

While we did not receive any comments specifically addressing our proposal to discontinue abstracting ED and IMM data from records sampled for CLABSI, we did receive numerous comments supporting our proposal to separate the validation processes for the clinical process of care and HAI measure sets, which this proposal was intended to support. Accordingly, we are finalizing our proposal to discontinue abstraction of ED and IMM data from records sampled for CLABSI.

(3) Selection and Sampling of HAI Measures for Validation

As explained in section VIII.A.6.a.(1) of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28053), we proposed separate selection, sampling, and validation scoring for

HAI measures. The HAI measures we proposed to validate for the FY 2015 payment determination and subsequent years are CLABSI, CAUTI, and SSI (77 FR 28054).

HAI Measures in the Hospital Inpatient Quality Reporting (IQR) Program to be Validated for the FY 2015 Payment Determination and Subsequent Years
Measures Continued for Validation for the FY 2014 Payment Determination ● Central line-associated blood stream infection (CLABSI) among intensive care unit (ICU) patients
Additional Measures Proposed for Validation for the 2015 Payment Determination ● Surgical Site Infection (SSI) among patients with procedures for colon surgery or abdominal hysterectomy ● Catheter-associated urinary tract infection (CAUTI) among ICU patients

Because the events reported in the HAI measure set occur rarely, they require a targeted approach to validation. For the FY 2015 payment determination and subsequent years, we proposed to validate these measures by identifying records that are "candidate HAI events," which we define below. We would construct three separate lists of candidate events, one for each HAI measure. The proposed process to construct these lists is detailed further below. Each listing of candidate events will include both actual HAI events as well as many non-events. The purpose in creating these listings would be to identify records that are more likely to contain HAI events than CMS could obtain through a simple random sample of hospital discharges each quarter. In each case, this proposed process would minimize burden to hospitals while enriching the validation sample by targeting candidate events. As described later in this section, a combined list of candidate HAI events would be created from the three separate candidate HAI lists (for CLABSI, CAUTI, and SSI). The final list would be used to generate a random sample of medical records to be reviewed and evaluated for the presence or absence of one or more

of the HAI events. We describe the proposed sample size later in this section and describe the scoring process in section VIII.A.6.a.(4) of this preamble.

Comment: Two commenters recommended that CMS should add no more than one new HAI measure to the validation process in a single year.

Response: We disagree with this recommendation. In response to our proposals regarding the Hospital VBP Program in section VIII.C.3.b. of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28079), many commenters emphasized the need for rigorous validation of HAI measures before their inclusion in the Hospital VBP Program. Our validation efforts are designed to ensure accurate baseline data for potential future Hospital VBP Program years.

After consideration of the public comments we received, we are finalizing our proposal to validate the CLABSI, CAUTI, and SSI measures by producing a list of candidate HAI events as detailed below in this section.

(i) Selecting Cases for CLABSI and CAUTI Validation

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28055), we proposed to discontinue the practice finalized in FY 2012 IPPS/LTCH final rule (76 FR 51648) of abstracting CLABSI data from the records selected for the chart-abstracted clinical process of care measure sets (AMI, ED/IMM, HF, PN, SCIP). We proposed this change in order to be consistent with the policy described in section VIII.A.6.a.(1) of this preamble to calculate separate scores for HAI and chart-abstracted clinical process of care measure sets. We invited comments on this proposal.

Comment: A few commenters supported our proposal to discontinue abstracting CLABSI data from the clinical process of care measures.

Response: We agree that abstracting CLABSI data from the clinical process of care measures should be discontinued, as proposed.

After consideration of the public comments we received, we are finalizing our proposal to discontinue abstracting CLABSI data from records submitted for the clinical process of care measure sets for the FY 2015 payment determination and future years.

We finalized a two-phase process for identifying and constructing lists of candidate CLABSI events in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648). This process is summarized for the readers' information. In the first phase, each sampled hospital quarterly provides CMS with listings of positive blood cultures drawn from ICU patients. The listings include ''all blood cultures positive for infection status taken from ICU patients conducting CLABSI surveillance[97] during the discharge quarter'' (76 FR 51646). These listings are annotated to identify each ICU patient on this list who had a central venous catheter (CVC). The listings are then reviewed by a CMS contractor who produces a list of unique episodes of care for ICU patients with a CVC and that include either at least one positive blood culture for a known pathogen, or at least two positive blood cultures for the same common commensal. A blood culture which is positive for a common commensal may reflect a contaminated sample. Therefore, when the only positive blood culture result is for a common commensal, the second culture bearing the same result must be drawn from the patient within 48 hours of the first; this would confirm that the first positive common

[97] http://www.cdc.gov/nhsn/PDFs/FINAL-ACH-CLABSI-Guidance.pdf.

commensal result is not a consequence of contamination. A list of common commensals is provided by CDC.[98]

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28055), we proposed to modify this process for FY 2015 and subsequent years by requiring the Medicare health insurance claim (HIC) number to be added to the positive blood culture list if a patient has one. As explained further below, we proposed this addition specifically so that we may identify candidate CLABSIs that we also identify as candidate SSIs. Because the candidate SSIs would be identified through claims, the HIC number is needed to match patients from the candidate CLABSI list with those from the candidate SSI list. To protect this sensitive information, we proposed that positive blood culture lists be submitted through the Secure Data Exchange on the QualityNet Web site. We invited public comment on each of these proposed modifications to the identification of candidate CLABSI events.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 20855) for the FY 2015 payment determination and subsequent years, we proposed to adapt the process finalized to identify candidate CLABSI events in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) to identify candidate CAUTI events. In the first stage of this process, a CMS contractor would request a listing of positive urine cultures among ICU patients from the hospitals targeted for validation. The culture list would indicate the name of each pathogen detected and the number of colony forming units per ml. For the same reasons and following the same processes as those explained for CLABSI

[98] http://www.cdc.gov/nhsn/XLS/Common-Skin-Contaminant-List-June-2011.xlsx.

above, we proposed to require the hospital to report the Medicare HIC number for Medicare patients included on this list.

In the second stage of this process, the CMS contractor would apply NHSN criteria to eliminate those urine cultures that are not consistent with the definition of an ICU-associated CAUTI. The contractor would then remove duplicates from the same patient to produce a list which would include only one entry per ICU patient. Our intent is to target a set of patient discharges with a higher probability of having a CAUTI event than one could obtain from a simple random sample of patient discharges. We invited public comments on this proposal.

Comment: Numerous commenters supported rigorous HAI validation and separating the HAI validation process from the validation process for chart-abstracted measures. Commenters emphasized the value of validating CLABSI before including it in the Hospital VBP Program, and the importance of validating both CLABSI and CAUTI before expanding the specifications for these measures for the Hospital IQR Program beyond the ICU setting. In addition, several commenters specifically supported the 'individualized approach' to sampling each HAI included in validation.

Response: We agree that HAI validation is important and that a rigorous and individualized approach to HAI validation is needed, and have sought to take such an approach through our proposal.

Comment: Many commenters opposed both the current CLABSI process and CMS' specific proposals to expand it to CAUTI due to the level of burden. Some

commenters opposed any data submission beyond submission to the NHSN. One commenter stated that CDC's process was "strict enough."

Response: We appreciate the many concerns related to the burden of HAI validation. We disagree with commenters who feel that no burden is appropriate above and beyond that associated with NHSN submission. Although the NHSN data entry process does provide users with feedback regarding consistency of information to minimize data entry errors, this process cannot replace the assessment of reliability made by comparing the hospital's submission with that of an independent abstraction.

Moreover, HAI reduction is a HHS priority, quality reporting is an important component of HAI reduction, and quality reporting is not meaningful if data quality have not been evaluated and shown to be reliable. Therefore, HAI validation is needed to support HAI reduction. We also note that section 1886(B)(3)(b)(viii)(XI) of the Act requires the Secretary to establish a process to validate Hospital IQR measures as appropriate. We believe that this proposal meets this statutory requirement and ensures the accuracy of publicly reported data for the HAI measures. Therefore, although we continuously work to minimize burden associated with validation under the Hospital IQR Program, we believe that the value of validation for these measures justifies some added burden.

Comment: A few commenters explained that burden arises from the requirement for submission of information from multiple data streams, which are difficult for hospitals to link, or that may require a manual process in some hospitals. One commenter specifically referenced the difficulty in correlating the dates that positive

blood cultures are drawn with the dates of the patients' stays in the ICU to ensure that the positive blood cultures were obtained during the pertinent time period for the CLABSI measure during the ICU stay or within 48 hours thereafter.

Response: We understand that some hospitals' systems might not be set up to handle the current CLABSI and proposed CAUTI processes efficiently at this time. However, under the current process some hospitals already successfully submitted the required data for CLABSI validation an entire month before the first submission deadline. As hospitals become more familiar with our requirements for these validation activities, we anticipate that they will have better capabilities to support the required validation.

We recognize, however, as one commenter noted, that identifying the positive blood cultures that align with the correct timeframes for the CLABSI measure can be particularly challenging. Accordingly, in response to this comment, we are reducing the burden on hospitals associated with validating CLABSI by redefining "positive blood cultures among ICU patients" for purposes of validating CLABSI. According to NHSN specifications, ICU units are supposed to conduct surveillance on positive blood cultures attributable to an ICU patient if they are drawn within 48 hours of discharge or transfer from the ICU.[99] Therefore, CMS has previously interpreted the universe of "positive blood cultures among ICU patients" for purposes of CLABSI validation to include those cultures drawn within 48 hours of transfer from the ICU.[100] However, as the commenter noted, identifying the positive blood cultures that align with the correct timeframes may

[99] http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.
[100] Hospital Inpatient Quality Reporting (IQR) Program Quick Reference Guide: Central Line-Associated Bloodstream Infection (CLABSI), www.qualitynet.org http://www.qualitynet.org

be especially challenging because finding those cultures can require that hospitals access different systems. If hospitals are not required to obtain blood cultures taken within the 48 hour period after discharge or transfer from the ICU, some hospitals may be able to use the patient's location at the time of the blood draw to identify positive blood cultures for ICU patients. For these hospitals, we believe using this location to identify the appropriate blood cultures and not having to access different systems will alleviate the burden associated with this process.

Therefore, we are redefining "positive blood culture" for purposes of CLABSI validation to include only those blood cultures drawn from ICU patients during their actual ICU stay during the discharge quarter for the FY 2014 payment determination and future years. Consistent with this change, hospitals would only be required to report on the positive blood culture list cultures identified during the ICU stay even if this means that our validation support contractor is unable to confirm, and therefore cannot include in the validation sample, a common commensal with a second culture that was drawn within 48 hours after ICU discharge. We recognize that this means excluding from validation sampling a limited number of cases that must be reported for the CLABSI measure. We believe, however, that the potential reduced burden for hospitals more than compensates for the potential inability to validate what we believe will be a limited number of CLABSI cases. We are adopting this change to the definition of "positive blood culture" beginning with the FY 2014 payment determination. However, for the FY 2014 payment determination only we will accept as submitted all templates either including or excluding positive blood cultures drawn within 48 hours of ICU discharge or

transfer, and will not penalize hospitals during scoring for including cases drawn within 48 hours of ICU discharge. For the FY 2014 payment determination only, we will score these records but will not penalize hospitals if records submitted from this time frame do not match records in NHSN. Beginning with the FY 2015 payment determination, we will require hospitals to submit records consistent with the new definition of "positive blood culture."

One other way that we are reducing burden now is, as discussed further below, by reducing the base annual random sample size by 50 percent, which reduces total burden nationally even if burden may be somewhat higher for hospitals selected for validation in a given year.

We will also work with CDC to consider proposing the inclusion of the HIC number as a required field for Hospital IQR Program reporting of NHSN measures in the future. This may further alleviate some of the burden associated with the demographic data elements that we currently require hospitals to submit for CLABSI validation and that will be required as part of CAUTI validation. These elements are necessary to link records selected for CLABSI and CAUTI validation with records included in the NHSN database. Hospitals would no longer be required to include these elements with the other information that they submit for validation of CLABSI and CAUTI, however, if Medicare beneficiaries' records could be identified in NHSN through the HIC number provided when hospitals report the CLABSI and CAUTI measures.

Comment: Many commenters viewed the proposed HAI validation efforts as duplicative in States that already have validation, but supported a more rigorous process

in States that have no validation process. Some commenters acknowledged the need for national validation because State-based CLABSI validation efforts are not standardized.

Response: We understand that some hospitals in States with their own rigorous validation methodologies will experience multiple validation activities, and that each activity has burden associated with it. However, as many commenters noted, State-based efforts are not standardized at this time, and therefore, we believe it is still very important to validate hospitals in these States. In addition, we note that section 1886(B)(3)(b)(viii)(XI) of the Act requires us to establish a process to validate Hospital IQR Program measures that includes the auditing of a number of randomly selected hospitals sufficient to ensure validity of the program as a whole. It is our responsibility to ensure that, through our validation process, we ensure the validity of the Hospital IQR Program.

Comment: One commenter indicated that only HAIs identified in NHSN should be validated.

Response: We do not agree that validation should be limited to events detected in NHSN. Evaluation of CLABSI and CAUTI events not reported to the NHSN is an important component of validation because of the rarity of these infection events relative to events to which the clinical process of care measures apply. If validation were restricted to events already included in the NHSN, we would have no capacity to evaluate under-reporting. Moreover, evaluation of unreported infection events is an important component of State validation efforts, which are coordinated by CDC. As noted by many

commenters, to have a less rigorous process nationally would disadvantage hospitals in those States that have more rigorous infection control processes.

Comment: Some commenters specifically opposed the proposed additions of the data elements "colony forming units (CFUs) per ml" for CAUTI and "HIC number" for both CLABSI and CAUTI.

Response: Based on these comments, to reduce the burden associated with the validation process for CAUTI, we will not require hospitals to submit the "colony forming units (CFUs) per ml" data element for this measure. To eliminate this data element, we will restrict the proposed requirement for 'all positive urine cultures among ICU patients' to just those positive urine cultures with concentrations of greater than or equal to 10^3 CFUs/ml.

We believe that the inclusion of the HIC number is essential. As explained in the proposed rule (77 FR 28055), the HIC number is needed to align sampling for CLABSI and CAUTI with the proposed SSI validation process described further below. Moreover, as discussed above in this section, requiring hospitals to submit HIC numbers as part of validation may in the long run support a streamlined validation process by making it easier to link records selected for validation with records in the NHSN database.

Comment: Several commenters expressed opposition to the proposed CAUTI process because it was not sufficiently detailed to be evaluated, but stated that if we were proposing to use the same process as the one we adopted for CLABSI, they could not

support it because of the burden. Another commenter stated more generally that the proposed HAI validation methodology was 'not well defined."

Response: As we explained in the proposal, the methodology for validating CAUTI is an adaptation of the methodology we will use to validate CLABSI. The template for CLABSI is available at https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021. The CAUTI process we proposed differed from the CLABSI process in two ways. First, positive urine cultures (defined >=10^3 colony forming units (CFUs) per ml) were to be reported instead of positive blood cultures. Second, the current process for CLABSI requires hospitals to annotate which patients had central lines, but we did not propose to require hospitals to annotate which patients had urinary catheters for CAUTI. By not requiring identification of patients with urinary catheters, the resulting process proposed for CAUTI is simpler than the process for CLABSI.

In addition, because we have proposed to utilize the same validation process for CAUTI that we use for CLABSI, we are making the same change to the definition of "positive urine culture" for purposes of validating the CAUTI measure that we made to the definition of "positive blood culture" for purposes of validating CLABSI. In particular, for purposes of validating the CAUTI measure for FY 2015 and subsequent years, we will not require hospitals to submit positive urine cultures drawn within 48 hours after discharge or transfer from the ICU for the same reasons we stated above for changing the definition of "positive blood culture" for CLABSI. Comment: One

commenter recommended pilot testing of CLABSI and CAUTI processes prior to finalization because so many steps are involved in validation. A few commenters indicated that HAI validation should not be expanded beyond CLABSI until hospitals had more experience with CLABSI.

Response: We do not agree that the CLABSI and CAUTI processes must be piloted further before a process for validation can be finalized. The process proposed for CLABSI validation for the FY 2015 and future years' payment determinations is the same as that finalized for the FY 2014 payment determination with only the addition of HIC number.

CMS and hospitals have already begun to gain the kinds of experience that they might obtain from a pilot through the process that was finalized for the FY 2014 payment determination in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) for CLABSI. Some hospitals have already successfully submitted positive blood culture templates, and as reflected above in this section, we are already using our experience to reduce burden by eliminating the validation requirement to include positive blood cultures for patients discharged from the ICU within the past 48 hours. Moreover, because the validation process for CAUTI will be so similar to that for CLABSI, we believe that hospitals that have prepared themselves for CLABSI validation are prepared to handle the CAUTI validation process as well.

Comment: Some commenters observed that the proposed processes for CLABSI and CAUTI do not include validation of denominator data. These commenters described this limitation as "a significant flaw" because it "allows for improper reporting by

over-reporting denominators." These commenters argued that CLABSI cannot be included in the Hospital VBP Program until the validation process includes validation of the denominator, and similarly that the Hospital IQR Program should not expand the CLABSI and CAUTI measures to include non-ICU settings until the validation process includes validation of a denominator.

Response: We recognize that not validating denominator data is a limitation of the proposed CLABSI and CAUTI processes, but we disagree that it is such a significant flaw that validation is meaningless without it. Attribution of bloodstream and urinary tract infections to central lines and urinary catheters, respectively, is an extremely complex process that requires a significant amount of clinical judgment. In contrast, recognizing and reporting the number of device days associated with a particular patient is considerably easier. Therefore, hospitals need more detailed assessment and feedback on the process of numerator reporting than they need on denominator reporting. In addition, CLABSI and CAUTI are both very rare events. Therefore, an error made in reporting even one or two infections has the potential to greatly influence the total rate reported. In contrast, because central line and urinary catheter days are much more numerous, a misstatement of a few line [or catheter?] days makes a much smaller difference in terms of the overall accuracy of the rates reported for these measures. For both of these reasons, validation of numerator data is much more crucial to overall validation than validation of denominator data. In light of the many comments regarding burden associated with validating numerator data for CLABSI and CAUTI, we disagree

that it would be appropriate to add any new burden at this time by adding denominator validation.

Comment: One commenter indicated that CMS should require the CMS auditors that review NHSN data be qualified with certification and proof of competency in the use of the NHSN module. Two other commenters "hoped that CMS contractors will go through the same training as the field and comment to CMS on their experience because NHSN contractor feedback is critical to improvement processes."

Response: We agree with the observation that personnel conducting HAI validation need specialized training in the use of NHSN. All CMS validation abstraction will be conducted by the employees of CMS' validation contractor, who will receive training similar to the training hospitals receive from CDC. In addition, some of our employees plan to attend this training and will monitor contractor feedback closely.

After consideration of the public comments we received, we are finalizing the proposals to identify candidate CLABSI as proposed. The differences between the policy we are finalizing and the policy finalized for the FY 2014 payment determination and subsequent years (76 FR 51645-51648) are the requirements that hospitals include the HIC number as a data element on the positive blood culture template[100] and that hospitals submit the blood culture template through the Secure Data Exchange on the QualityNet Web site, as well as the redefinition of "positive blood culture" for purposes of CLABSI validation to include only those cultures obtained during a patient's stay in the ICU.

In addition, for the FY 2015 payment determination and future years, we are finalizing the process to identify candidate CAUTI as proposed, including HIC number,

except that we will restrict the list of positive urine cultures to those with >= 10^3 CFU/ml, and will not require hospitals to provide the concentration of CFUs in the urine on the urine culture template we provide. Moreover, consistent with the change we are making to the definition of "positive blood culture" for CLABSI validation, we are redefining positive urine cultures from ICU patients for CAUTI validation to include only those cultures sampled during the patient's actual ICU stay during the discharge quarter being validated, and not those cultures sampled during the 48 hour period following discharge from the ICU.

We will also consider proposing in future rulemaking that hospitals participating in the Hospital IQR Program must report the HIC number to their NHSN for CLABSI, CAUTI, SSI, MRSA, and Clostridium Difficile infection events. We believe that this information would reduce burden by allowing us to link NHSN information to demographic and clinical information on Medicare claims. We believe that this linkage would reduce burden to hospitals by reducing the number of data elements requested in blood and urine culture lists used in our validation process, which we could obtain directly from NHSN.

(ii) Targeting SSI for Validation

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28055-28056), the final HAI measure we proposed for targeted validation is SSI. Consistent with Hospital IQR Program reporting requirements for this measure, we proposed that validation will target SSIs among patients with colon surgeries and abdominal hysterectomy procedures.[101] We proposed a process for identifying candidate SSIs that is different from that which we

[101] http://www.cdc.gov/nhsn/PDFs/FINAL-ACH-SSI-Guidance.pdf.

proposed for candidate CLABSI and CAUTI both because post-discharge follow-up is so critical to proper ascertainment and because SSIs are reported more consistently in claims data than CLABSI and CAUTI. Thus, claims data provide a resource for selecting candidate events for SSI using a methodology which limits burden to hospitals.

Accordingly, we proposed to select candidate events from among Medicare FFS claims for patients who have had colon surgeries or abdominal hysterectomies as defined by NHSN.[5] For each Medicare FFS patient who had a relevant surgery in the period under validation, a CMS contractor would review the index claim (that is, the one denoting the surgery) and all subsequent readmissions to the index hospital within a 30 day post-discharge period. To identify "candidate SSI events," we would look specifically for discharge diagnoses on the index claim and all inpatient claims in the 30 days post-discharge that might indicate infection. Examples of such diagnoses include "post-operative shock" (ICD-9-CM: 998.0), "post-operative wound disruption (ICD-9-CM: 998.3), and postoperative infection (ICD-9-CM: 998.5). A description of our general approach, and a list of ICD-9-CM codes which we proposed to use to identify applicable candidate SSIs is included in Appendix 1 of "Platt R, Kleinman K, Thompson K, et al. Using automated health plan data to assess infection risk from coronary artery bypass surgery. Emerg Infect Dis. 2002 Dec;8(12):1433-41," which may be accessed online at http://www.cdc.gov/eid/content/8/12/pdfs/v8-n12.pdf.[102]

Comment: Several commenters requested that the addition of SSI not add any new burden to the HAI validation process.

---

[102] Platt R, Kleinman K, Thompson K, et al. Using automated health plan data to assess infection risk from coronary artery bypass surgery. Emerg Infect Dis. 2002 Dec;8(12):1433-41.

Response: The proposed process to target candidate SSI cases for validation requires only that hospitals submit HIC numbers for CLABSI and CAUTI. We will compile the list of candidate SSI events using claims data, and then we will be able to remove duplicates from the three lists of candidate HAI events using the HIC numbers that are reported for CLABSI and CAUTI. As discussed above, submission of HIC numbers may ultimately provide an opportunity to streamline CLABSI and CAUTI validation efforts. Therefore, we believe that the proposed sampling process introduces little new burden to hospitals.

Comment: Several commenters indicated that all of the denominator data necessary to validate SSI is available from the NHSN database, such that this measure could be validated "in the customary way," which we interpret to mean using the same process as the clinical process of care measures.

Response: We understand that the SSI data differ from CLABSI and CAUTI in that it would be possible to draw a sample of data for patients who had the colon and abdominal hysterectomy procedures from within the NHSN database, and that therefore it would be possible to validate SSI reporting in the "customary way," or the same way we validate chart-abstracted measures. However, like CLABSI and CAUTI, SSI is a rare event. Therefore, to effectively evaluate under-reporting, a sample rich in actual SSI events is needed. The "customary sample" from Medicare claims without using any targeting criteria would have a low yield of any actual SSI events (less than 6 percent for

colon surgeries, less than 2 percent for abdominal hysterectomy surgeries),[103] and would therefore be ineffective in producing a sample rich in actual SSI events. We estimate that our proposed for identifying candidate SSIs for validation using targeted diagnosis and procedures codes for these procedures would generate a much richer yield (about 33 percent for colon and about 50 percent for abdominal hysterectomy).[104]

Comment: Two commenters objected to the proposal to introduce a process for SSI validation that differed from the process for CLABSI and CAUTI. These same commenters stated that CMS should only introduce one new validation process per year. In contrast, many commenters opposed making the SSI validation process the same as the proposed CLABSI and CAUTI validation processes.

Response: Although we appreciate the commenters' concerns about adding new processes, we also recognize that we must have a process to support validation of HAIs to ensure accuracy of hospital reported HAI quality data. Moreover, we agree with the many commenters who opposed making the SSI validation the same as the proposed CLABSI and CAUTI validation processes. Because the proposed process employs claims data and does not require submission of supplemental data other than the sampled records, we believe that the proposed process for SSI is less burdensome for hospitals than adopting a validation data collection process similar to the CLABSI or CAUTI process, which would impose an added burden by requiring hospitals to submit additional

---

[103] Mu Y, Edwards JR, Horan TC, Berrios-Torres SI, Fridkin S. "Improving Risk-Adjusted Measures of Surgical Site Infection for the National Healthcare Safety Network," Infection Control and Hospital Epidemiology,Vol. 32, No. 10 (October 2011), pp. 970-986.

[104] Letourneau AR, Calderwood MS, Huang SS, Bratzler DW, Ma A, Platt R, Yokoe D, for the CDC Prevention Epicenters Program. Claims-Based Surveillance Improves Detection of Surgical Site Infections Following Hysterectomy and Colorectal Surgery. IDWeek (1st Annual Joint Meeting of IDSA, SHEA, HIVMA, and PIDS), October 17-21, 2012 (San Diego, CA).

data such as culture results. We believe the process we proposed will validate SSI effectively while minimizing burden on hospitals.

Comment: A few commenters supported the SSI validation approach. One commenter expressed concern that the specific ICD-9 codes proposed to define candidate SSIs were not entirely appropriate for colon surgery and abdominal hysterectomy.

Response: We agree with the commenter who observed that it is possible to tailor the SSI process more specifically to the colon surgery and abdominal hysterectomy under surveillance. Since the release of the proposed rule, two new analyses have become available to inform our decision making process.[105,106] These analyses offer an improved evidence base focused more specifically on colon surgery and abdominal hysterectomy. Based on these studies and the commenter's concern, we have identified a set of ICD-9 diagnosis and procedure codes that more strategically target candidate SSIs for these two procedures.

Therefore, after consideration of the public comments we received, we are finalizing the proposal to identify "candidate SSI events" by using the process as proposed, except that instead of using the ICD-9 codes contained in the paper by Platt et al. (2002: referenced in text above), we will target Medicare claims data using the following set of ICD-9 codes:

---

[105] Letourneau AR, Calderwood MS, Huang SS, Bratzler DW, Ma A, Platt R, Yokoe D, for the CDC Prevention Epicenters Program. Claims-Based Surveillance Improves Detection of Surgical Site Infections Following Hysterectomy and Colorectal Surgery. IDWeek (1st Annual Joint Meeting of IDSA, SHEA, HIVMA, and PIDS), October 17-21, 2012 (San Diego, CA).

[106] Haley VB, Van Antwerpen C, Tserenpuntsag B, et al. Use of administrative data in efficient auditing of hospital-acquired surgical site infections, New York State 2009-2010. Infection Control and Hospital epidemiology 2012;33:565-71.

Abdominal Hysterectomy	
ICD-9 Codes	**Description**
567.22	Peritoneal abscess
682.2	Other cellulitis and abscess - Trunk
998.31	Disruption of internal operation (surgical) wound
998.32	Disruption of external operation (surgical) wound
998.51	Infected postoperative seroma
998.59	Other postoperative infection
Colon Surgery	
ICD-9 diagnoses	
567.2	Peritonitis and retroperitoneal infections –other suppurative peritonitis
567.21	Peritonitis (acute) generalized
567.22	Peritoneal abscess
567.29	Other suppurative peritonitis
567.38	Other retroperitoneal abscess
569.5	Abscess of intestine
569.61	Infection of colostomy or enterostomy
569.81	Fistula of intestine, excluding rectum and anus
682.2	Other cellulitis and abscess - Trunk
879.9	Open wound(s), (multiple) of unspecified site(s), complicated
998.31	Disruption of internal (surgical) operation wound
998.32	Disruption of external (surgical) operation wound
998.51	Infected postoperative seroma
998.59	Other postoperative infection
998.6	Persistent postoperative fistula
ICD-9 procedures	
54.0	Incision of abdominal wall
54.11	Exploratory laparotomy
54.19	Other laparotomy
86.04	Other incision with drainage of skin and subcutaneous tissue
86.22	Excisional debridement of wound, infection, or burn
86.28	Nonexcisional debridement of wound, infection, or burn

Although diagnoses which identify candidate SSIs may also be identified during readmission to hospitals other than the index hospital, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28055) we proposed to exclude these candidate events for

validation of SSI for the FY 2015 payment determination. We proposed this approach because we will be unable to distinguish between a candidate SSI that the index hospital determined was not an actual SSI because it did not meet properly applied NHSN case definitions, and an actual SSI that the index hospital failed to properly identify and document. Although records from the readmitting hospital may provide evidence as to the likelihood that a candidate SSI was an actual SSI, the index hospital may not have had access to this information. Therefore, if the index hospital does not report a candidate SSI event associated with a readmission to another hospital, and also does not document this event, we do not know what information, if any, the index hospital used to assess the candidate event.

This situation arises because although our regulation at 42 CFR 482.24 requires hospitals to maintain medical records that document HAI, it does not require hospitals to document that follow-up was performed. We understand that this represents a gap in our validation program for SSI, and solicited public comments on how we might fill this gap in the future.

Comment: Some commenters noted that hospitals rarely receive more than a phone call to document SSIs detected at readmission to hospitals other than their own, with no documentation in the medical record. Thee commenters requested clarification on CMS' intended approach to address this issue. Another commenter noted that there are other federal and State agencies actively working to identify standard practices for post-discharge surveillance and urged CMS to delay adoption of post-discharge surveillance methods until these groups are able to develop formal recommendations

related to this specific issue. This commenter further suggested that CMS CoPs could be changed to incorporate post-discharge surveillance reporting once a preferred and valid methodology is identified.

Response: We thank the commenters for the information provided about the level of documentation available for SSI readmissions occurring other than at the index hospitals, and for providing the opportunity for us to clarify our plans regarding these readmissions. We will use claims data to assess how frequently this situation arises in hospitals sampled for validation. However, we do not intend to use our claims-based analysis of SSI readmissions to hospitals other than the index hospital for Hospital IQR validation-related payment determination at this time. We agree that it would be premature to develop validation procedures to address this situation. We believe that our best approach is to partner with other federal and State agencies interested in developing a valid methodology for post-discharge surveillance. We thank the commenters for the suggestion regarding using our CoP to require post-discharge surveillance and will consider this suggestion.

After consideration of the public comments we received, for the FY 2015 payment determination and future years we are finalizing as proposed our proposal to exclude from SSI validation cases identified during readmission to hospitals other than the index hospital.

(iii) Sample size per hospital for HAI validation

After identifying the three separate sets of candidate events for CLABSI, CAUTI, and SSI, we will combine the lists and remove any duplicates for a given episode of care.

Removing duplicates is a standard statistical practice which is important for the accuracy of the estimates.[107] Next, we proposed to draw a random sample of 12 candidate events per quarter from which to assess reliability of HAI reporting for the FY 2015 payment determination and subsequent years. Over four quarters, this would yield a sample size of 48 candidate events per year. Whenever a sample is used to estimate a statistic such as reliability for the entire population of events, that estimate is said to be made with error, commonly referred to as the margin of error. For hospitals with 480 or more candidate HAI events each year, and assuming a relatively constant number of candidates per quarter, the annual sample size will be sufficient to estimate a score of 75 percent with a margin of error plus or minus 10 points with 90 percent confidence. We believe this is the smallest sample size that would be sufficient to identify hospitals that are reporting HAI data poorly and have 480 or more candidate events.

However, if there are fewer than 480 candidate events per year, the finite population correction applies, such that the margin of error will decrease as the total number of candidate events per year gets smaller.[108] Based on our analysis of CLABSI data previously reported under the Hospital IQR Program, estimating the relative occurrence of CLABSI, CAUTI, and SSI, and allowing for the fact that there may be many candidates for every confirmed HAI, we expect that most hospitals will have fewer than 480 candidate HAI events per year (or 120 per quarter), which will allow us to estimate a score of 75 percent for these hospitals with a margin of error even less than plus or minus 10 points with 90 percent confidence. In the event that a hospital has 12 or

[107] ''Duplicate listings'' in Kish L. *Survey Sampling,* John Wiley & Sons, New York: 1995, pp.58–59.
[108] ''2.6 The finite population correction.'' Cochran WG. *Sampling Techniques,* third edition. John Wiley & Sons, New York, 1977, pp. 24–25.

fewer candidate HAIs in a given quarter, it is still possible to produce accurate estimates of reliability. In quarters in which a hospital has 12 or fewer candidate HAI events, we proposed to select all candidates, which will allow us to measure reliability without any margin of error. These quarterly estimates will have no sampling error because we will not be drawing a sample, but rather will be using the entire population for that quarter. If a hospital has 12 or fewer cases in every quarter, we may estimate reliability of HAI reporting for the year without any margin of error. If a hospital has no candidate events in the year, we would not be able to estimate a reliability rate. Therefore, as discussed in section VIII.A.6.a.(4) of this preamble, we would not attempt to estimate an HAI score for hospitals with 0 cases. We invited public comment on these proposed sample sizes.

Comment: Some commenters stated that the sample size of 27 per quarter per hospital for validation, including 15 for the clinical process of care measures, which has not changed, and 12 for HAI measures, was excessive and diverted time which could be spent on quality improvement towards reporting and validation. One commenter requested clarification as to how increasing the sample size from 18 to 27 would reduce burden on hospitals.

Response: We did not mean to imply that increasing the quarterly sample size from 18 to 27 records would decrease burden for individual hospitals that participate in validation in a particular year. Instead, our proposal in section [insert reference] below to reduce the number of hospitals included in the targeted validation sample is intended to reduce the overall burden of our validation process because it will result in fewer hospitals being validation each year. We understand that some medical charts are

voluminous, but given that we reimburse hospitals for the cost of photocopying, including labor (42 CFR 476.78(c)) we do not believe that the burden resulting from photocopying 27 records per quarter will be excessive, or divert resources from quality improvement to validation.

Comment: Two commenters expressed the opinion that selecting all candidate HAIs in hospitals with 12 or fewer candidate events per quarter is a flawed process that requires further study.

Response: We disagree with the commenters that selecting all candidate events when a hospital has 12 or fewer candidate HAI events for a particular quarter is a flawed process. Unlike selecting a sample of a population, which could result in sampling or random errors, selecting an entire population as we will do for hospitals with 12 or fewer candidate HAI events in a particular quarter has no such sampling or random error. Our statistical experts have no reservations about selecting the entire population of records with candidate HAIs when there are fewer than 12 per quarter. The discipline of sampling statistics was developed to address the problem that many populations are too large to study in their entirety, however, in the event the entire population is selected, as opposed to a sample of the population, the resulting estimate will have no sampling (random) error.[109] While every estimate suffers from potential inaccuracies arising from non-sampling errors such as incomplete enumeration of the population or simple variation from year to year,[15] the estimates obtained from studying all candidate episodes

[109] "Population values and statistics", in Kish L, Survey Sampling, Wiley Classics Library Edition, New York: 1995, page 9.

of care with HAIs will be at least as accurate as that obtained from a sample, and therefore this process is not flawed.

After consideration of the public comments we received, for the FY 2015 payment determination and subsequent years we are finalizing our proposal to use a sample size of 12 records per hospital per quarter for hospitals with more than 12 candidate events per quarter, and using all records with candidate events in hospitals with 12 or fewer records with candidate events in a quarter. We did not receive any public comments regarding our proposal not to estimate an HAI score for hospitals with 0 candidate events per year for the FY 2015 payment determination and subsequent years, and accordingly, we are finalizing that policy as proposed.

(4) Validation Scoring for Chart-Abstracted Clinical Process of Care Measures and HAI Measures

As noted in section VIII.A.6.a(1) of this preamble, HAIs occur rarely relative to the clinical process of care measures. The rarity of HAIs creates problems for validation scoring of this measure set. To produce an overall score that combines the scores for the individual measure sets, CMS computes a weighted average of each measure set score for each quarter.[110] The weight applied to each measure set is proportionate to the occurrence of records that were submitted to the Warehouse for that measure set. Because CLABSI, CAUTI, and SSI occur rarely, we anticipate that the total number of records targeted for validation of these measures will account for much less than 25 percent of the combined total of all records submitted to the Warehouse. Consequently,

[110]"Confidence Interval Calculation", http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115987129, last accessed March 19, 2012.

if the scores for HAI were combined with the other measure sets, a hospital could potentially report incorrectly for all HAI targeted records, and still meet our established reliability criterion of 75 percent, thus passing validation. This would mean that our process would fail to offer proper quality control for the HAI measure set. Although HAIs are rare, we believe that validation of HAI reporting is critical because it supports HHS' priority to reduce these infections.

For all of these reasons, we proposed separate scoring processes for the HAI and chart-abstracted clinical process of care measure sets, and to require hospitals to receive passing scores on both processes to pass validation for the FY 2015 payment determination and subsequent years. We proposed changes to our regulations at § 412.140(d)(2) to address this proposed requirement. In particular, our regulation currently states that "A hospital meets the validation requirement with respect to a fiscal year if it achieves a 75-percent score as determined by CMS." We proposed to change this language to state: "A hospital meets the validation requirement with respect to a fiscal year if it achieves a passing score, as determined by CMS, on applicable measure sets." We proposed to define "passing score" to mean a score of 75-percent on both of the chart-abstracted clinical process of care and HAI measure set groupings that apply to the hospital. The proposed computation and evaluation of passing for these separate scores are described further below.

Comment: Several commenters supported requiring hospitals to receive passing scores for both measure sets.

Response: We thank these commenters for their support, but have revised this proposal based on comments described below.

Comment: Two commenters expressed concern about the proposal to include two scores. While agreeing with the proposed approach of assessing the clinical process of care score separate from the HAI score, these commenters opposed a requirement to pass both scores on their own, particularly because the HAI score would be so new. The same commenters believed that the proposed process would give hospitals too many opportunities to fail.

Response: We agree that our proposal requiring hospitals to receive passing scores on the clinical process of care and HAI measure sets would provide too many opportunities for hospitals to fail validation. In particular, the proposed process would weigh the HAI measure and clinical process of care measures scores equally and require hospitals to pass both scores, even though only 3 of the 24 measures that will be validated for FY 2015 are HAI measures, while the remaining 21 measures are clinical process of care. The proposed requirement for two passing scores, even though one score would be based on validation of just 3 measures while another would be based on validation of 21 measures, would increase opportunities for failure by eliminating the chance for hospitals to compensate for poor performance on one set of measures with strong performance on the other set of measures.

Therefore, after consideration of the public comments we received, we are not finalizing the proposal to require hospitals to receive passing scores on each of the clinical process of care and HAI measure sets, nor are we changing our regulations at

§412.140(d)(2) to account for this proposal. Instead, for the FY 2015 payment determination and subsequent years, we will calculate a total score reflecting a weighted average of each of the two individual scores. Hospitals will be required to receive a total score of 75 percent, consistent with our regulations at §412.140(d)(2), to pass validation.

For the FY 2015 payment determination and subsequent years, the HAI and clinical process of care measures sets' scores will be weighted proportionate to the number of measures validated in each set. For the FY 2015 payment determination, there are 24 total measures that will be validated, 21 of which are clinical process of care measures and 3 of which are HAI measures. Therefore, the clinical process of care measures would account for 87.5% (21/24) of the total validation score and the HAI measures would account for 12.5% (3/24) of the total validation score. We will adjust these percentages as necessary in future years to reflect the numbers and types of measures we are validating. We believe using this weighting scheme while also calculating separate scores for the HAI and clinical process of care measure sets will allow us to meaningfully validate both types of measures while avoiding unduly penalizing hospitals for their reporting on one of the two measure sets.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28057) for the chart-abstracted clinical process of care measures, we did not propose any changes to the methodology for reviewing charts, computing the score for each measure set, computing a summary score across all measure sets, or computing the variance around these summary scores. This process was described in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226).

Comment: One commenter observed that the validation process for measures that assess time from admission to discharge "seems very stringent." The commenter observed that if there is a discrepancy of even 1 minute between the time reported for the Hospital IQR Program by the hospital for those measures and the time identified when the measures are validated, the hospital would fail validation for these measures.

Response: We agree with the commenter that requiring time values to match exactly is not realistic based on our historical experience with clinical data abstraction, the recognition that hospital clocks may vary from system to system such that the same time may be recorded differently depending on the source, and the limited clinical significance of small deviations in time. We note that this particular concern affects the validation score for FY 2014 payment determination as well as for future years [because the ED throughput measures will be validated beginning with this year?].

Accordingly, after considering the public comments we received, for the FY 2014 payment determination and future years when scoring the ED throughput measures (ED-1: "Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital" and ED-2: "Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status"), we will not require these measures to have matching numerator and denominator states. Instead, for scoring of these ED throughput measures, we will allow a 5 minute variance between the time abstracted by the hospital and that abstracted by CDAC.

In the FY 2013 IPPS/LTCH PPS proposed rule, for the FY 2015 payment determination and subsequent years (77 FR 28057), we proposed to use the same basic approach to CLABSI scoring that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51647), but to modify this scoring process to include consideration of all three HAI measures simultaneously. For example, if a sampled record is determined to include a CLABSI event and no CAUTI or SSI events, and one CLABSI event was reported to NHSN, we proposed to assign the record a score of 1/1. If a sampled record had two independent episodes of CLABSI, CAUTI, or SSI, or a combination of infections, both events would have to be reported to NHSN to receive a score of 1/1. Similarly, if no events were reported to NHSN and the medical record indicated there were no events, we proposed that the record would receive a score of 1/1. We proposed to assign a score of 0/1 to a record if no event was reported to NHSN and at least one CLABSI, CAUTI, or SSI was detected, or if an event was reported but for the wrong infection. For example, if an SSI was reported to NHSN as a CLABSI, the record would receive a 0/1. We also proposed to assign a score of 0/1 to a record if an event was reported to NHSN for CLABSI, CAUTI, or SSI, and the CMS contractor determined that there was no such event.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28057) for the FY 2015 payment determination and subsequent years, we proposed a slightly different process for requesting medical records for SSI. Specifically, we proposed that when a candidate SSI is identified based on a readmission diagnosis, CDAC would request two records per candidate SSI event. This proposal is necessary because many SSIs are not diagnosed

until after patient discharge. In these circumstances, the hospital might first become aware of the SSI upon readmission. Therefore, the information needed to evaluate the presence or absence of an SSI for these candidate events would be divided across two records: (1) the medical record for the hospitalization during which surgery was performed; and (2) the medical record for the readmission to treat the candidate infection. Therefore, we further proposed for the FY 2015 payment determination and subsequent years that when a candidate SSI is identified based on a readmission diagnosis, we evaluate the occurrence of an SSI event related to the index hospitalization using data in both records. In contrast, we proposed to limit evaluation of CLABSI and CAUTI to the record for the index hospitalization. We proposed these changes to incorporate CAUTI and SSI into HAI scoring, which were not part of previous validation efforts. We invited comments on these proposals.

Comment: A few commenters noted that hospitals need time and feedback to learn how to abstract new data elements, and that the proposed validation process does not provide hospitals with a grace period during which they may better learn the rules for abstracting new elements. A commenter urged CMS to release CLABSI validation results publicly so that all might learn from the experience.

Response: We agree that an important purpose of validation is to educate hospitals on how to improve their reporting processes. As with other Hospital IQR Program measures, CAUTI and SSI were added to the Hospital IQR Program in the year before are being added to the Hospital IQR Program validation program. Therefore, hospitals will have three quarters (Q1-Q3 2012) in which to develop experience reporting

CAUTI and SSI before they will be validated on these measures. In addition, like all IQR program data, CAUTI and SSI data are publicly reported. It is therefore important to begin validation soon after new measures are added to the Hospital IQR Program.

In all years, we will work with CDC, our State QIOs, and our national validation support contractor to widely disseminate lessons learned from HAI validation efforts on a timely basis. Hospitals will benefit either from direct participation in the CLABSI validation process for the FY 2014 payment determination, or through dissemination of lessons learned to help them improve when reporting their CLABSI and other NHSN data for the FY 2015 payment determination. Similarly, hospitals not validated for the FY 2015 payment determination will receive education in the form of lessons learned to help them improve their own reporting processes on all three NHSN measures.

Comment: Two commenters expressed concern that a hospital's probability of failure is unfairly increased by giving hospitals a maximum of 1 point for each candidate HAI sampled instead of giving hospitals a maximum of 3 points per sampling candidate HAI, one for each properly reported infection

Response: We agree that giving hospitals up to 3 points instead of 1 per record sampled would increase the probability of success on individual cases for particular hospitals, but disagree that we should adopt this approach on the grounds that it does not accurately reflect the incidence of these infections. Although a patient may conceivably acquire both a CLABSI and a CAUTI, this is very rare. An individual HAI event can either be CLABSI or CAUTI, but it can never be both. In addition, overlap between CLABSI and SSI and CAUTI and SSI is rare. Therefore, we anticipate that most records

sampled will have at most one infection. Were we to give each record up to 3 points, we would essentially be offering hospitals a score of 2 for every opportunity that we have to evaluate them on reporting of the third infection. In other words, to adopt a denominator of 3 per sampled record would give hospitals a base score of 67 percent, without having to do anything correctly. Given that the requisite score for passing validation is 75%, we believe this would be an inappropriately lenient standard.

Comment: Some commenters supported the review of two medical records to assess SSI.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing as proposed, the scoring process for CLABSI, CAUTI, and SSI for the FY 2015 payment determination and subsequent years. We are also finalizing for the FY 2015 payment determination and future years, the proposal to request two medical records per candidate SSI event when a candidate SSI is identified based on a readmission diagnosis.

The process finalized above in this section will be used to create a mean HAI score for each hospital. The mean will equal the number of HAI records correctly classified divided by the total number of HAI records scored. As described in section VIII.A.6.a.(3) of this preamble, a sample of up to 12 records is to be drawn quarterly, for an annual sample of up to 48. The approach of dividing the year into 4 quarters and drawing an independent random sample from each is known as stratified random sampling. When the validation sample includes all of the candidate HAI events that a hospital generates in a year, reliability is measured without error. In this case, the upper

bound of the confidence interval will be exactly the same as the estimate of reliability. However, when this score is based on only a sample of records containing candidate HAIs, we must compute a variance around this mean. We proposed to compute the confidence interval by applying the appropriate formula for the variance of a proportion in a stratified random sample.[111]

We received no comments directly on this proposal. However, this proposal is sensible only in the context of the earlier proposal to require hospitals to receive passing scores on both the clinical process of care and HAI measures. As we are not finalizing the proposal to receive two passing scores, we must also modify this one. Rather than computing a confidence interval for the HAI measure set specifically, we are finalizing the process to apply the appropriate formula for the variance of a proportion in a stratified random sample as proposed. We will then obtain a total variance for the combined clinical process of care and HAI scores using the appropriate formula for the variance of the weighted sum of two independent random variables.[112] A single confidence interval will be computed based on this total variance.

(5) Criteria to Evaluate Whether a Score Passes or Fails

Historically, we have used two criteria for passing validation in the Hospital IQR Program, which were described in FY 2011 IPPS/LTCH PPS final rule (75 FR 50226):

---

[111] "Section 5.10 Stratified sampling for proportions" in Cochran WG. Sampling Techniques, third edition. John Wiley and Sons, New York,1977, pp. 107-108.

[112] "Equation 5-40, in Section, 5-4 Linear combination of two random variables" in Wonnacott TH and Wonnacott RJ, "Introductory Statistics for Business and Economics, second edition, John Wiley and Sons, New York, 1977, pp. 131.

- Require all Hospital IQR Program participating hospitals selected for validation to attain at least a 75-percent validation score per quarter to pass the validation requirement.

- Use the upper bound of a one-tailed 95 percent confidence interval to estimate the validation score.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28057), we proposed for the FY 2015 payment determination and subsequent years to compute validation scores for each of the chart-abstracted and HAI measure sets by combining the data across all four quarters, instead of by considering the quarters separately. We proposed what we believed was a change in our current policy because 4 quarters of data combined can provide a more accurate estimate of reliability than could be attained from a single quarter.

We would like to clarify that what we characterized in the FY 2013 IPPS/LTCH PPS proposed rule as a proposal is actually consistent with our current policy, which was finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226). We stated in that rule that we would require Hospital IQR Program "participating hospitals selected for validation to attain at least a 75-percent validation score per quarter to pass the validation requirement," which could suggest that we are requiring hospitals to pass validation on a quarterly basis. In actuality, we finalized a policy in that rule to calculate "an annual confidence interval," or to require hospitals to pass validation annually, not quarterly. Accordingly, what we presented in the FY 2013 IPPS/LTCH PPS proposed rule as a

proposal – computing annual validation scores by combining data across all four quarters – is consistent with our current policy.

Comment: Some commenters expressed preference for a quarterly score, because the commenters valued receiving timely feedback regarding their hospitals' performance.

Response: We thank the commenters for the opportunity to clarify our current process. We will continue to provide hospitals with feedback regarding the performance on validation on a quarterly basis. However, we will also continue to evaluate a hospital's validation score by combining data across all quarters included in the validation year and by computing a confidence interval once annually for the basis of a payment determination only.

After consideration of the public comments we received, we are continuing for the FY 2015 payment determination and future years our current policy of providing hospitals with feedback quarterly and producing a single annual confidence interval per hospital.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28057) we proposed that if a hospital has no candidate CLABSI, CAUTI, or SSI in the year to be validated or a hospital has been excepted from NHSN reporting for all three HAIs, it will only be required to achieve a 75 percent score for the chart-abstracted clinical process of care measures to pass validation. We made this proposal because, in these instances, no HAI score can be computed.

We did not receive any public comments on this proposal and, therefore, we are finalizing this process as proposed.

In the FY 2013 IPPS/LTCH PPS proposed rule for the FY 2015 payment determination and subsequent years, we proposed to replace the use of a one-tailed 95 percent confidence interval with a two-tailed 90 percent confidence interval. The reason for this proposal is so that we may identify hospitals passing our annual 75 percent threshold that also have scores within the statistical margin of error for not passing this annual requirement. The upper bound of a two-tailed 90 percent confidence interval is exactly the same number as the upper bound of a one-tailed 95 percent confidence interval. Therefore, this proposal will have no impact on the number of hospitals in the base annual sample that pass or fail validation. The Government Accountability Office (GAO) has noted that CMS does not have a methodology to address hospitals, for which "the statistical margin of error for their accuracy included both passing and failing levels."[113] For data included in the GAO report, one-quarter to one-third of hospitals fell into this category. CMS has subsequently taken steps to address other GAO concerns, which has reduced the percentage of hospitals that neither passed nor failed validation to 7 percent in the FY 2012 payment determination.

Nonetheless, we believe that there is value in looking more closely at the remainder of these hospitals. For the FY 2015 payment determination and subsequent years, we proposed to identify those hospitals which have neither passed nor failed, using a two-tailed confidence interval. In addition, for the purpose of payment determination in FY 2015 and subsequent years, we proposed to continue to pass these hospitals, while

[113] Government Accountability Office. "Hospital Quality Data. CMS needs more rigorous methods to ensure reliability of publicly released data". GAO-06-54, January 2006.

also targeting these hospitals for validation the next year, which we finalize in section VIII.C.6.c. of this preamble.

If, as in previous years, our only concern was in hospitals with an upper bound for the reliability rate below 75 percent, we would have 95 percent confidence in the upper bound. However, because we proposed to identify hospitals for which "the statistical margin of error for their accuracy included both passing and failing levels," we must consider both an upper and lower confidence bound. Therefore, the same interval provides only 90 percent confidence (5 percent of samples will have lower interval bounds based on the sample that are higher than the actual reliability for the population and 5 percent will have upper interval bounds that are lower than the actual reliability rate for the population). Computing a two-tailed interval and adjusting its confidence level from 95 to 90 percent is the only way to maintain the computation for the upper bound using the same formula as that used in previous years and also calculate the lower bound,[10,114] which will allow us to identify hospitals that would otherwise neither pass nor fail validation. We invited public comment on this proposal.

Comment: Two commenters expressed concern that the proposed change would make passing validation more difficult.

Response: As stated above, the formula for the proposed two-tailed 90 percent confidence interval is identical to the formula for the one-tailed 95 percent confidence interval now used. Therefore, this change will not negatively impact hospitals in any

[114] "Chapter 8 Interval estimation" in Wonnacott TH, Wonnacott RJ. Introductory statistics for business and economics, 2nd edition, 1977, John Wiley & Sons, New York, pp.199-201, 231-232.

given year, but it will allow us to accomplish the other policy goals that we have outlined above.

After consideration of the public comments we received, we are finalizing this process as proposed for the FY 2015 payment determination and subsequent years.

b. Number and Manner of Selection for Hospitals Included in the Base Annual Validation Random Sample

As finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225-50227), validation of chart-abstracted measures in the Hospital IQR Program uses a base annual random sample of 800 hospitals. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28058), for the FY 2015 payment determination and subsequent years, we proposed to reduce the total base sample size of hospitals included in the annual validation random sample from 800 to 400. One of our goals in targeting a certain number of hospitals for our base annual random sample is to estimate the total percentage of hospitals that have been reporting unreliable data for the Hospital IQR Program. The minimum sample size required to assess the percentage of hospitals in the Hospital IQR Program that have been reporting unreliable data depends on the expected percentage of hospitals that fail validation. Because a very high percentage of Hospital IQR Program hospitals pass validation (more than 99 percent of the hospitals in the FY 2012 payment determination), we believe that we can reduce burden on hospitals by selecting fewer hospitals for the base annual random sample without adversely affecting our estimate of this percentage. We did not propose to change the criteria for selecting the annual

validation random sample because we believe that these criteria are appropriate for sample selection.

We proposed no change to the criteria for selecting the annual validation random sample, which we provided for informational purposes. The finalized definition of a hospital eligible for validation, as provided in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227) are the subset of subsection (d) hospitals who successfully submitted ‘‘at least one [IQR] case for the third calendar quarter of the year two years prior to the year to which the validation.’’ For example, for the FY 2015 payment determination, we would select the sample in early 2013, and all Hospital IQR Program-eligible hospitals that submitted at least one Hospital IQR case for third quarter 2012 discharges would be eligible to be selected for validation. We invited comments on these proposals.

Comment**:** We received many comments in support of this proposal.

Response: We thank these commenters for their support.

Comment: A few commenters raised concern that hospitals already go too many years without feedback regarding their performance. In contrast, another commenter suggested that hospitals should not have to undergo validation at all more often than once every 3 years unless a problem was uncovered during the validation process.

Other commenters expressed concern that CMS could not guarantee reliability (for example, what the hospital submitted matches what is observed by CDAC) across all hospitals and asked for clarification regarding how CMS planned to approach this problem.

Response: Although we could conduct validation on every hospital every year, such an approach to reliability assessment uses significantly more CMS and hospital resources than necessary. Conducting validation on any individual hospital less frequently reduces burden, which we consider to be very important. The basic premise behind random sampling is that one can learn something about all hospitals by gathering data on just a subset of hospitals. Using an estimated passing rate of 99 percent, our power calculations indicate that with 400 hospitals, we can be highly confident that least 98 percent of all hospitals in the IPPS population are achieving the requisite reliability score. Hospitals that would like to learn more about common pitfalls associated with quality reporting may receive this from their QIO and Hospital IQR Program validation support contractor.

We cannot exclude hospitals from validation if they have been selected in the previous 3 years as suggested by one commenter, because we are required by section 1886(b)(3)(B)(xii) of the Act to randomly select hospitals to validate the Hospital IQR measures as a whole. We believe that random sampling requires all hospitals to review data accuracy, because all hospitals are eligible to be selected in our annual random sample. We have a validation support contractor who provides QIOs with feedback regarding common pitfalls identified during the validation process. Moreover, these QIOs have a contractual obligation with CMS to educate hospitals regarding Hospital IQR Program requirements. Therefore, each individual hospital has access to education about the Hospital IQR Program process, regardless of whether it is selected for validation.

After consideration of the public comments we received, we are finalizing the process to reduce the base annual random sample from 800 to 400 as described above for the FY 2015 payment determination and subsequent years.

c. Targeting Criteria for Selection of Supplemental Hospitals for Validation

We have established policies for supplementation to the base annual random sample of hospitals. In particular, our supplemental validation sample includes all hospitals that fail validation in the previous year (75 FR 50227 through 50229), a policy that we do not intend to change. We also finalized a policy in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51646), that the validation sample drawn for the FY 2015 payment determination and subsequent years will include in the fourth year all hospitals not randomly occurring in the sample in the previous 3 years. We have reassessed this policy.

We believe that we have identified an approach with comparable benefits to reliability which would have a smaller total burden to hospitals, and at less cost to CMS. Based on chance alone, we would expect that about 1,500 (slightly less than half of all IPPS-eligible) hospitals would not have been sampled in the previous 3 years. Of these, less than 200 would be expected to be randomly selected as part of the base validation sample of 400 hospitals for the FY 2015 payment determination. Accordingly, this means that for the FY 2015 payment determination, the supplemental sample size would be about 1,300 hospitals. To increase the sample size by 1,300 hospitals in a single year is unnecessarily burdensome; we believe we can have the same influence on hospitals that have not been recently validated simply by increasing their probability of selection

through targeting in subsequent years. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28058), therefore, for the FY 2015 payment determination and subsequent years, we proposed to discontinue our policy of including hospitals in the supplemental validation sample in the fourth year that have not been validated in the previous 3 years. We proposed, however to use the lack of recent validation as one of several targeting criteria for a supplemental random sample described further below. For the FY 2015 payment determination and subsequent years, we proposed to add targeting criteria as a supplement to the base random sample of up to 200 additional hospitals. We believe that this proposal would improve data quality by increased targeting of hospitals with possible or confirmed past data quality issues. As finalized in the FY 2011 IPPS/LTCH PPS final rule, the supplement will include all hospitals that fail validation in the previous year. We invited public comment on the proposal to include a targeted sample, and to use the following as criteria for targeting the additional hospitals:

- Any hospital with abnormal or conflicting data patterns. An example of abnormal data pattern would be if a hospital has extremely high or extremely low values for a particular measure. Consistent with the Hospital OQR Program, we proposed to define an extremely high or low value as one that falls more than 3 standard deviations from the mean (76 FR 74485). An example of a conflicting data pattern would be if two records were identified for the same patient episode of care but the data elements were mismatched for primary diagnosis. Primary diagnosis is just one of many fields that should remain constant across measure sets for an episode of care. Other examples of fields that should remain constant across measure sets are patient age and sex. Any

hospital not included in the base validation annual sample and with statistically significantly more abnormal or conflicting data patterns per record than would be expected based on chance alone ($p < .05$), would be included in the population of hospitals targeted in the supplemental sample.

- Any hospital with rapidly changing data patterns. For this targeting criterion, we proposed to define a rapidly changing data pattern as a hospital which improves its quality for one or more measure sets (that is, AMI, HF, PN, SCIP, ED, IMM, or HAI) by more than 2 standard deviations from one year to the next, and also has a statistically significant difference in improvement (one-tailed $p < .05$).

- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed.

- Any hospital that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated.

- Any hospital that has not been randomly selected for validation in any of the previous 3 years.

Comment: Some commenters favored the proposal to target hospitals based on the criteria described above.

Response: We agree that these proposed policies will be useful.

Comment: Commenters expressed concern that for hospitals failing validation, the amount of time elapsing between the determination and the deadline for submitting records in the following year may not be sufficient to improve the hospital's performance.

Response: We disagree that the time between the determination that a hospital has failed and the time it has to submit data for the following year would present difficulties for hospitals, because a hospital has no reason to wait until it receives a failing payment determination to improve its reporting. As described above in this section, we provide feedback on validation quarterly, and QIOs are available to provide education and feedback to hospitals regardless of their quarterly scores. A poorly performing hospital should receive feedback after validation of the very first quarter in a validation year. This feedback would come long before the next year's reporting process would start. For example, a hospital will receive all feedback on data submitted in the 4th quarter of 2012 by the end of October 2013, but would not be required to complete submission of data for the 4th quarter of 2013 until May 2014.

Comment: One commenter questioned whether reserving one-third of the sample for targeted validation "would diminish the randomization and thus diminish the validation process."

Response: As described above, we approached the problem of sample size for the base annual random sample by considering the power needed to assess reliability, which we determined to be 400. The random sample size needed is unaffected by the size of our targeted validation sample. Compared with the current policy, which was finalized for the FY 2015 payment determinations and subsequent years in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51646), and which targeted all hospitals not included in the three previous years, the new proposal to target up to 200 hospitals includes a much lower ratio of 'targeted' to random sampling. Moreover, the

sample targeted under current policy is less informative than the proposed targeted sample because the current process does not identify and target hospitals most likely to need validation based on data previously submitted. Accordingly, we do not believe that reserving one third of the sample for targeted validation reduces the integrity of the validation process, and in fact, we believe it will strengthen validation.

After consideration of the public comments we received, we are finalizing this targeting proposal for the FY 2015 payment determination.

For the FY 2016 payment determination and subsequent years, we proposed to add to the targeting criteria proposed for the 2015 payment determination by identifying hospitals that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent. Relative to hospitals whose confidence interval lies entirely above the target reliability rate of 75 percent, a confidence interval that includes 75 percent would indicate a higher level of uncertainty as to the reliability of data for that particular hospital. This proposal is related to the proposal to produce a two-sided confidence interval (discussed in section VIII.A.6.b of this preamble). It is intended to respond to concerns that CMS does not have a methodology to address hospitals, for which "the statistical margin of error for their accuracy included both passing and failing levels." The reason that we proposed implementation of this criterion beginning with the 2016 payment determination is that it is not feasible to implement this change until after we implement changes to the confidence interval, as described in section VIII.A.6.b. of this preamble.

We received no comments on this proposal, and therefore, we are finalizing this proposal to add a targeting criterion for the supplemental sample of hospitals that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent. This process will begin with the FY 2016 payment determination and continue in subsequent years.

As noted above, the established procedure for drawing the base random sample involves selection of hospitals "early" in the calendar year two years prior to the payment determination FY 2011 IPPS/LTCH PPS final rule (75 FR 50227). For example, the base sample for the FY 2015 payment determination will be drawn early in 2013. We proposed that the selection of hospitals targeted in the supplemental sample for the FY 2015 payment determination occur after the FY 2014 payment determination; this will separate the timing of selection of base and supplemental samples. We proposed to do so because CMS may need extra time to review hospital data before identifying the hospitals to include in the supplemental sample. Moreover, information regarding a hospital's status as failing or passing is not known at the time the base sample is drawn.

We received no comments on this proposal, and we are finalizing as proposed the process to separate the timing for drawing the base and supplemental samples. We provide the reader with the validation timeline for finalized in the FY 20111 IPPS/LTCH PPS final rule (75 FR 50219) for the FY 2013 payment determination and subsequent years for informational purposes only. We did not propose any changes or invite comment on this timeline. The quarters included in the validation effort for each year's payment determination will be the fourth calendar quarter of the year that occurs 2 years

before the payment determination and the first 3 calendar quarters of the following calendar year. For example, for the FY 2015 payment determination, the quarters included in validation would be the fourth quarter of calendar year 2012 through the third quarter of calendar year 2013.

7. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2015 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28059), we proposed to require hospitals to continue to electronically acknowledge their data accuracy and completeness once annually. For the FY 2014 payment determination, the submission deadline for the Data Accuracy and Completeness Acknowledgement was aligned with the final submission quarter for each fiscal year. We proposed to continue this approach for FY 2015 and subsequent years. For example, we proposed that the submission deadline for the Data Accuracy and Completeness Acknowledgement would be May 15, 2014, with respect to the time period of January 1, 2013, through December 31, 2013. We invited public comment on this proposal.

We received no comments on this proposal; therefore, we are finalizing our proposal to align the Data Accuracy and Completeness Acknowledgement with the final submission quarter for each fiscal year for FY 2015 and subsequent years.

8. Public Display Requirements for the FY 2015 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), we continued, for the FY 2014 payment determination and subsequent years, the approach we adopted in the

FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for public display requirements for the FY 2012 payment determination and subsequent years. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28059), we did not propose any changes to these requirements.

The Hospital IQR Program quality measures are typically reported on the Hospital Compare Web site at: http://www.hospitalcompare.hhs.gov, but on occasion are reported on other CMS Web sites. We require that hospitals sign a Notice of Participation form when they first register to participate in the Hospital IQR Program. Once a hospital has submitted a form, the hospital is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS (72 FR 47360). Hospitals signing this form agree that they will allow us to publicly report the quality measures included in the Hospital IQR Program.

We will continue to display quality information for public viewing as required by section 1886(b)(3)(B)(viii)(VII) of the Act. Before we display this information, hospitals will be permitted to review their information as recorded in the QIO Clinical Warehouse.

9. Reconsideration and Appeal Procedures for the FY 2015 Payment Determination

The Hospital IQR Program reconsideration and appeals requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651) and are found at 42 CFR 412.140(e) of our regulations. The form for reconsiderations and a detailed description of the reconsideration process are available on the QualityNet Web site at: http://www.qualitynet.org/ > Hospitals-Inpatient>Hospital Inpatient Quality Reporting Program>APU Reconsiderations.

10. Hospital IQR Program Disaster Extensions or Waivers

The Hospital IQR Program disaster extensions or waiver requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51652) and can be found at 42 CFR 412.140(e) and (c)(2), respectively. The forms and a detailed description of the extension or waiver process are available on the QualityNet Web site at: http://www.qualitynet.org/ > Hospitals-Inpatient>Hospital Inpatient Quality Reporting Program.

11. Electronic Health Records (EHRs)

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from the EHRs directly to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program.

b. HITECH Act EHR Provisions

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified

EHR technology. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(iii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. All measures must be proposed for public comment prior to their selection, except in the case of measures previously selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act.

We continue to believe there are important synergies with respect to the two programs. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage the adoption and use of certified EHRs for the anticipated future reporting of clinical quality measures under the Hospital IQR Program. Through the EHR Incentive Programs we expect that the anticipated future submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS to receive, quality measures via hospital EHRs for certain Hospital IQR Program measures in the future.

The HITECH Act requires that the Secretary seek to avoid redundant and duplicative reporting, with specific reference to the Hospital IQR Program for eligible hospitals. To the extent that quality measures are included in both the Hospital IQR

Program and the EHR Incentive Programs, this would mean that the Hospital IQR Program would need to transition to use of certified EHR technology rather than manual chart abstraction. We are considering what the most practical approach to effect such a transition might be. One option is to select a date after which chart-abstracted data would no longer be used in the Hospital IQR Program where it is possible to report the data via certified EHR technology. This would require sufficient advance notice to hospitals for hospitals to report the data via certified EHR technology. At that point, we believe that it is likely that nearly all IPPS hospitals will have implemented certified EHR technology as incentivized by the HITECH Act. Another option would be to allow hospitals to submit the same measure for the Hospital IQR Program based on either chart-abstraction or, when available, EHR-based reporting. This would require extensive testing to ensure equivalence given that the data for the Hospital IQR Program supports both the public reporting of such information and the Hospital VBP Program. We are concerned that this option would not be feasible.

Ultimately, we do not anticipate having two different sets of clinical quality measures for the EHR Incentive Programs and the Hospital IQR Program. Rather, we anticipate a single set of hospital clinical quality measures, most of which we anticipate would be electronically specified. We envision a reporting infrastructure for electronic submission as an additional reporting mechanism in the future, and will strive to align the hospital quality initiative programs to seek to avoid redundant and duplicative reporting of quality measures for hospitals. We note that some important Hospital IQR Program quality measures such as HCAHPS experience of care measures are based on survey data

and do not lend themselves to EHR reporting. Similarly, certain outcome quality measures, such as the current Hospital IQR Program readmission measures, are based on claims data rather than clinical data. Thus, not all Hospital IQR Program quality measures will necessarily be capable of being submitted through EHRs. As a consequence, not all Hospital IQR Program quality measures would necessarily be appropriate for inclusion in the EHR Incentive Programs.

We note that the provisions in this proposed rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

Comment: Many commenters strongly supported CMS's direction to move toward EHR-based reporting for quality measures. Commenters shared our vision to implement a single set of hospital clinical quality measures, most of which would be electronically specified. Commenters supported the alignment of measures across public reporting programs using EHR technology. A commenter believed that use of certified EHR technology would be widespread by 2015 among hospitals. One commenter stated that some hospitals will still be unprepared for EHR-based reporting by 2015 and commenter noted that implementing EHR-based reporting prematurely may negate quality improvement efforts. One commenter recommended postponing EHR-based reporting until all hospitals have reached Stage 3 of meaningful use under the HITECH Act EHR Incentive Program.

Response: We appreciate the support of our intention to move toward EHR-based reporting for quality measures. We also believe that large numbers of hospitals would be

able to report quality measures electronically from EHRs, which are currently chart-abstracted. We expect in the future to propose a specific date for transition from chart-abstracted to EHR-based measures for the Hospital IQR Program. We expect this to be facilitated by the EHR Incentive Program, which has proposed certain clinical quality measures that align with the Hospital IQR Program, and the related electronic reporting pilot for hospitals (see 75 FR 74489).

Comment: Many commenters supported a defined strategy to effect a transition from chart-abstraction to EHR-based submissions. Several commenters indicated that they would like to have the option to submit data either using chart-abstractions or via EHR but cautioned that extensive pre-implementation testing and validation of e-measures for accuracy are crucial. One commenter encouraged CMS to engage in more e-measure pilot testing. While many commenters supported EHR submission as the sole mechanism for data submission, commenters added that the existence of a transition period, which accommodates both of the data collection mechanism, is necessary.

Response: We have not decided the best approach to transitioning from chart-abstracted measures to EHR-based reporting. We agree that significant testing is needed to assure accuracy of EHR-based reporting. We do not believe that is practical to provide alternative options for the Hospital IQR Program with some hospitals reporting based on chart abstracted measures while others use EHR-based reporting, where such measures are publicly reported and are the basis for value based purchasing. Ultimately, we believe a transition, when feasible, needs to be accomplished by all hospitals for the Hospital IQR Program.

Comment: A few commenters suggested registry-based reporting as an alternative alongside with EHR-based technology for hospitals.

Response: We support the use of registries. As stated above, however, we do not believe it is practical to have alternative measures data sources due to the degree of testing that would be necessary to assure equivalence of results.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

Section 3005 of the Affordable Care Act added new subsections (a)(1)(W) and (k) to section 1866 of the Act. Section 1866(k) of the Act establishes a quality reporting program for a hospital described in section 1886(d)(1)(B)(v) of the Act (hereafter referred to as a "PPS-Exempt Cancer Hospital" or "PCH"). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH shall submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such a fiscal year. Section 1866(k)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, each hospital described in section 1886(d)(1)(B)(v) of the Act shall submit data to the Secretary on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, specified by the Secretary.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies. The National Quality Forum (NQF) currently holds this contract. The NQF is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development processes. We have generally adopted NQF-endorsed measures in our reporting programs. However, section 1866(k)(3)(B) of the Act provides an exception. Specifically, it provides that, in the case of a specified

area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under section 1866(k)(3)(C) of the Act, the Secretary must publish the measure selection for PCHs no later than October 1, 2012, with respect to FY 2014.

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making public the data submitted by PCHs under the PCHQR Program. Such procedures must ensure that a PCH has the opportunity to review the data that is to be made public with respect to the PCH prior to such data being made public. The Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished by PCHs on the CMS Internet Web site.

Comment: Several commenters supported the PCHQR Program, and some commenters encouraged PCHs to participate in "public reporting programs."

Response: We appreciate the commenters for their support.

Comment: Several commenters stated that there will be a 2-percent point reduction to a PCH's rate-of-increase limit if the PCH fails to report the PCHQR quality measures.

Response: We did not propose in the FY 2013 IPPS/LTCH proposed rule to adopt a policy on what the consequence would be if a PCH failed to report the quality

measures specified under the PCHQR Program. We plan to address this issue in future rulemaking.

2. Covered Entities

Section 1886(d)(1)(B)(v) of the Act excludes particular cancer hospitals from payment under the IPPS. This final rule covers only those PPS-excluded cancer hospitals meeting eligibility criteria specified in 42 CFR § 412.23(f).

3. Quality Measures for PCHs for the FY 2014 Program and Subsequent Program Years

a. Considerations in the Selection of the Quality Measures

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless section 1866(k)(3)(B) of the Act applies. Section 1866(k)(3)(B) of the Act states that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We have taken a number of principles into consideration when developing measures for the PCHQR Program, and many of these principles are modeled on those we use for measure development under the Hospital IQR Program:

- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of care measures, including measures of care transitions and changes in patient functional status.

- The measure set should evolve so that it includes a focused core set of measures appropriate to cancer hospitals that reflects the level of care and the most important areas of service furnished by those hospitals. The measures should address gaps in the quality of cancer care.

- We also considered input solicited from the public. For instance, CMS held a Listening Session on September 8, 2011 for the purpose of receiving input from consumers, advocacy groups, and providers on the measures under consideration for the PCHQR Program and other program implementation issues.

- We considered suggestions and input from a PCH Technical Expert Panel (TEP), convened by a CMS measure development contractor, which rated potential PCH quality measures for importance, scientific soundness, usability, and feasibility. The TEP membership includes health-care providers specializing in the treatment of cancer, cancer researchers, consumer and patient advocates, disparities experts, and representatives from payer organizations.

Like the Hospital IQR Program, the PCHQR Program also supports the National Quality Strategy, national priorities, HHS Strategic Plans and Initiatives, and CMS Strategic Plans, as well as takes into consideration the recommendations of the Measure Application Partnership (MAP) and strives for burden reduction whenever possible. We refer readers to the discussion of these topics in section VIII.A.3.a. of the preamble of this final rule on "Additional Considerations in Expanding and Updating Quality Measures" under the Hospital IQR Program.

Comment: For burden reduction purposes, a commenter encouraged the use of existing registries and data sources to expand the PCHQR Program.

Response: We appreciate the commenter for the suggestions. We took the issue of burden into consideration when selecting the measures to propose to include in the PCHQR Program for FY 2014 and subsequent program years, and if feasible, we will work to develop data collection methods that further minimize the burden on PCHs.

b. PCHQR Program Quality Measures for the FY 2014 Program and Subsequent Program Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28061), we proposed to adopt five quality measures for the FY 2014 program and subsequent program years. Specifically, we proposed to adopt two CDC/NHSN-based HAI quality measures (outcome measures): (1) Central Line-Associated Bloodstream Infection (CLABSI); and (2) Catheter-Associated Urinary Tract Infection (CAUTI); and three cancer process of care measures: (1) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer; (2) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer; and (3) Adjuvant hormonal therapy.

All five of these proposed measures were reviewed by the MAP, and were recommended for inclusion in the PCHQR Program. For details regarding MAP input, please refer to the MAP Annual Pre-Rulemaking Final Report, which can be accessed at:

http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.

(1) CDC/NHSN-Based Healthcare-Associated Infection (HAI) Measures

HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[115] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the number of days of hospitalization required for patients and add considerable health care costs.

The reduction of HAIs is a priority for HHS, as evidenced by HHS's 2009 publication of an Action Plan to Prevent HAIs. This Plan is available on the HHS Web site at: http://www.hhs.gov/ash/initiatives/hai/actionplan/. To maximize the efficiency and improve the coordination of HAI prevention efforts across the Department, HHS established in 2008 a senior-level Steering Committee for the Prevention of HAIs. In 2009, a Steering Committee, which included scientists and program officials across the Government, developed the HHS Action Plan to Prevent HAIs, providing a roadmap for HAI prevention in acute care hospitals. In the first iteration of the Action Plan, the Steering Committee chose to focus on infections in acute care hospitals because the associated morbidity and mortality were most severe in that setting and the scientific information on prevention and the capacity for measure improvement was most complete.

[115] McKibben L, Horan T, Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217-26.

Thus, prevention of HAIs in acute care hospitals became the first phase of the Action Plan, and it focuses on six high priority HAI-related areas.

HAIs are largely preventable with widely publicized interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, the public reporting of HAIs has been of great interest to many health care consumers and advocacy organizations because it promotes awareness and permits health care consumers to choose the hospitals with lower HAI rates, as well as gives hospitals an incentive to improve infection control efforts. We note that the House Committee on Appropriations asked in a 2009 Report that CMS include in its "pay for reporting" system for subsection (d) hospitals two infection control measures, one of which was a central line-associated bloodstream infections measure (H. Rep. No. 111-220, at 159 (2009)). In the Report, the Committee stated that "[i]f the measures are included in Hospital Compare, the public reporting of the data is likely to reduce HAI occurrence, an outcome demonstrated in previous research."

In the FY 2013 IPPS/LTCH proposed rule, we proposed to adopt two NQF-endorsed HAI measures for the FY 2014 PCHQR Program and subsequent program years: (1) National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure; and (2) National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure. These proposed measures were developed by the CDC and are currently collected by the CDC via the NHSN. We proposed to adopt these two measures for several reasons. First, we believe that these measures support the National Quality

Strategy priority of patient safety as these measures focus on serious infections that can prolong patient hospital stays and increase the risk of mortality.[116] Second, the Technical Expert Panel (TEP) convened by our measure development contractor identified CLABSI and CAUTI as high priority quality issues for PCHs because they address an important area of quality measurement and have potential to promote improved outcomes. Third, the MAP reviewed these HAI measures and supported inclusion of them in the PCHQR Program because they address the National Quality Strategy's priority of safer care (see MAP Annual Pre-Rulemaking Final Report at: http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx).

Fourth, these two HAI measures foster alignment with other our quality reporting programs. In the FY 2011 IPPS/LTCH PPS final rule, we adopted the CLABSI measure for the Hospital IQR Program. The CLABSI measure is currently being collected as part of the FY 2013 Hospital IQR Program measure set, and data submission on the measure began with January 2011 events.[117] In the Hospital IQR Program, collection of this measure is limited to ICU locations. This measure also has been adopted for the FY 2014 payment determination under the LTCHQR Program. For the LTCHQR Program, data collection for this measure extends to all inpatient locations in the LTCH.

In the FY 2012 IPPS/LTCH PPS final rule, we adopted the Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days for Intensive Care Unit Patients measure for both the FY 2014 Hospital IQR and LTCHQR measure sets. In

---

[116] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf, accessed on January 20, 2011.

[117] The CDC captures HAI data based on the onset of an event, rather than based on the discharge date.

the Hospital IQR Program, collection of this measure is limited to ICU locations; for the LTCHQR Program, collection of this measure extends to all inpatient locations except neonatal ICUs. This measure is a high priority HAI measure that is included among the prevention metrics established in the HHS Action Plan to Prevent HAIs, which, as we noted above, underscores the importance of reducing HAIs.

We proposed to collect data for these two HAI measures via the NHSN, which is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be used by many types of health care facilities in the United States, including acute care hospitals, cancer hospitals, long term care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, and ambulatory surgery centers. The NHSN enables health care facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events.

Some States use the NHSN as a means for health care facilities to submit patient-level data on measures mandated through their specific State legislation. Currently, 28 States require hospitals to report HAIs using the NHSN, and the CDC provides support to more than 5,000 hospitals that are using the NHSN.

NHSN data collection occurs via manual data entry into a Web-based tool hosted by the CDC provided without charge to providers and via electronic reporting by providers directly to NHSN. The NHSN Agreement to Participate and Consent Form specifies the purposes to which NHSN data are put, including enabling providers, such as

cancer hospitals, to report data via NHSN to CMS in fulfillment of CMS's quality measurement reporting requirements for those data.

In addition, we understand from the CDC that data submission for HAI measures through electronic health record technology (EHRs) may be possible in the near future, and this would further reduce the reporting burden for PCHs.

Comment: Two commenters supported using the CDC/NHSN as a data collection mechanism for the two proposed HAI measures because it is less burdensome than chart abstraction.

Response: We agree that the NHSN data collection mechanism is less burdensome than chart abstraction and aligns with HAI measures in other quality reporting programs.

(A) Central Line-Associated Blood Stream Infections Measure ((CLABSI), NQF #0139)

The proposed CLABSI measure was originally developed by CDC to assess the percentage of ICU and high-risk nursery patients who, over a certain amount of days, acquired central line catheter-associated bloodstream infections. CDC recently updated this measure to expand the care setting to all inpatient settings (not just ICUs). As indicated previously, the measure has been renamed the National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure and we proposed to adopt this measure for use for the FY 2014 program and subsequent program years. This measure is considered an outcome measure by the NQF because it assesses the results of the quality of care provided to patients; it is risk-adjusted in that the observed infection rate for a particular location or locations in a

hospital is compared to an expected infection rate for those locations (which is calculated using national NHSN data for those locations in a predictive model). Measure specifications may be accessed at: http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.

A central line is a catheter that health care providers often place in a large vein in the neck, chest, or groin to give medication or fluids or to collect blood for medical tests. Many patients are discharged from short-term acute care hospital intensive care units (ICUs) or ICU stepdown units with these central lines in place.

Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality.[118] An estimated 248,000 bloodstream infections occur in U.S. hospitals each year.[119] Furthermore, despite the preventability of these infections, CLABSIs result in thousands of deaths each year and billions of dollars in added costs to the U.S. health care system. CDC is providing guidelines and tools to the health care community to help reduce central line catheter-associated bloodstream infections. CLABSIs can be prevented through proper management of the central line. CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) Guidelines for the Prevention of Intravascular Catheter-Related Infections recommends evidence-based central line insertion practices known to reduce the risk of subsequent central line-associated bloodstream infection.[120]

---

[118] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf, accessed on January 20, 2011.
[119] Klevens RM, Edward JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007; 122:160-166.
[120] O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, et al., Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002; 51(No. RR-10:1-26).

These include hand-washing by inserters, use of maximal sterile barriers during insertion, proper use of a skin antiseptic prior to insertion, and allowing that skin antiseptic to dry before catheter insertion. Despite the scientific evidence supporting these practices, several reports suggest that adherence to these practices remains low in U.S. hospitals.

This measure is NQF-endorsed and, therefore, meets the requirement of section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program must be endorsed by the entity with a contract under section 1890(a) of the Act.

We invited public comment on our proposal to adopt the NHSN Central Line-Associated Bloodstream Infection (CLABSI) outcome measure for the PCHQR Program for collection in both ICU and non-ICU locations for the FY 2014 program and subsequent program years.

Comment: Two commenters supported the inclusion of this measure in the PCHQR program. A commenter supported the recently updated measure specifications to include non-ICU locations.

Response: We thank the commenters for the support of the measure and its expansion into non-ICU locations. We believe the measure expansion beyond ICU locations will provide a more comprehensive picture of how prevalent CLABSIs are throughout a PCH.

Comment: One commenter opposed the inclusion of the CLABSI measure in its current form. The commenter was concerned that this measure may mislead consumers about the quality of care provided at cancer centers. The commenter asserted that cancer

patients while under treatment often have comprised immune systems, which cause them to be more prone to contract HAIs such as CLABSI. The commenter also pointed out that stem cell transplantation can sometimes cause bacteria from the gastrointestinal tract to enter the bloodstream and cause infection. The commenter strongly urged CMS to delay the adoption of this measure until the measure is stratified and risk-adjusted based on stakeholder input.

Response: While we recognize the complexity of treating hospital-acquired infections in patients with compromised immune systems, we also believe it is important to track HAI rates at all hospitals for all patients – regardless of whether they are immune-compromised or not. The current NQF-endorsed CLABSI measure does not contain adjustments for immune-compromised patients. For all hospitals, CLABSI is stratified by CDC-specified ICU and Specialty Care Area (SCA) locations, and oncology locations would be included as SCAs, making the measure appropriate for PCHs.

After consideration of the public comments we received, we are finalizing the CLABSI measure (NQF #0139) for the PCHQR Program for FY 2014 and subsequent program years.

(B) Catheter Associated Urinary Tract Infection Measure ((CAUTI), NQF #0138)

The catheter-associated urinary tract infection (CAUTI) measure was developed by CDC to measure the percentage of patients with CAUTIs in the ICU context. CDC has recently updated the specifications of this measure to include all inpatient settings (not just ICUs). This measure has been renamed as National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure, and

we proposed to adopt this measure for use in the FY 2014 program and subsequent program years. This measure is considered an outcome measure as it relates to the results of the quality of care provided to patients; it is risk adjusted by which the observed infection rate for a particular location in a hospital is compared to an expected infection rate calculated based on the specific location within other facilities that report to the NHSN. Measure specifications may be accessed at: http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.

The urinary tract is the most common site of HAIs, accounting for more than 30 percent of infections reported by acute care hospitals.[121] Healthcare-associated urinary tract infections (UTIs) are commonly attributed to catheterization of the urinary tract. CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI cause discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.[122] Prevention of CAUTIs is discussed in the CDC/HICPAC document, Guideline for Prevention of Catheter-associated Urinary Tract Infections, which includes recommendations for proper insertion techniques, including

[121] Klevens RM, Edward JR, et al., Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007; 122:160-166.
[122] Wong ES., Guideline for prevention of catheter-associated urinary tract infections. Infect Control 1981; 2:126-30.

hand washing, insertion by trained staff, use of sterile gloves, drapes, sponges and antiseptic or sterile solution for cleaning and lubricant jelly for insertion.[123]

UTIs are a major cause of morbidity and mortality. The HHS Action Plan to Prevent HAIs identified catheter associated urinary tract infections as the leading type of HAI that is largely preventable, and the occurrence of which can be drastically reduced in order to reduce adverse health care related events and avoid excess costs.

This measure is NQF-endorsed and, therefore, meets the requirement of section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless section 1866(k)(3)(B) of the Act applies.

We invited public comment on our proposal to adopt the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) outcome measure for the PCHQR Program for collection in both ICU and non-ICU locations within a facility to align with the recently-expanded NQF-endorsed measure specifications for the FY 2014 program and subsequent program years.

Comment: Two commenters supported the inclusion of this measure in the PCHQR program.

Response: We thank the commenters for the support of this measure.

Comment: One commenter opposed the inclusion of the CAUTI measure in its current form. The commenter was concerned that this measure may mislead consumers about the quality of care provided at cancer centers. The commenter asserted that cancer

[123] Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA, et al., Guideline for prevention of catheter-associated urinary tract infections. Infect Control 2009; 31:319-326.

patients while under treatment often have comprised immune systems which cause them to be more prone to contract hospital-acquired infections such as CAUTI. The commenter strongly urged CMS to delay the implementation of this measure until the measure is stratified and risk-adjusted based on stakeholders input.

Response: While we recognize the complexity of treating HAIs in patients with compromised immune systems, such as those treated at PPS-exempt cancer hospitals, we also believe it is important to track HAI rates at all hospitals for all patients – regardless of whether they are immune-compromised or not. The current NQF-endorsed CAUTI measure does not contain adjustments for immune-compromised patients. For all hospitals, CAUTI is stratified by CDC-specified ICU and Specialty Care Area (SCA) locations, and oncology locations would be included as SCAs, making the measure appropriate for PCHs.

After consideration of the public comments we received, we are finalizing the CAUTI measure (NQF #0138) for the PCHQR Program for FY 2014 and subsequent program years.

(2) Cancer-Specific Measures

We proposed to adopt three measures related to the treatment of colon cancer and two types of breast cancer (hormone receptor-negative and hormone receptor-positive). Specifically, these proposed measures are: (i) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (NQF # 0223); (ii) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for

women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer (NQF #0559); and (iii) Adjuvant hormonal therapy (NQF # 0220). The proposed measures were developed by the American College of Surgeons/Commission on Cancer.

We proposed to adopt these three cancer treatment-related quality measures for several reasons. First, trends in national cancer incidence rates suggest that breast and colon cancer will become two of the more common diagnoses[124] and these cancers are highly prevalent among Medicare beneficiaries. We believe the high incidence of these types of cancer creates an opportunity for measurements to make an impact on the quality of cancer care. Second, these measures support the National Quality Strategy's priority to promote the most effective prevention and treatment practices for the leading causes of mortality due to cancer. Third, the TEP convened by our measure development contractor identified the treatment of breast and colon cancer as high priority quality issues for PCHs due to the high incidence of these types of cancers and rated these measures highest compared to other potential program measures based on an assessment of the importance, scientific acceptability, usability, and feasibility of these measures. Also, participants in a CMS-convened Listening Session on September 8, 2011 expressed support for the proposed measures. The transcript for this Listening Session can be found at: http://www.cms.gov/HospitalQualityInits/05_HospitalHighlights.asp#TopOfPage. Fourth, the MAP reviewed these cancer-specific measures and supported inclusion of these measures in the PCHQR Program. All of the three proposed cancer-specific measures are NQF-endorsed; therefore they satisfy the requirement of section 1866(k)(3)(A) of the Act relating to the selection of endorsed measures for the PCHQR

[124] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10-29.

Program. Furthermore, section 1866(k)(4) of the Act provides that quality measures reported in the PCHQR Program should assess process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to PCHs. We believe these three proposed cancer-specific measures meet the above statutory criteria, as they track important processes in the treatment of colon and breast cancer.

Although these measures are not currently reported in other HHS programs, they are reported by over 1,500 cancer programs as part of their accreditation by the Commission on Cancer, a program of the American College of Surgeons (see http://www.facs.org/cancer/ncdb/index.html), further indicating their importance as the Commission on Cancer has taken a leading role in establishing national standards to ensure quality in the provision of cancer care.

We proposed that PCHs would submit the data needed to calculate these measures to a CMS contractor.

(A) Adjuvant Chemotherapy is Considered or Administered within 4 Months (120 days) of Surgery to Patient under the Age of 80 with AJCC III (Lymph Node Positive Colon Cancer) (NQF #0223)

This proposed measure examines whether adjuvant chemotherapy is delivered within a specified period of time after a diagnosis of colon cancer. Specifically, it looks at the proportion of patients 18-79 with AJCC Stage III (lymph node positive) colon cancer for whom adjuvant chemotherapy is considered or administered within 4 months of diagnosis. Stage III colon cancer is colon cancer that has spread outside the colon to one or more lymph nodes. The adjuvant chemotherapy measure is a process measure as

it addresses whether a defined treatment was delivered to a patient; the measure is not risk adjusted. That is, the measure does not attempt to account for hospital patient populations or other differences between hospitals. Rather, it only assesses the specific process was performed. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons at: http://www.facs.org/cancer/ncdb/colonmeasures.pdf. Additionally, CMS will provide a link to the Specifications Manual on the QualityNet Web site.

Colorectal cancer plays a sizeable role in affecting both health and health care costs in the United States. The American Cancer Society estimates that 51,690 Americans will die of colorectal cancer in 2012[125]. According to the National Cancer Institute, more than $14.1 billion was spent on colorectal cancer in 2010.[126]

Appropriate treatment may improve survival rates and reduce the likelihood of costly recurrence. Strong evidence suggests that treating Stage III colon cancer patients with adjuvant chemotherapy improves overall survival and disease-free survival.[127] In addition to being supported by evidence, this measure is consistent with the National Comprehensive Cancer Network's (NCCN) guidelines for the treatment of colon cancer (COL-4: T3-4, N1-2, MO), which recommend that colon cancer patients should receive adjuvant chemotherapy.

---

[125] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10-29.
[126] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, and Brown ML. Projections of the Cost of Cancer Care in the United States: 2010-2020. JNCI 2011; 103:117-128.
[127] André T, Boni C, Navarro M, et al. Improved Overall Survival With Oxaliplatin, Fluorouracil, and Leucovorin As Adjuvant Treatment in Stage II or III Colon Cancer in the MOSIAC Trial. J Clin Onc 2009; 27:3109-3116.

Section 1866(k)(3)(A) of the Act requires quality measures selected for the PCHQR Program to be endorsed by the entity with a contract under section 1890(a) of the Act, unless 1866(k)(3)(B) applies. This measure is NQF-endorsed and therefore, it meets the statutory endorsement requirements.

We invited public comment on our proposal to adopt the adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patient under the age of 80 with AJCC III (lymph node positive colon cancer) measure for the PCHQR Program for the FY 2014 program and subsequent program years.

Comment: Many commenters supported the inclusion of this measure and noted that it is already widely used in PCHs.

Response: We appreciate the support for this measure.

After consideration of the public comment we received, we are finalizing our adoption of the adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive colon cancer) measure (NQF #0223) for FY 2014 and subsequent program years.

(B) Combination Chemotherapy is Considered or Administered within 4 Months (120 days) of Diagnosis for Women under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559)

This proposed measure assesses the proportion of women ages 18-69 who have their first diagnosis of breast cancer at AJCC Stage IC, II or III and whose primary tumor is hormone (estrogen and progesterone) receptor negative for whom combination chemotherapy is considered or administered within 4 months of diagnosis. Hormone receptor negative means that hormones, such as estrogen, do not drive tumor growth. This measure is a process measure as it addresses whether a defined treatment was delivered to a patient; the measure is not risk adjusted in that the measure does not attempt to account for differences in hospital patient populations or other differences between hospitals. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons, at: http://www.facs.org/cancer/ncdb/breastmeasures.pdf. In addition, CMS will provide a link to the Specifications Manual on the QualityNet Web site.

The number of deaths from breast cancer has declined while spending has increased. The American Cancer Society estimates that 39,510 Americans will die of breast cancer in 2012.[128] Spending on breast cancer care is higher than for any other type of cancer. According to the National Cancer Institute, more than $16.5 billion was spent on breast cancer care in 2010[129]. Evidence shows that treating hormone receptor negative breast cancer patients with combination chemotherapy is associated with a reduced risk

[128] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10-29.
[129] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, and Brown ML. Projections of the Cost of Cancer Care in the United States: 2010-2020. J Natl Cancer Inst 2011; 103:117-128.

of relapse or death.[130] This measure is also consistent with NCCN's guidelines for the treatment of invasive breast cancer (BINV-4, 7-8), which recommend adjuvant chemotherapy for patients with hormone receptor negative tumors, and therefore the measure aligns with recognized standards of treatment.

This measure is NQF-endorsed and, therefore, it meets the requirements under section 1866(k)(3)(A) of the Act which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless section 1866(k)(3)(B) of the Act applies.

We invited public comment on our proposal to adopt the combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer (NQF #0559) quality measure for the PCHQR Program for the FY 2014 program and subsequent program years.

Comment: One commenter supported the inclusion of this measure and noted that it is already widely used in PCHs.

Response: We appreciate the support for this measure.

After consideration of the public comment we received, we are finalizing our adoption of the combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer measure (NQF #0559) for FY 2014 and subsequent program years.

---

[130] Fisher B, Jeong JH, Anderson S, et al.: Treatment of axillary lymph node-negative, estrogen receptor-negative breast cancer: updated findings from National Surgical Adjuvant Breast and Bowel Project clinical trials. J Natl Cancer Inst 96 (24): 1823-31, 2004.

(C) Adjuvant Hormonal Therapy (NQF #0220)

This proposed measure assesses whether recommended treatment is delivered within a specified period of time from a patient's breast cancer diagnosis. Specifically, it tracks the proportion of eligible women 18 years or older who have their first diagnosis of breast cancer at AJCC T1c or Stage II or III and whose primary tumor is hormone (estrogen or progesterone) receptor positive breast cancer for whom tamoxifen or a third generation aromatase inhibitor is considered or administered within 1 year of diagnosis. Hormone receptor positive means that estrogen or progesterone promotes the growth of cancer cells. This measure is a process measure as it relates to whether a defined treatment was furnished to a patient; it is not risk adjusted. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons, at: http://www.facs.org/cancer/ncdb/breastmeasures.pdf. Additionally, we will provide a link to the Specifications Manual on the QualityNet Web site.

The American Cancer Society estimates that two-thirds of breast cancer cases are hormone receptor positive.[131] As stated previously, appropriate and effective treatment is important to both the health and cost outcomes of breast cancer care. The measure is consistent with NCCN's guidelines (BINV-5, 6 and 9 and BINV-E) for the treatment of invasive breast cancer, which recommend hormone therapy for patients with hormone receptor positive breast cancer, and with the American Society of Clinical Oncology's (ASCO) Update on adjuvant endocrine therapy for women with hormone receptor

[131] American Cancer Society. Breast Cancer Hormone Therapy. http://www.cancer.org/Cancer/BreastCancer/DetailedGuide/breast-cancer-treating-hormone-therapy Last revised 01/06/2012.

positive breast cancer. The ASCO guideline cites a wide body of supporting evidence for this method of treatment.

This measure is NQF-endorsed and therefore, it meets the requirement under section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless section 1866(k)(3)(B) of the Act applies.

We invited public comment on our proposal to adopt the adjuvant hormonal therapy measure for the PCHQR Program for the FY 2014 program and subsequent program years.

Comment: Many commenters supported the inclusion of this measure and noted that it is already widely used in PCHs.

Response: We appreciate the support for this measure.

After consideration of the public comment we received, we are finalizing the adjuvant hormonal therapy measure (NQF #0220) for FY 2014 and subsequent program years.

After consideration of the public comments we received, we are finalizing all five measures as proposed for the FY 2014 PCHQR Program and subsequent program years. The measures we are adopted are shown below.

Topic	Final Measures for PCHQR Program Beginning with FY 2014 Program and Subsequent Program Years
Safety and Healthcare Acquired Infections—HAI	
	● (NQF#0139) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure ● (NQF#0138) NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure
Cancer-Specific Treatments	

	● (NQF#0223) Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer ● (NQF#0559) Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer ● (NQF#0220) Adjuvant Hormonal Therapy

4. Possible New Quality Measure Topics for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the cancer hospital setting. Therefore, through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain cancer services through the widespread dissemination and use of performance information. In addition, we are considering initiating a call for input to assess the following measure domains: clinical quality of care, care coordination, patient safety, patient and caregiver experience of care, population/community health and efficiency. We believe this approach will promote better cancer care while bringing the PCHQR Program in line with other established quality reporting and pay for performance programs such as the Hospital IQR Program, the Hospital OQR Program, the ESRD QIP, and others within CMS' purview.

We welcomed public comment and suggestions for these, or other, measurement areas.

Comment: One commenter urged CMS to expand the PCHQR Program to include measures regarding patient-centered outcomes specific to oncology, quality of

life, and functional assessment. Specifically, the commenter recommended the Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (NQF #0209) and Proportion Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210) measures. Further, the commenter noted CMS should expand the PCHQR Program to include measures for additional cancer types. Specifically, the commenter recommended the Recording of Clinical Stage for Lung Cancer (and Esophageal Cancer Resection (NQF #0455) and Recording of Performance Status Prior to Lung Esophageal Cancer Resection (NQF #0457) measures.

Response: We appreciate the commenter for the suggestions and will take them into consideration for future measure selection.

Comment: One commenter recommended the development or adoption of a measure to address the risk of febrile neutropenia in cancer patients undergoing myelosuppressive chemotherapy since this is consistent with a measure gap identified by NQF.

Response: We thank the commenter for the suggestion and will take it into consideration for future measure selection.

Comment: One commenter suggested a measure to detect early diagnosis of cancer. Another commenter requested that CMS focus on measures that provide data on risk-adjusted state-specific survival curves for various types of cancer and report these measures in three separate perspectives: stage, overall survival, and disease-free survival.

Response: We agree with the commenters that these are important aspects in cancer detection and treatment. We thank the commenters for the suggestions and will take them into consideration for future measure selection.

5. Maintenance of Technical Specifications for Quality Measures

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28066), we proposed that if the NQF updates an endorsed

measure that we have adopted for the PCHQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the CMS QualityNet Web site at https://www.QualityNet.org. We would provide sufficient lead-time for PCHs to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate NQF updates to NQF-endorsed PCH measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invited public comment on this proposal.

We also proposed to provide a Specifications Manual that will contain links to measure specifications, data abstraction information, data submission information, and other information necessary for PCHs to participate in the PCHQR Program. This Specifications Manual would be posted on the QualityNet Web site at: https://www.QualityNet.org. We would maintain the technical specifications for the quality measures by updating this Manual periodically, which would include detailed instructions for PCHs to use when collecting and submitting data on the required

measures. These updates would be accompanied by notifications to PCHQR Program-participating users, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems. We would revise the Specifications Manual and provide links to reflect such endorsement changes which also would be posted on the QualityNet Web site at: https://www.QualityNet.org. We invited public comment on the previously described proposed policy on maintenance of technical specifications for quality measures.

Comment: One commenter objected to the proposed subregulatory process to incorporate updates arising from NQF maintenance review on an endorsed measure adopted for the PCHQR Program. The commenter believed CMS should provide an opportunity for the public to comment on the updates.

Response: The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates made by the NQF into the measure specifications we have adopted for the PCHQR Program so that these measures remain up-to-date. We also recognize that some changes the NQF might make to is endorsed measures are substantive in nature and might not be appropriate for adoption using a subregulatory process. Therefore, after consideration of the public comments we received, we are finalizing a policy under which we will use a subregulatory process to make nonsubstantive updates to NQF-endorsed measures used for the PCHQR Program. With

respect to what constitutes a substantive versus nonsubstantive change, we expect to make this determination on a case-by-case basis. Examples of nonsubstative changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures used in the Hospital IQR and Hospital VBP Programs). We also believe that nonsubstantive changes might include updates to NQF-endorsed measures based upon changes to guidelines upon which the measure are based.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the PCHQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

These policies regarding what is considered substantive versus nonsubstantive changes would apply to all PCHQR Program measures.

After consideration of the public comments we received, we are adopting a policy for making updates to PCHQR Program measures as explained in the response to the comment above.

6. Public Display Requirements for the FY 2014 Program and Subsequent Program Years

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures shall ensure that a PCH has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospital on the CMS Web site. In order to meet these requirements, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28066), we proposed to publicly display the submitted data on the Hospital Compare Web site (http://www.hospitalcompare.hhs.gov/). Before the data are publicly displayed, we proposed that PCHs will have the opportunity to review their data prior to the public reporting of the measure rates consistent with section 1866(k)(4) of the Act. We proposed that PCHs have the opportunity to review their data 30 days prior to the public reporting of the measure rates because that aligns with our established preview process under the Hospital IQR Program.

The Hospital Compare Web site serves to encourage consumers to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby

providing an additional incentive to hospitals to improve the quality of care that they furnish.

However, some information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations that may not make them suitable for inclusion on the Hospital Compare Web site may be made available on other CMS Web sites, such as http://www.cms.gov and/or http://www.qualitynet.org. In such circumstances, affected parties would be notified via CMS listservs, CMS e-mail blasts, and QualityNet announcements regarding the release of confidential hospital-specific preview reports to individual hospitals followed by the posting of data on a CMS Web site other than Hospital Compare.

We invited public comment on the previously described proposals regarding the public display of quality measures.

After consideration of the public comments we received we are adopting our proposals, without modification, regarding the public display of data submitted under the PCHQR Program.

7. Form, Manner, and Timing of Data Submission for FY 2014 Program and Subsequent Program Years

a. Background

Section 1866(k)(2) of the Act requires that, for the FY 2014 program and each subsequent program year, each PCH must submit to the Secretary data on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time as specified by the Secretary.

The complete data submission requirements and submission deadlines will be posted on the QualityNet Web site at: http://www.QualityNet.org/. In general, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28067), we proposed that PCHs submit data to the CDC for the HAI measures (CLABSI and CAUTI), and the CMS contractor for the three cancer-specific measures (Adjuvant Chemotherapy for Stage III Colon Cancer; Combination Chemotherapy for AJCC T1c or Stage II or III Hormone Receptor-Negative Breast Cancer; and Adjuvant Hormonal Therapy). As described below, we proposed to utilize the data submission and reporting standard procedures that have been established by CDC for NHSN participation in general and for submission of the proposed HAI measures to NHSN. We refer readers to the CDC's Web site for detailed data submission and reporting procedures. We also proposed procedures for PCHs to follow when submitting data on the three proposed cancer-specific measures.

b. Procedural Requirements for FY 2014 Program and Subsequent Program Years

In order to participate in the PCHQR Program for the FY 2014 program and subsequent program years, we proposed that PCHs must comply with the procedural requirements outlined in this section. We stated that we have aligned these proposed procedural requirements with the Hospital IQR Program to the extent possible to streamline the procedural requirements across different types of providers. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28067), we proposed that PCHs must do the following:

- Register with QualityNet prior to reporting and regardless of the method used for submitting the data.

- Identify QualityNet Administrator(s) who will follow the registration process located on the QualityNet Web site (http://www.QualityNet.org).

- Complete an online Data Accuracy and Completeness Acknowledgement (DACA) via QualityNet, which states that the quality measure results and any and all data including numerator and denominator data provided, are accurate and complete. We proposed that, beginning with the FY 2015 program, the deadline for submitting the DACA would be August 31 of the preceding fiscal year. For more information on DACA, please refer to the section below entitled, "Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2014 Program and Subsequent Program Years."

- Enroll in CDC/NHSN and register with the CMS contractor collecting the cancer-specific measures prior to reporting.

We strongly encouraged PCHs to complete an online Notice of Participation (NOP) via QualityNet. This form would grant CMS written authorization from the PCH to publicly report the PCH's measure rate on a CMS Web site. We believe that requiring PCHs to complete this form will inform and educate them about program and other related requirements.

Proposed CMS Notice of Participation Timeframe	
Program Year (Fiscal Year)	**Notice of Participation (NOP) Deadline**
FY 2014	August 15, 2013
FY 2015	August 15, 2014
Subsequent Fiscal Years	August 15 of the preceding fiscal year

Comment: One commenter supported NHSN and CMS QualityNet enrollment and registration prior to data submission.

Response: We appreciate the commenter for the support of our proposal.

Comment: Several commenters urged CMS to use American College of Surgeons (ACoS) to serve as the CMS contractor for the following reasons: 10 out of 11 PCHs are currently submitting the cancer-specific measures to ACoS; ACoS is the cancer-specific measures developer and maintains the rights to these measures; and ACoS has in place sound methodologies for data validation and measure calculations. One commenter stated that the PCHQR Program data submission requirement could pose a "sizeable expense for each participating institution and a significant time investment."

Response: We recognize the concerns surrounding the burden of participating in the PCHQR Program and the possibility that PCHs might be reporting similar or the same cancer-specific measure data to two different entities. We are currently procuring the services of a contractor to collect the cancer-specific measure data. We intend to align as much as possible with the ACoS data infrastructure and reporting format in an effort to minimize the reporting burden, because we recognize that this is the process already being used by the majority of PCHs to report this data.

Comment: Commenters asked for more information regarding registering with the CMS contractor and the flow of data from the PCHs to CMS' QualityNet Web site.

Response: We intend to procure a CMS contractor, which will collect the cancer-specific measure data from the PCHs, calculate the measure rates, and submit those rates to CMS. Once we have procured a contractor, PCHs will have to register with the contractor prior to the time when they begin to submit cancer-specific measure data.

We anticipate awarding a contract in the fall of 2012, and will outline more detailed instructions at that time.

After consideration of the public comments we received, we are finalizing the procedural requirements for the FY 2014 program and subsequent program years.

c. Reporting Mechanisms for the FY 2014 Program and Subsequent Program Years

For the purpose of reporting quality measures under the PCHQR Program, we proposed to adopt the following data submission mechanisms. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28067), with respect to the proposed HAI measures (CLABSI and CAUTI), we proposed that PCHs submit the data to the CDC through the NHSN database. We proposed to use the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of the proposed HAI measures to NHSN. We refer readers to the CDC's Web site (http://www.cdc.gov/nhsn/) for detailed data submission and reporting procedures. After the final submission deadline has passed, CMS will obtain the PCH-specific calculations that have been generated by the NHSN for the PCHQR Program.

With respect to the three proposed cancer-specific measures, we proposed that PCHs submit the data to the CMS contractor. The CMS contractor would then calculate the quality measures rates and submit those rates to CMS on a quarterly basis.

We invited public comment on our proposed reporting mechanisms.

(1) Reporting Mechanism for the HAI Measures

We proposed to adopt a quarterly submission process for the proposed HAI measures -- CLABSI AND CAUTI -- that uses a reporting mechanism similar to the one

finalized for the Hospital IQR program (75 FR 50223) starting with October 1, 2012 infection events. We have successfully implemented this reporting mechanism in the Hospital IQR program and intend to use similar reporting mechanism to collect data for the PCHQR Program. We welcomed public comment on this proposal.

Comment: One commenter supported reporting HAI measures to NHSN.

Response: We appreciate the commenter's support.

(2) Reporting Mechanism for the Cancer-Specific Measures

We proposed to collect the three cancer-specific measures data using a CMS contractor starting with the FY 2014 program. Similar to the reporting mechanism we proposed to adopt the proposed HAI measures, we anticipate that PCHs would report their measure data to the contractor, which would then calculate the measure rates and submit those rates to CMS. We stated that if these proposed measures were finalized, we would publish the technical specifications and file layouts necessary for reporting in enough time to enable PCHs to incorporate any necessary changes to their information systems. We invited public comment on our proposed reporting requirements.

Comment: A commenter suggested leveraging existing ACoS data reporting requirements to reduce financial burden because the PCHQR program could pose a "sizeable expense for each participating institution and a significant time investment."

Response: We understand that the PCHQR Program will create a new reporting burden for PCHs, and as we have stated above, one of our goals is to minimize that burden as much as possible. For that reason, we intend to align the data collection process for the cancer-specific measures after the process currently used by the ACoS,

the measure steward for these measures, because we recognize that this is the process already being used by the majority of PCHs to report this data.

After consideration of the public comment we received, we are finalizing the data reporting mechanisms described above.

d. Data Submission Timelines for the FY 2014 Program and Subsequent Program Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28067 through 28068), we proposed that PCHs must adhere to certain timelines in reporting their measure data.

Proposed PCHQR Data Submission Timelines		
Time Line (Calendar Year)	**Quality Measures***	**CMS Submission Deadline**
Q4 (October-December 2012)	**(NQF #0139)** NHSN CLABSI Outcome Measure**	May 15, 2013
	(NQF #0138) NHSN CAUTI Outcome Measure**	May 15, 2013
	(NQF # 0223) Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer+	August 15, 2013
	(NQF #0559) Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer+	August 15, 2013
	(NQF # 0220) Adjuvant Hormonal Therapy+	May 15, 2014
Q1 (January-March 2013)	**(NQF #0139)** NHSN CLABSI Outcome Measure**	August 15, 2013
	(NQF #0138) NHSN CAUTI Outcome Measure**	August 15, 2013
	(NQF # 0223) Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer+	November 15, 2013

Proposed PCHQR Data Submission Timelines		
Time Line (Calendar Year)	**Quality Measures***	**CMS Submission Deadline**
	(NQF #0559) Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer+	November 15, 2013
	(NQF # 0220) Adjuvant Hormonal Therapy+	August 15, 2014
Subsequent calendar quarters	**(NQF #0139)**NHSN CLABSI Outcome Measure**	November 15 of each respective year
	(NQF #0138) NHSN CAUTI Outcome Measure**	November 15 of each respective year
	(NQF # 0223) Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer+	February 15 of each respective year
	(NQF #0559) Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer+	February 15 of each respective year
	(NQF # 0220) Adjuvant Hormonal Therapy+	November 15 of each respective year

*Referred to as the HAI and Cancer-Specific Treatment Quality Measures
**HAI event occurred in applicable quarter
+Initial diagnosis in applicable quarter

We stated that our principal rationale for these proposed timeframes is to align the HAI measure submission deadlines with existing CMS deadlines to collect the same quality measure information. We also seek to align our timeframes with those of the ACoS, which separately collects the same type of cancer-specific measure data from many PCHs. By aligning these deadlines by measure, we strive to reduce the reporting burden by using information already collected by many PCHs in their own quality measurement and improvement efforts. The proposed quarterly CDC/NHSN submission timeframes and deadlines also match the existing Hospital IQR quarterly submission

timeframes for the same HAI measures. In the case of the three cancer-specific quality measures, we also believe that these proposed submission timeframes will give PCHs enough time to measure follow-up chemotherapy (4 months following the cancer diagnosis) and hormone therapy visits (12 months following the cancer surgery), as well as identify and correct discordant submitted data (2 months for the two proposed chemotherapy measures, and 3 months for the proposed adjuvant hormone therapy measure).

We invited public comment on the proposed data submission methods and timelines.

Comment: One commenter pointed out that PCHs may not have adequate time to submit HAI data by May 15, 2013 because PCHs may not be familiar with the data reporting processes and the reliability and validity of measures will not be fully tested in the new settings such as the PCHs.

Response: In further assessing the proposed data submission timeline, we agree with the commenter's concerns. We have also been informed by CDC that modifications to its IT infrastructure (for example, defining and mapping new locations) are on-going and will not be completed in time for the proposed first quarter of data submission (Q4 of 2012 [October-December, 2012]). Therefore, in response to this comment, we will finalize a one quarter data collection period for the two HAI measures (CLABSI and CAUTI) for purposes of the FY 2014 PCHQR Program. PCHs will be required to report data on this measure for 1st quarter 2013 events (that is, January 1-March 31, 2013 events), and that data will be due to the CDC on or before August 15, 201.

We believe that the reliability and validity of these two HAI measures is sufficient for purposes of the PCHQR Program. This reliability and validity has been demonstrated through collection of these measures in the Hospital IQR Program, and existing HAI reporting mandates in over 20 States. The NQF also endorsed these measures, and the MAP recommended these measures for purposes of PCHQR data collection.

We also strive to align data collection processes, public reporting of data, outreach, and education to PCHs with the Hospital IQR Program and other quality reporting programs to the extent feasible and clinically appropriate.

Comment: One commenter believed that this proposed reporting timeline violates the statute and its intent. The commenter viewed two provisions of the statute authorizing the PCHQR Program as relevant: the provision in section 1866(k)(2) of the Act, which requires that for FY 2014 and each subsequent fiscal year, PCHs "shall submit to the Secretary data on quality measures specified under paragraph (3)"; and the provision in section 1866(k)(3)(C) of the Act which requires the Secretary to publish the measures applicable with respect to fiscal year 2014 by October 1, 2012. The commenter believed that it was unreasonable for CMS to conclude that Congress, in enacting this provision, would require the Secretary to announce the measures on the date that the measurement would begin. The commenter believed that Congress intended for the measures to be announced with sufficient lead time – a minimum of two years – for the PCHs to begin reporting. The commenter urged CMS to adopt a delay in mandatory reporting and to start mandatory measurement reporting no earlier than October 1, 2014.

Response: We believe that our proposals are consistent with sections 1866(k)(2) and (k)(3)(C) of the Act, and note that they are consistent with our approach we have taken in a number of other new quality reporting programs, including the Long-Term Care Hospital Quality Reporting (LTCHQR) Program and the Inpatient Rehabilitation Hospital (IRF) Quality Reporting Program.

However, we recognize that it may be difficult for PCHs to start reporting the cancer-specific measure data starting with 4th calendar quarter 2012 data because we do not expected to award a contract for the collection of this data until fall 2012. We believe that deferring the initial data reporting period until January 1, 2013 for the cancer-specific measure data addresses this concern, as well as makes the starting quarter for data collection consistent with that we are finalizing for the HAI measures. Accordingly, we are finalizing that the reporting period will begin on January 1, 2013 for all measures. This change is reflected in the table below.

Comment: Some commenters asked CMS to provide more information about the timeline for data submission and the frequency of public data displayed under the PCHQR Program for all measures. Commenters also requested alignment of the data submission timeline with that used for the Hospital IQR Program measures.

Response: We agree that the quality information displayed on the Hospital Compare Web site increases the transparency of the quality of care provided at PCHs and we appreciate the commenters for their support.

We recognize that we update many measures, including the two HAI measures, on a quarterly basis under the Hospital IQR Program. Because acute care hospitals

already report HAI data on a quarterly basis for purposes of the Hospital IQR Program, we believe that quarterly reporting of HAI data is also feasible for PCHs. We seek to align our public reporting and data collection frequency of PCH HAI data with Hospital IQR Program quarterly updates of HAI data. We believe that requiring quarterly data submissions beginning with 1st calendar quarter 2013 discharges will provide the public with more current information on the Hospital Compare Web site than our current annual data submission proposal.

We also intend to provide the public with the most currently available information on the three cancer-specific measures. We recognize that the ACoS currently collects data for these measures on a quarterly basis. We believe that our data collection schedule for the cancer-specific measures should align with some of the measures currently reported on the Hospital Compare Web site, which is on a quarterly basis. Data for many Hospital IQR and OQR chart-abstracted process of care measures are collected using quarterly submission deadlines, and measure rates are publicly displayed on the Hospital Compare Web site using quarterly updates to reflect the most current data.

We believe that quarterly data collection of both HAI and cancer-specific measure data is not unduly burdensome for PCHs because we understand that the vast majority of PCHs are currently reporting these data to the CDC and ACoS on at least a quarterly basis. We believe that aligning the data collection frequency and deadlines with other programs collecting similar information has the potential to reduce the data reporting burden for PCHs.

Accordingly, we are finalizing that beginning with the FY 2014 PCHQR Program, PCHs will be required to submit data on a quarterly basis. For purposes of the FY 2014 program, the only data that we will require is 1st quarter 2013 data, with that data being due by August 15, 2013 for the two HAI measures, and November 15, 2013 for: (1) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer measure; and (2) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer measure. Data will be due on May 15, 2014 for the adjuvant hormonal therapy measure. We are changing the due date for the adjuvant hormonal therapy measure because the measure is specified to include an assessment of the 12-month therapeutic effect from the time of diagnosis to hormonal therapy.

PCHs will also be required to submit data on all measures on a quarterly basis, and data will be due on or before the deadlines shown in Table 1 below. We are revising these deadlines because the timelines are in alignment with some of the current measures reported on the Hospital Compare Web site. For purposes of determining whether a PCH has met the reporting requirements for a particular program year, we will look at the data quarters submitted during the 12 months preceding the applicable fiscal year. For example, CMS would assess only CLABSI and CAUTI data submitted by August 15, 2013, for purposes of the FY 2014 payment determination. For the FY 2015 payment determination, we would assess quarterly data submission deadlines occurring

between October 1, 2013 and September 30, 2014. In subsequent payment determination years, we would assess quarterly submission deadlines occurring in the previous fiscal year. The applicable discharge quarters applicable to an annual payment determination would vary by measure because the quarterly submission deadlines vary by measure.

After consideration of the public comments we received, we are finalizing data submission timelines for the PCHQR Program for FY 2014 and subsequent program years. PCHs will submit the data on the HAI and cancer-specific measures beginning with Q1 of CY 2013 (January through March 2013). Information on the data submission timeline for both the HAI measures and cancer-specific measures is listed in the table below.

Final PCHQR Data Submission Timelines		
Time Line (Calendar Year)	**Quality Measures***	**CMS Submission Deadline**
Q1 2013 (January-March 2013)	**(NQF #0139)** NHSN CLABSI Outcome Measure**	August 15, 2013
	(NQF #0138) NHSN CAUTI Outcome Measure**	August 15, 2013
	(NQF # 0223) Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer+	November 15, 2013
	(NQF #0559) Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer+	November 15, 2013
	(NQF # 0220) Adjuvant Hormonal Therapy+	May 15, 2014

Final PCHQR Data Submission Timelines		
Time Line (Calendar Year)	**Quality Measures***	**CMS Submission Deadline**
Subsequent calendar quarters	**(NQF #0139)** NHSN CLABSI Outcome Measure**	4 and ½ months following last quarterly event date
	(NQF #0138) NHSN CAUTI Outcome Measure**	4 and ½ months following last quarterly event date
	(NQF # 0223) Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer+	7 and ½ months following last quarterly admission date
	(NQF #0559) Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer+	7 and ½ months following last quarterly admission date
	(NQF # 0220) Adjuvant Hormonal Therapy+	13 and ½ months following last quarterly admission date

*Referred to as the HAI and Cancer-Specific Treatment Quality Measures
**HAI event occurred in applicable quarter, begins on January 1, 2013 and beyond.
+Initial diagnosis in applicable quarter, begins on January 1, 2013 and beyond.

e. Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2014 Program and Subsequent Program Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28068), we proposed that PCHs acknowledge their data accuracy and completeness once annually. PCHs would submit an electronic acknowledgement that the data provided to meet the applicable annual PCHQR Program data submission requirement is accurate and complete to the best of the facility's knowledge at the time of data submission. We proposed to begin annual DACA submission starting with the FY 2015 program, and such submission deadline would be due to CMS no later than August 31, 2014. We proposed to begin the

DACA with the FY 2015 program in an effort to provide ample opportunity for the PCHs to become familiar with the reporting processes. Therefore, we did not propose submission of a DACA for the PCHQR Program for FY 2014. We proposed that the DACA submission deadline for each program year, beginning with FY 2015, be August 31 preceding the respective PCHQR Program year. We proposed August 31 as the DACA deadline for two reasons. First, requiring PCHs to acknowledge their data's accuracy and completeness by August 31 preceding the respective PCHQR Program year provides us with sufficient time to ensure compliance with the program by October 1, the start of the fiscal year. Secondly, we proposed this date to align our DACA deadline with other quality reporting programs, such as the Hospital IQR Program.

We invited public comment on our proposed data accuracy and completeness acknowledgement requirements.

Comment: Several commenters supported the proposed DACA requirements for the PCHQR Program.

Response: We appreciate the commenters for their support of our proposal.

Comment: One commenter stated that the process by which PCHs complete the DACA form does not ensure that publicly reported quality measures will be accurate because CMS has not proposed to validate the data.

Response: We are finalizing a requirement that, beginning with the FY 2015 PCHQR Program, PCHs participating in the PCHQR Program acknowledge the accuracy and completeness of their data to their best knowledge, which will provide us with some assurance that the submitted data are accurate. We would like to provide PCHs with an

opportunity to become familiar with the new program before we consider establishing a process to validate the quality measure data. This approach is consistent with our approach to validation in the Hospital OQR Program during the initial years of the program. Initially, we want to encourage PCHs to begin reporting quality data and using the quality measure information for quality improvement purposes.

After consideration of the public comments we received, we are finalizing the DACA requirements for the FY 2014 and subsequent program years. These timeframes are shown below.

Final CMS Data Accuracy and Completeness Acknowledgement (DACA) Timeframes	
Program Year (Fiscal Year)	**Data Accuracy and Completeness Acknowledgement (DACA) Deadline**
FY 2014	Not required
FY 2015	August 31, 2014
Subsequent Fiscal Years	August 31 of the preceding fiscal year

C. Hospital Value-Based Purchasing (VBP) Program

1. Statutory Background

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital Value-Based Purchasing (VBP) Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

Section 1886(o)(1)(B) of the Act states that the Hospital VBP Program applies to payments for hospital discharges occurring on or after October 1, 2012. In accordance with section 1886(o)(6)(A) of the Act, we are required to make value-based incentive payments under the Hospital VBP Program to hospitals that meet or exceed performance standards for a performance period for a fiscal year. As further required by section 1886(o)(6)(C)(ii)(I) of the Act, we will base each hospital's value-based payment percentage on the hospital's Total Performance Score (TPS) for a specified performance period. In accordance with section 1886(o)(7) of the Act, the total amount available for value-based incentive payments for a fiscal year will be equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as estimated by the Secretary. For FY 2013, the available funding pool will be equal to 1.00 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary, and the size of the applicable percentage will increase to 1.25 percent for

FY 2014, 1.50 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and successive fiscal years.

Section 1886(o)(1)(C) of the Act generally defines the term "hospital" for purposes of the Hospital VBP Program as a subsection (d) hospital (as that term is defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term "hospital," with respect to a fiscal year: (1) a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the FY 2013 Hospital VBP Program

In April 2011, we issued the Hospital Inpatient VBP Program final rule to implement section 1886(o) of the Act (76 FR 26490 through 26547). As described more fully in that final rule, for the FY 2013 Hospital VBP Program, we adopted 13 measures, including 12 clinical process of care measures and 8 dimensions from the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS), that we categorized into two domains (76 FR 26495 through 26511). We grouped the 12 clinical process of care measures into a Clinical Process of Care domain, and placed the

HCAHPS survey measure into a Patient Experience of Care domain. We adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these measures (76 FR 26494 through 26495), and performance standards on which hospital performance will be evaluated. To determine whether a hospital meets or exceeds the performance standards for these measures, we will assess each hospital's achievement during this specified performance period, as well as its improvement during this period as compared with its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We will then calculate a TPS for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights will be clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We will convert each hospital's TPS into a value-based incentive payment percentage using a linear exchange function and will then convert the value-based incentive payment percentage into a per discharge value-based incentive payment amount. We will incorporate the reduction to each hospital's base operating DRG payment amount for each discharge, as well as the value-based incentive payment amounts that the hospital earned as a result of its performance (if applicable) into our claims processing systems in January 2013, and these adjustments will apply to FY 2013 discharges. We refer readers to the Hospital Inpatient VBP Program final rule for further explanation of the details of the FY 2013 Hospital VBP Program (76 FR 26490 through 26547).

We proposed to codify in our regulations at 42 CFR 412.160 a number of definitions that we previously finalized for the Hospital VBP Program in the Hospital Inpatient VBP final rule, including definitions of the terms achievement threshold, benchmark, domain, domain score, hospital, improvement threshold, performance period, and TPS. We did not receive any comments on the specific regulation text that we proposed with respect to these terms. In this final rule, we are making a number of technical, clarifying changes to these definitions and otherwise adopting them as final.

We also proposed to codify in our regulations at 42 CFR 412.164 that, as we previously finalized, we will select measures for purposes of the Hospital VBP Program, and that we will post data on each measure on the Hospital Compare Web site for at least one year prior to the beginning of the performance period for the measure under the Hospital VBP Program. We did not receive any comments on the specific regulation text that we proposed, and we are finalizing § 412.164 with one technical change.

We proposed to codify in our regulations at 42 CFR 412.165 and 42 CFR 412.166 the performance standards and performance scoring methodologies that we previously finalized for the Hospital VBP Program. We did not receive any comments on the specific regulation text that we proposed. We are finalizing this regulation text with a few technical changes, including combining the two provisions into one provision at 42 CFR 412.165.

3. FY 2014 Hospital VBP Program Measures

For FY 2014, we have adopted 17 measures for the Hospital VBP Program, including the 12 clinical process of care measures and the HCAHPS measure that we adopted for the FY 2013 Hospital VBP Program, 1 new clinical process of care measure (SCIP-Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2), and 3 mortality outcome measures (Acute Myocardial Infarction (AMI) 30-Day Mortality Rate, Heart Failure (HF) 30-Day Mortality Rate, Pneumonia (PN) 30-Day Mortality Rate). The clinical process of care, HCAHPS, and mortality measures are discussed in more detail in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26511) and SCIP-Inf-9 is discussed in more detail in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74530).

Although we also previously adopted 8 HAC measures, 2 AHRQ composite measures, and a Medicare Spending Per Beneficiary Measure for the FY 2014 Hospital VBP Program, we have suspended the effective date of these measures, with the result that these measures will not be included in the FY 2014 Hospital VBP Program (76 FR 74528 through 74530).

Set out below is a complete list of the measures adopted for the FY 2014 Hospital VBP Program:

Clinical Process of Care, Patient Experience of Care and Outcome Measures for the FY 2014 Hospital VBP Program	
Clinical Process of Care Measures	
IV. Measure ID	**Measure Description**
Acute myocardial infarction	

Clinical Process of Care, Patient Experience of Care and Outcome Measures for the FY 2014 Hospital VBP Program	
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival
Heart Failure	
HF-1	Discharge Instructions
Pneumonia	
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient
Healthcare-associated infections	
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2
Surgeries	
SCIP-Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery
Patient Experience of Care Measures	
V. Measure ID	**Measure Description**
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey*
Outcome Measures	

Clinical Process of Care, Patient Experience of Care and Outcome Measures for the FY 2014 Hospital VBP Program	
Measure ID	**Measure Description**
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate
MORT-30 PN	Pneumonia (PN) 30-Day Mortality Rate

*The finalized dimensions of the HCAHPS survey for use in the FY 2014 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions that we adopted for the FY 2013 Hospital VBP Program.

4. Other Previously Finalized Requirements for the Hospital VBP Program

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74547), we finalized a number of other policies for the FY 2014 Hospital VBP Program including: the minimum number of cases that a hospital must report to receive a score on a mortality measure; the minimum number of measures that a hospital must report in order to receive a score on the Outcome domain; the baseline and performance periods; the performance standards for the clinical process of care and patient experience of care measures (we previously finalized the performance standards for the 3 mortality outcome measures in the Hospital Inpatient VBP Program final rule (76 FR 26513)); the scoring methodology; and the domain weighting methodology. We also finalized for all years of the Program a process that will allow hospitals to review and correct the data that they submit to the QIO Clinical Warehouse on clinical process of care measures, their clinical process of care measure rates, their HCAHPS data, and their patient-mix and mode adjusted HCAHPS scores.

5. Hospital VBP Program Payment Adjustment Calculation Methodology

a. Definitions of the Term "Base Operating DRG Payment Amount" for Purposes of the Hospital VBP Program

Section 1886(o)(7)(D) of the Act generally defines the base operating DRG payment amount, with respect to a hospital for a fiscal year, as "the payment amount that would otherwise be made under section 1886(d) (determined without regard to subsection (q) [the Hospital Readmissions Reduction Program]) for a discharge if [the Hospital VBP Program] did not apply; reduced by any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d); and…such other payments under subsection (d) determined appropriate by the Secretary." Paragraphs (5)(A), (5)(B), (5)(F), and (12) of section 1886(d) of the Act refer to outlier payments, indirect medical education (IME) payments, disproportionate share (DSH) payments, and low-volume hospital payments, respectively.

We stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28070) that the payment that would otherwise be made with respect to a discharge is the applicable average standardized amount adjusted for resource utilization by the applicable MS-DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii), which is often referred to as the "the wage-adjusted DRG operating payment." The payment amount that would otherwise be made with respect to a discharge also includes any adjustments to the wage-adjusted DRG operating payment that the hospital qualifies

for, including an outlier adjustment (under section 1886(d)(5)(A) of the Act) an IME adjustment (under section 1886(d)(5)(B) of the Act), a disproportionate share payment adjustment (under section 1886(d)(5)(F) of the Act); a low-volume payment adjustment (under section 1886(d)(12) of the Act), an adjustment for new medical services or technologies under section 1886(d)(5)(K) of the Act (often referred to as "new technology add-on payments"), and/or any other adjustment determined appropriate by the Secretary.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28070), consistent with section 1886(o)(7)(D) of the Act, we proposed to generally define the term "base operating DRG payment amount" for purposes of the Hospital VBP Program as the wage-adjusted DRG operating payment plus any applicable new technology add-on payment. We proposed to include the new technology add-on payment amount in the definition of base operating DRG payment amount for the Hospital VBP Program because the provision of a new technology to a Medicare beneficiary is a treatment decision, unlike the other add-on payments which are excluded by statute (for example, IME and DSH add-ons). We believe that it represents a cost to the Medicare program that should be subject to the applicable percent reduction to the base operating DRG payment amount which creates the funding pool for value-based incentive payments. We also note that this proposed definition is consistent with the definition of "base operating DRG payment amount" that we proposed to adopt for the Hospital Readmissions Reduction Program, and we believe that maintaining consistency to the extent possible with other Medicare incentive payment programs is an important goal for the Hospital

VBP Program. There are no other subsection (d) payment adjustments that would otherwise apply to the discharge on a per-claim basis. As required by the statute, the "base operating DRG payment amount" would not include an outlier, IME, DSH, or low-volume payment adjustment that would otherwise apply to the discharge.

We proposed to codify the definition of the term "wage-adjusted DRG operating payment" and the definition of the term "base-operating DRG payment amount" as it would apply to most subsection (d) hospitals in our regulations at 42 CFR 412.160. We welcomed public comment on these proposed definitions.

Comment: The majority of commenters supported our proposed general definition of base-operating DRG payment amount. A few commenters suggested that applicable new technology add-on payments should not be included in the definition. These commenters expressed the belief that new technology add-on payments are extrinsic to the base rate and that their inclusion in the base operating DRG payment amount definition would be in conflict with ensuring adequate payment for new technologies. Two commenters suggested that CMS clarify the handling of capital costs in defining the base operating DRG payment amount, with one suggesting they should be included in the definition and one suggesting they should be excluded.

Response: We thank the commenters for their support of our proposed general definition of base operating DRG payment amount for the Hospital VBP Program. With respect to the new technology add on payments, we disagree with the commenters who suggested that they should be excluded from the definition of the term "base operating DRG payment amount." We acknowledge that new technology add on payments could

be viewed as extrinsic to the base rate, but we disagree that their inclusion in the definition of the term base operating DRG payment amount would be in conflict with ensuring adequate payments for the provision of new technologies. Under the Hospital VBP Program, hospitals that perform well on the selected measures may earn back more than the applicable percent reduction used to fund the value based incentive payments. Therefore, a hospital that provides an effective new technology and performs well on the measures would be able to earn an additional payment under the Program. We continue to believe that these payments represent treatment decisions made by hospitals, and are therefore appropriately captured in our definition for this Program. Further, we value consistency with the definition being used for the Hospital Readmissions Reduction Program, which includes new technology add-on payments. With respect to capital payments, we did not propose to include them in the definition of base operating DRG payment amount because section 1886(o)(7)(D)(i) of the Act defines the base operating DRG payment amount, with respect to most subsection (d) hospitals as "the payment amount that would otherwise be made under section 1886(d)" with certain exclusions. Capital payments are paid to most acute care hospitals under section 1886(g) of the Act and, therefore, are not included in the payment amount that would otherwise be made under section 1886(d) of the Act.

Comment: One commenter suggested that the transfer payment adjustment should be included in the definition of base-operating DRG payment amount.

Response: We agree with this comment and are revising our definition of the term "wage-adjusted DRG operating payment" at 42 CFR 412.160 to include an

applicable payment adjustment for a transfer under 42 CFR 412.4(f). The transfer adjustment is a reduction to the payment amount, which we apply when a patient leaves the hospital before the average length of stay for their DRG, and continues to receive treatment in either another acute hospital or a post acute setting. We believe that the transfer adjustment is appropriately included in the adjustment to the standardized amount for resource utilization because the transfer adjustment is applied in order to make the payment that would otherwise be made to a subsection (d) hospital that transfers a patient commensurate with the resources that the hospital used to treat that patient.

After consideration of the public comments we received, we are finalizing the definition of the term "wage-adjusted DRG operating payment" as the applicable average standardized amount adjusted for (i) resource utilization by the applicable MS-DRG relative weight, (ii) differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii), and (iii) an applicable transfer under 42 CFR 412.4(f). We are also finalizing the definition of the term "base operating DRG payment amount" as that term applies to most subsection (d) hospitals as the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under 42 CFR 412.4(f). We are finalizing that this amount is determined without regard to any payment adjustments under the Hospital Readmissions Reduction Program, and that it does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share

of low-income patients under § 412.106, outliers, or a low volume of discharges under § 412.101. We are codifying these definitions in our regulations at 42 CFR 412.160.

Section 1886(o)(7)(D)(ii)(I) of the Act states that in the case of a Medicare-dependent, small rural hospital (MDH) (with respect to discharges occurring during FY 2012 or FY 2013) or a sole community hospital (SCH), the base operating DRG payment amount is defined as the payment amount that would otherwise be made under section 1886(d) of the Act without regard to certain factors that affect payments to these categories of hospitals (sections 1886(b)(3)(I) and (L) of the Act, and section 1886(d)(5)(D) of the Act for SCHs, and section 1886(d)(5)(G) of the Act for MDHs). In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28071), consistent with the definition we proposed to adopt for other subsection (d) hospitals, we proposed to define the term "base operating DRG payment amount" for MDHs and SCHs as the wage-adjusted DRG operating payment amount plus any applicable new technology add-on payment. The proposed base operating DRG payment amount for SCHs and MDHs would not include an outlier, IME, DSH, or low-volume payment adjustment that would otherwise apply to the discharge. Consistent with section 1886(o)(7)(D)(ii)(I) of the Act, we also proposed to exclude from this definition of base operating DRG payment amount the difference between the hospital-specific payment rate and the Federal payment rate. This proposed definition is consistent with that being proposed under the Hospital Readmissions Reduction Program (discussed in section IV.A. of this preamble). We proposed to codify this definition in our regulations at 42 CFR 412.160.

We welcomed public comment on this proposed definition of the base operating DRG payment amount for MDHs and SCHs under the Hospital VBP Program. We note that, under current law, the MDH program is set to expire at the end of FY 2012, after which all MDH hospitals would be paid in the same manner as other subsection (d) hospitals, unless they qualify for SCH status, as discussed in section VIII.C.5.b. of this preamble.

Comment: Commenters were supportive of our proposed definition of "base operating DRG payment amount" for SCHs and MDHs. One commenter asked that we clarify that we would exclude the difference between the applicable hospital-specific payment rate and the Federal payment rate for both SCHs and for MDHs, should the MDH provision be extended beyond FY 2012.

Response: We thank the commenters for their support of the proposed definition of base operating DRG payment amount for SCHs and MDHs and are adopting it as final. If the MDH program is extended beyond FY 2012, we will continue to use this definition for MDHs. For an SCH or an MDH, the payment adjustment under the Hospital VBP Program for each discharge will be calculated by multiplying the SCH or MDH's value-based incentive payment adjustment factor by the base-operating DRG payment amount that is exclusive of the amount by which the hospital-specific payment rate exceeds the Federal payment rate. The resulting payment adjustment will then be added to or subtracted from the hospital's payment for the discharge, regardless of whether the hospital is paid based on the Federal rate or its hospital-specific rate. We finalize the

methodology for calculating individual hospitals' value-based incentive payment adjustment factors below, in section VIII.C.5.c. of this preamble.

After consideration of the public comments we received, we are finalizing the definition of the term "base operating DRG payment amount," with respect to a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) or a sole community hospital that receives payments under § 412.92(d), as the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of 42 CFR Part 412. We are finalizing that this amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of 42 CFR Part 412, or a low volume of discharges under § 412.101. This amount also does not include the difference between the hospital-specific payment rate and the Federal payment rate.

Section 1886(o)(7)(D)(ii)(II) of the Act states that in the case of a hospital that is paid under section 1814(b)(3) of the Act, "the term 'base operating DRG payment amount' means the payment amount under that section." Acute care hospitals located in the State of Maryland are not paid under the IPPS but are, instead, paid under a special waiver provided by section 1814(b)(3) of the Act. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28071), for these hospitals, we proposed that the term "base operating DRG payment amount" means the payment amount under section 1814(b)(3) of the Act. This proposed definition is consistent with the definition we proposed under the Hospital Readmissions Reduction Program (discussed in section IV.A. of this

preamble). We proposed to codify this definition in our regulations at 42 CFR 412.160. We welcomed public comment on the proposed definition of base operating DRG payment amount for Maryland hospitals under the Hospital VBP Program.

Comment: One commenter suggested that the definition of base operating DRG payment amount for Maryland hospitals should not be the payment made under section 1814(b)(3) of the Act because that payment is inclusive of payments for medical education, treatment of a disproportionate share of low income patients, uncompensated care, labor-market adjustors, and assessments to fund other initiatives. This commenter suggested that CMS should work with Maryland to develop an alternative definition. Another commenter also noted that the payment received by Maryland hospitals differs significantly from that received by other subsection (d) hospitals, urging that we continue to allow Maryland the flexibility to continue existing State-based initiatives for improvement in quality of care.

Response: Maryland hospitals are currently paid 94 percent of charges, and the Maryland Health Services Cost Review Commission includes IME, DSH, uncompensated care, and labor market adjusters in the charges that it submits to the Secretary for purposes of calculating the payment amounts for these hospitals under section 1814(b)(3) of the Act. We believe that as long as these amounts are included in the payment amounts made to these hospitals under section 1814(b)(3) of the Act, they are appropriately included in the definition of the base operating DRG payment amount for these hospitals under the Hospital VBP Program. With regard to the comment that Maryland should be allowed to continue existing State-based incentives, we note that

acute care hospitals located in the State of Maryland have been granted an exemption from the Hospital VBP Program for FY 2013 based on the State's submission of a report describing how a similar State program achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program. The State will also have the opportunity to request that these hospitals be exempted from future years of the Program, as discussed more fully in section VIII.C.13 of this preamble.

After consideration of the public comments we received, we are finalizing the definition of the term "base operating DRG payment amount" for hospitals that are paid under section 1814(b)(3) of the Act as the payment amount made under section 1814(b)(3) of the Act.

We are also codifying the definition of the term base-operating DRG payment amount, as that term is applied to SCHs, MDHs, and hospitals paid under section 1814(b)(3) of the Act, in our regulations at 42 CFR 412.160.

b. Calculating the Funding Amount for Value-Based Incentive Payments Each Year

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. To implement these sections, and create the funding pool for value-based incentive payments for each fiscal year, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28071),we

proposed that beginning with FY 2013 discharges, every hospital that meets the definition of a hospital in section 1886(o)(1)(C) of the Act (referred to here as an eligible hospital) would receive a reduction to its base operating DRG payment amount for each discharge in a fiscal year, regardless of whether we have determined that the hospital has earned a value-based incentive payment for that fiscal year. The total amount of the reductions across all eligible hospitals for a fiscal year would constitute the total amount available from which we could make value-based incentive payments for that fiscal year. We proposed to estimate the total amount of the reductions across all eligible hospitals and the size of the funding pool prior to the start of each fiscal year because that is the only way, operationally, that we can calculate each hospital's value-based incentive payment percentage in a manner such that the estimated sum total of the value-based incentive payments for hospitals for the fiscal year would be equal to the estimated total amount available for value-based incentive payments to all eligible hospitals.

The data we proposed to use to estimate these amounts is inpatient claims data from the Medicare Provider Analysis and Review (MedPAR) file. We believe that the use of MedPAR data is appropriate because we also use this data to calculate other IPPS payment adjustment amounts, including the DRG relative weights, budget neutrality factors, outlier thresholds, and standardized amounts. The proposed use of claims data from the MedPAR file is also consistent with our proposal to determine applicable hospitals' base operating DRG payment amounts, for purposes of determining the readmissions payment adjustment factor under the Hospital Readmissions Reduction Program (section IV.A. of this preamble).

We proposed to run the MedPAR data for purposes of estimating the base operating DRG payment reduction amounts, as well as the size of the funding pool that will apply to a fiscal year, in December of the previous fiscal year so that we can provide preliminary estimates in the IPPS/LTCH PPS proposed rule. We also proposed to provide the final estimates in the IPPS/LTCH PPS final rule using the March update. The data will contain inpatient claims information related to discharges from the fiscal year that ended the previous September. For example, with respect to the FY 2014 Hospital VBP Program, we would run the MedPAR data in December, 2012 and that data would contain claims related to FY 2012 discharges. We would use that data to provide preliminary estimates in the FY 2014 IPPS/LTCH PPS proposed rule. The March 2013 update of this MedPAR data would then be used to provide final estimates in the FY 2014 IPPS/LTCH PPS final rule.

We believe that this proposed approach will enable us to gather the most recent Medicare utilization data available in order to estimate the total amount of the base operating DRG payment amount reductions and the size of the value based incentive payment funding pool for the applicable fiscal year. We also believe that this approach will enable us to calculate each hospital's value based incentive payment adjustment factor that will apply to its discharges in the applicable fiscal year, and to notify each hospital of such at the same time that we proposed to notify each hospital regarding its performance for purposes of making this information publicly available under section 1886(o)(10)(A) of the Act. In this way, hospitals will be able to consider this information during the review and correction period (which is discussed below). We believe that it is

important to notify a hospital of its value-based incentive payment adjustment factor at the start of review and corrections, so that hospitals can consider the payment impact of the TPS in their determination of whether or not to request review and corrections.

In order to estimate the total base operating DRG payment reductions across all hospitals for a fiscal year, we proposed to sum the estimated total base operating DRG payment amount per discharge for each hospital in that fiscal year. We would then multiply that estimated total annual base operating DRG payment amount by the applicable percent, which we proposed to define in our regulations at § 412.160 as the percentages specified in section 1886(o)(7)(C) of the Act. The product of the estimated total annual base operating DRG amount for a hospital and the applicable percent would be equal to taking the applicable percent reduction from each individual base operating DRG payment amount per hospital and then summing those reductions. We welcomed public comment on this proposed approach to calculating the available pool of funds for value-based incentive payments.

Comment: Commenters were supportive of our proposals.

Response: We thank the commenters for their support of these proposals and we are adopting them as final.

After consideration of the public comments we received, we are finalizing our proposal to estimate the total amount of the reductions across all eligible hospitals and the size of the funding pool for value-based incentive payments under the Hospital VBP Program, prior to the start of each fiscal year, using MedPAR data. We are finalizing our proposal to use the December update to MedPAR for the purposes of providing the

estimates in the IPPS/LTCH PPS proposed rule each year, and to utilize the March update to provide the final estimates in the IPPS/LTCH PPS final rule each year. We are also finalizing the definition of the term "applicable percent" in 42 CFR 412.160 of our regulations as the percentages specified in section 1886(o)(7)(C) of the Act. Finally, we are finalizing our proposal to sum the estimated total base operating DRG payment amount per discharge for each hospital in a fiscal year and then multiply that amount by the applicable percent in order to estimate the total base operating DRG payment reductions across all hospitals for a fiscal year.

For the purpose of estimating the total amount available for value-based incentive payments for a fiscal year, we proposed to apply an inflation factor so that our estimate of the available pool of funds will more accurately reflect estimated total base operating DRG payments in the fiscal year in which the value-based incentive payments will actually be made. For example, in estimating the size of the FY 2013 funding pool, we inflated the FY 2011 MedPAR data to FY 2013 dollars because the value-based incentive payment amounts will actually be paid in FY 2013.

Our actuaries provided us with this inflation factor, which included assumptions on changes in Medicare fee-for-service case mix and discharge levels. According to this proposed methodology, we originally estimated the available amount for FY 2013 value-based incentive payments to be $956 million. We then issued a correction notice, because reductions to base operating DRG payment amounts for Maryland hospitals had inadvertently been included in the total estimated amount available for FY 2013 when Maryland hospitals have been excluded from the Hospital VBP Program for FY 2013.

The revised estimated available amount was $917 million (CMS-1588-CN). As noted above, under our proposed methodology, we proposed that we would update this estimate using the March 2012 update of the FY 2011 MedPAR data for purposes of finalizing it in the FY 2013 IPPS/LTCH PPS final rule.

We note that, for the purposes of calculating the value-based incentive payment adjustment factors under the Hospital VBP Program, we would be able to use FY 2011 claims to accurately calculate the value-based incentive payment percentage, without application of this inflation factor. This is because a constant inflation factor applied across all hospitals' total annual base-operating DRG payment amounts will not change the slope of the linear exchange function which we previously adopted for use in determining each hospital's value-based incentive payment amount. Application of an inflation factor would, therefore, not impact the amount of a hospital's value-based incentive payment amount under the Hospital VBP Program for the fiscal year.

We considered adopting a different approach that would apply only to the FY 2013 Hospital VBP Program because we do not anticipate beginning to make value-based incentive payments to hospitals for that program year until January 2013. Under this approach, we would have estimated the total amount of funding available to make the value-based incentive payments using the latest available FY 2011 claims data from MedPAR, with payment amounts modeled using the rates, factors and policies finalized in the FY 2013 IPPS/LTCH PPS final rule. This data would include claims information that was not available at the time we ran the March update. However we did not propose to adopt this approach, because we believe that is important to establish a consistent

process for annually estimating the total amount available to make value-based incentive payments to hospitals, as well determining the value-based incentive payment adjustments that will be made to hospitals as a result of their performance under the Hospital VBP Program. Beginning with the FY 2014 Hospital VBP Program, we intend to make the value-based incentive payments to hospitals as part of the claims payment process, beginning at the start of the fiscal year, so it would not be possible to use the modeled base-operating DRG payment amount estimates based on the finalized rates, factors and policies established in the IPPS/LTCH PPS final rule applicable to the fiscal year, as they will typically not be finalized in time to notify hospitals of their value-based incentive payment adjustments at the start of the review and corrections process.

Further, these factors, rates, and policies would not typically be finalized in time for us to notify hospitals of the net result of the base operating DRG payment amount reduction and the value-based incentive payment adjustment no later than 60 days prior to the start of the fiscal year, as required by section 1866(o)(8) of the Act. We also believe that our proposal to use the March update of the MedPAR file represents an accurate estimate of annual base operating DRG amounts because it reflects the most recently available utilization data, while preserving the interest in notifying hospitals of the payment impact in time for them to request review and correction.

We proposed to use a different methodology for purposes of estimating the reduced annual base operating DRG payment amounts for SCHs and MDHs. In general, eligible hospitals in the Hospital VBP Program include SCHs and current MDHs (we note that MDH status is set to expire under current law after FY 2012 and would,

therefore, no longer exist in FY 2013), because they meet the definition of a "subsection (d)" hospital. SCHs are paid in the interim (prior to cost report settlement) on a claim by claim basis at the amount that is the higher of the payment based on the hospital-specific rate or the IPPS Federal rate based on the standardized amount. At cost report settlement, the fiscal intermediary or A/B MAC determines if the hospital would receive higher aggregate operating IPPS payments using the hospital-specific rate (for all claims) or the Federal rate (for all claims). MDHs are paid the sum of the Federal payment amount plus 75 percent of any amount by which the hospital-specific rate payment exceeds the Federal rate payment amount.

Although MDH status is to expire at the end of FY 2012, the payments reflected on FY 2011 claims for current MDHs may be based on the hospital-specific rate. As discussed above, we generally proposed to use historical MedPAR data to determine the base operating DRG payment amounts that would be used to estimate the amount of funding available for value-based incentive payments for the FY 2013 Hospital VBP Program. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28072), consistent with that proposal, for SCHs and hospitals that have MDH status in FY 2012, we proposed to use MedPAR data to model the reduced base operating DRG payment amount for each claim as if it were paid based on the Federal standardized amount, rather than using the payment information on the claim (that is, regardless of whether a claim was paid under the hospital-specific rate or the Federal rate, the reduced base operating DRG payment amounts for SCHs and current MDHs would be estimated using the Federal rate).

We welcomed public comment on these proposals. We also welcomed comment

on other suggested approaches to most accurately estimate these amounts.

Comment: One commenter asked CMS to verify that Maryland hospitals had not been included in the estimated available funding pool for value-based incentive payments in FY 2013. One commenter questioned whether the amount stated in the proposed rule was correct, because they arrived at significantly different number.

Response: We inadvertently included reductions to payments for Maryland hospitals in the estimated total amount available for value-based incentive payments under the Hospital VBP Program for FY 2013, in the FY 2013 IPPS/LTCH PPS proposed rule. As noted above, we subsequently issued a correction notice (CMS-1588-CN; 77 FR 34326), including a new estimated $917 million total amount available for value-based incentive payments under the Hospital VBP Program for FY 2013. Both the original and the corrected estimates were calculated using the December 2011 update to the FY 2011 MedPAR data and with the application of an inflation factor of 9.75 percent. As stated in the proposed rule, this inflation factor was provided by CMS actuaries and included assumptions regarding changes in Medicare fee-for-service case-mix and discharge levels. We verified with our actuaries that the estimated $917 million total amount available was correct.

After consideration of the public comments we received, we are adopting our proposed methodology for estimating the total amount available for value-based incentive payments in a fiscal year under the Hospital VBP Program. The final estimate for FY 2013, based on the March, 2012 update to the FY 2011 MedPAR file, is $963 million.

c. Methodology to Calculate the Value-Based Incentive Payment Adjustment Factor

In accordance with section 1886(o)(6)(C)(i) of the Act, for each eligible hospital that receives a TPS greater than zero with respect to a fiscal year, we proposed to calculate a value-based incentive payment percentage for that hospital for that fiscal year. We proposed that, in accordance with section 1886(o)(6)(C)(ii) of the Act, the value-based incentive payment percentage that we calculate for the hospital will be based on that hospital's individual TPS, and the total amount of value-based incentive payments to all hospitals in the fiscal year will be equal to the total amount available for value-based incentive payments for the fiscal year, as estimated by the Secretary. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28073), we proposed to define the term "value-based incentive payment percentage" in § 412.160 as the percentage of the total base operating DRG payment amount that a hospital has earned back, based on its TPS for that fiscal year. The hospital may earn a value-based incentive payment percentage that is less than, equal to, or more than the applicable percent. The applicable percent that we will use to reduce the base operating DRG payment amount for each FY 2013 discharge is 1.0 percent.

A hospital may earn a value-based incentive payment percentage that is greater than the applicable percent, which would result in that hospital receiving a value-based incentive payment adjustment factor that is greater than one and a higher base operating DRG payment amount for each discharge than it would have received in the absence of the Hospital VBP Program. The proposed calculation of the value-based incentive payment adjustment factor is discussed in further detail below. A hospital may earn a

value-based incentive payment percentage that is equal to the applicable percent, which would result in the hospital receiving a value based incentive payment adjustment factor of 1 and the same base operating DRG payment amount that it would have received for each discharge in the absence of the Hospital VBP Program. Alternatively, a hospital may earn a value-based incentive payment percentage that is less than the applicable percent, which would result in the hospital receiving a value-based incentive payment adjustment factor that is less than one and a lower base operating DRG payment amount for each discharge than it would have received in the absence of the Hospital VBP Program.

In order to convert a hospital's TPS into a value-based incentive payment factor that would be applied to each discharge in the applicable fiscal year, we proposed to use the linear exchange function that we finalized in the Hospital Inpatient VBP Program final rule (76 FR 26534). Under this proposed methodology, we would use the following computed amounts:

- The hospital's estimated total annual base-operating DRG amount for all discharges for the applicable fiscal year;
- The applicable percent for the fiscal year (1.0 percent in FY 2013);
- The (linear) exchange function slope; and
- The hospital's TPS.

The following six (6) steps illustrate our proposed methodology:

Step 1: Estimate the hospital's total annual base-operating DRG amount. First, we would estimate each hospital's total annual base operating DRG amount for all

discharges in the applicable fiscal year. As we discussed above, we proposed to estimate this amount using Medicare inpatient claims data taken directly from the most recently available MedPAR files.

Step 2: Calculate the total annual estimated base operating DRG payment reduction amount across all eligible hospitals. Second, we proposed to estimate the total base operating DRG reduction amount across all eligible hospitals (which is the total amount available for value-based incentive payments) according to the following two steps:

Step 2a: Repeat Step 1 for all eligible hospitals, and multiply the estimated total amount for each hospital by the applicable percent. For FY 2013, the applicable percent is 1.0 percent; then

Step 2b: Add together the amount for each hospital calculated under Step 2a . This sum is the total amount available for value-based incentive payments, and the numerator of the linear exchange function slope that is calculated in Step 3 below.

Step 3: Calculate the linear exchange function slope. Third, we would calculate the linear exchange function slope. As noted above, we finalized the use of a linear exchange function for the purpose of converting a hospital's TPS into a value-based incentive payment percentage. We would calculate the linear exchange function slope using the following steps:

Step 3a: Convert the TPS for each hospital into a decimal by dividing it by 100. The TPS may range from zero to 100. In this step, we express it as a number between zero and 1.

Step 3b: Multiply each hospital's estimated total base-operating DRG payment reduction amount for the applicable fiscal year (from Step 2a above) by the hospital's TPS (decimal between zero and one from Step 3a above).

Step 3c: Add together the numbers computed in Step 3b above. This sum represents the denominator of the linear exchange function slope that is calculated in Step 3d below.

Step 3d: The exchange function slope equals the sum computed in Step 2b above divided by the sum computed in Step 3c above.

Step 4: For each hospital, calculate the hospital's value-based incentive payment percentage for the fiscal year. We proposed to use the exchange function slope (from Step 3) and the hospital's TPS to calculate the hospital's value-based incentive payment percentage that it earned as a result of its performance under the Hospital Inpatient VBP Program for the fiscal year. We could calculate the value-based incentive payment percentage by multiplying the applicable percent by the amount computed for the hospital in Step 3a and the exchange function slope as computed in Step 3d above. This is the mathematical approach to locating the place along the linear exchange function where a given hospital's TPS score would be located and identifying the corresponding value-based incentive payment percentage. As we note above, the value-based payment percentage could be greater than, equal to, or less than the applicable percent that is applied to reduce the base operating DRG payment amount for each discharge.

Step 5: Compute the net percentage change in the hospital's base-operating DRG payment amount for each discharge. Fifth, we proposed to calculate the net percentage

change to the hospital's base operating DRG payment amount for each discharge in the applicable fiscal year. We would calculate the net change as an intermediate step, in order to determine the value-based incentive payment adjustment factor described in Step 6, below. The net percentage change in the hospital's base operating DRG payment amount for each discharge would be the difference between the applicable percent and the value-based incentive payment percentage. We would calculate this net change for each hospital by subtracting the applicable percent used in Step 2a (1 percent for FY 2013) from the value based incentive payment percentage computed for the hospital in Step 4. This net change in the base-operating DRG payment amount would be expressed as a percentage and could be positive, zero, or negative, depending on the hospital's TPS and the exchange function slope.

Step 6: Calculate the value-based incentive payment adjustment factor. To calculate this factor, we would convert the hospital's individual net percentage change in its base-operating DRG payment amount, from Step 5, from a percentage into a number (by removing the percent sign and dividing it by 100) and add it to 1. The 1 would reflect the base operating DRG payment amount that the hospital would have received for a discharge in the absence of the Hospital VBP Program. The result is that a hospital with a positive net percentage change to its total base operating DRG payment amount would have a value-based incentive payment adjustment factor that is greater than one. This means that we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number greater than one.

A hospital with no net percentage change to its total base operating DRG payment amount percentage would have a value-based incentive payment adjustment factor of one. This means that we would multiply its base operating DRG payment amount for each discharge occurring in the applicable fiscal year by 1, and its base-operating DRG payment amount would be equal to what it would have been in the absence of the Hospital VBP Program.

A hospital with a negative net percentage change to its total base-operating DRG payment amount percentage would have a value-based incentive payment adjustment factor that is less than one. This means that we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number less than one.

Example Calculation of the Value-Based Incentive Payment Adjustment Factor:

As an example, assume the following information:

- The hospital's estimated total annual base operating DRG payment amount for all discharges in the applicable fiscal year = $1,000,000;
- The applicable percent that is applied to all discharges of eligible hospitals in FY 2013 = 1.0 percent;
- The exchange function slope = 2.0;
- The hospital's TPS = 80

Under our proposal, we would replicate the six steps to convert a hospital's TPS into a value-based incentive payment adjustment factor as follows:

Step 1: Estimate the hospital's total annual base operating DRG payment amount. We would add together the estimated base-operating DRG payment amount for each FY 2013 discharge. In this example, we assume this total amount would be $1,000,000.

Step 2: Calculate the total annual estimated base operating DRG payment reduction amount across all eligible hospitals. Second, we would:

Step 2a: Repeat Step 1 for all eligible hospitals, and multiply the total amount for each hospital by the applicable percent, which is 1.0 percent in this example: $1,000,000 * 0.01 = $10,000; and

Step 2b: Add together the amount for each hospital calculated in Step 2a above. In this example, we assume this amount is a given. We note that computing this amount requires knowledge of all eligible hospitals' estimated total base operating DRG payment reduction amount.

Step 3: Calculate the linear exchange function slope, which we assume in this example to be 2.0. We note that computing the slope requires knowledge of all eligible hospitals' estimated total base operating DRG payment reduction amount and their TPS to compute the relevant sums that are used in the numerator and denominator of the slope.

Step 4: Calculate the hospital's value-based incentive payment percentage. The hospital's value-based payment percentage would be computed as follows: 0.01 (the applicable percent would be multiplied by 0.80 (the hospital's TPS divided by 100) and 2.0 (the exchange function slope). Mathematically, 0.01 * 0.80 * 2.0 = 0.016, which can be written as 1.60 percent. Therefore, the hospital's value-based incentive payment

percentage for the FY 2013 Hospital VBP Program would be 1.60 percent ($16,000 in this example).

Step 5: Compute the net percentage change in the hospital's base-operating DRG payment amount for each discharge by subtracting 1.0 percent (the applicable percent) from the value-based incentive payment percentage that the hospital earned based on its TPS.

In this example, the net percentage change would equal 1.60 percent minus 1.00 percent, or 0.60 percent. In this example, the net percentage change is positive and corresponds to a dollar amount of 0.60 percent of the estimated total annual base operating DRG payment amount for the hospital of $1,000,000(0.60 percent * $1,000,000 = $6,000).

Step 6: Compute the value-based incentive payment adjustment factor as equal to: the net percentage change (calculated in Step 5), expressed as a number, plus one. In this example, the hospital's value-based incentive payment adjustment factor would equal the sum of 0.006 (0.60 percent expressed as a number) plus one.

Therefore, this hospital's value-based incentive payment adjustment factor would equal 1.006, and this factor would be multiplied by the base operating DRG payment amount for each discharge occurring in FY 2013. This hospital had a positive net percentage change to its total base operating DRG payment amount and would have a value-based incentive payment adjustment factor that is greater than one, so we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number greater than one. In this example, the

hospital would earn a total value-based incentive payment estimated at $16,000 for all discharges in the fiscal year), which is greater than the 1.0 percent base operating DRG payment reduction amount applied to each discharge in the fiscal year (estimated $10,000 total reduction), which would result in the hospital receiving a higher payment amount for each discharge occurring in FY 2013 than it otherwise would have received, in the absence of the Hospital VBP Program (an estimated $6000 total increase in base operating DRG payments for the fiscal year).

We welcomed comments on this proposal.

We proposed to codify in our regulations at § 412.160 definitions of value-based incentive payment adjustment factor and value-based incentive payment percentage.

We proposed to codify in our regulations at § 412.162 the process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program. We also proposed regulation text at § 412.162 regarding the value-based incentive payment amount for a discharge; the total amount available for value-based incentive payments; the methodology for calculating the value-based incentive payment amount; the methodology for calculating the value-based incentive payment percentage; and the methodology for calculation of the value-based incentive payment adjustment factor.

Comment: Commenters supported our proposed methodology to calculate the value-based incentive payment adjustment factor for each hospital. Some commenters requested that CMS provide hospitals with a statement at the beginning and end of each fiscal year. These commenters also suggested that this statement contain the hospital's

TPS, estimated and actual payments withheld, estimated and actual gross incentive payments, and estimated and actual net incentive payments made.

Response: We appreciate the commenters' support of these proposals and appreciate their interest in receiving a summary report. We will provide each hospital with a hospital-specific report detailing its TPS and value-based incentive payment adjustment factor prior to implementation of payment adjustments, each fiscal year. We will provide this report after the end of the performance period for the applicable fiscal year. We do not intend to estimate the resulting payment differences, because these will vary, depending on the hospital's discharge volume and case mix in the applicable fiscal year. We may explore the possibility of providing a payment summary report at the end of the fiscal year, in the future.

Comment: Some commenters expressed concern that CMS or its contractors might inadvertently include payments for IME, DSH, and outliers in the base operating DRG payment amount to which value-based incentive payment adjustment factors are applied under this Program. The commenters further suggested that CMS articulate and allow comment on how we will instruct contractors to apply the payment adjustments, to ensure that these payments are not affected.

Response: We appreciate the importance of ensuring that the base operating DRG payment amounts are calculated correctly for purposes of applying the value-based incentive payment adjustment factor. We do not believe it is necessary to propose and solicit public comment on the operational instructions that we will provide to our

contractors, but we will make every effort to ensure that the payment adjustments under the Hospital VBP Program are appropriately processed.

Comment: One commenter noted that CMS did not indicate the performance period or exchange function slope used to calculate the proxy value-based incentive payment adjustment factors used in Table 16 of proposed rule.

Response: The value-based payment incentive adjustment factors that we used for purposes of generating Table 16 were based on baseline and performance periods of April 1 through December 31 of 2008 and 2010, respectively. We note that these are not actual Hospital VBP Program baseline or performance periods. We used these periods to calculate the FY 2013 Hospital VBP proxy adjustment factors because at the time we issued the proposed rule, they were the most recently available periods for which we had data to calculate hospital TPSs. We were unable to use the actual TPS scores for the FY 2013 performance period to calculate these factors for the final rule, because hospitals had not yet had the opportunity to review their own performance. We note that these proxy adjustment factors will not be used to adjust hospital payments. The exchange function slope, calculated based on the TPSs and base operating DRG payment reduction amounts for all hospitals eligible for this simulated performance period, was 1.931871792. As discussed above, we have updated the estimated total amount available for value-based incentive payments in FY 2013, using the March, 2012 update to the FY 2011 MedPAR file. The use of this MedPAR update affects the linear exchange function slope and the resulting proxy value-based payment incentive adjustment factors,

and we have updated Table 16 to reflect these new figures. The new linear exchange function slope used for these calculations in this final rule is 1.93621799.

We are also taking this opportunity to clarify that the slope of the payment exchange function will be calculated before hospitals receive their initial confidential reports at the start of the review and corrections period. This slope will then be applied to each hospital's TPS, in order to calculate the hospital's value-based incentive payment adjustment factor for discharges occurring in a fiscal year. Should a hospital identify an error that requires us to recalculate its TPS, we will not recalculate the exchange function slope. Rather, we will apply the established payment exchange function slope for the fiscal year to the newly calculated TPS score. We believe that this is the most straightforward approach to calculating value-based incentive payment adjustment factors, taking into account the review and corrections and appeals periods.

Comment: One commenter suggested that CMS increase the applicable percent reduction to the base operating DRG payment amounts to 2 percent sooner than the FY 2017 program year, if CMS believes hospitals have met or exceeded current quality measure standards.

Response: We agree that incentivizing high performance on measures is an important goal; however, the applicable percent reduction for each fiscal year is specifically defined in section 1886(o)(7)(C) of the Act. We believe that this gradual increase in the applicable percent is valuable, because it allows hospitals time to gain experience with the Hospital VBP Program before their payments are more significantly impacted.

After consideration of the public comments we received, we are finalizing our proposal to calculate the value-based incentive payment adjustment factor for each eligible hospital each fiscal year under the Hospital VBP Program using the six steps detailed above.

We received no comments on our proposed regulatory definitions of value-based incentive payment adjustment factor and value-based incentive payment percentage, and we are finalizing them, with revisions. We are codifying in our regulations at § 412.160 that the value-based incentive payment adjustment factor is defined as the number by which we will multiply the base operating DRG payment amount for each discharge from a hospital, during a fiscal year, in order to adjust the hospital's payment, as a result of its performance under the Hospital VBP Program. We are also codifying in our regulations at § 412.160 that value-based incentive payment percentage is defined as the percentage of the base operating DRG payment amount for each discharge that a hospital has earned with respect to a fiscal year, based on its total performance score for that fiscal year.

We received no public comments on our proposed regulatory language at § 412.162, regarding the process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital VBP Program; the value-based incentive payment amount for a discharge; the total amount available for value-based incentive payments; the methodology for calculating the value-based incentive payment amount; the methodology for calculating the value-based incentive payment percentage; or the methodology for calculation of the value-

based incentive payment adjustment factor. We are codifying the proposed regulatory text, with technical revisions.

We are codifying in our regulations at § 412.162 that, in general, if a hospital meets or exceeds the performance standards that apply to the Hospital VBP Program for a fiscal year, we will make value-based incentive payments to the hospital under the requirements and conditions specified in this section.

We are codifying in our regulations at § 412.162 that the value-based incentive payment amount for a discharge is the portion of the payment amount that is attributable to the Hospital VBP Program and that the total amount available for value based incentive payments to all hospitals for a fiscal year is equal to the total amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

We are codifying in our regulations at § 412.162 that the value-based incentive payment amount is calculated by multiplying the base operating DRG payment amount by the value-based incentive payment percentage.

We are codifying in our regulations at § 412.162 that the value-based incentive payment percentage is calculated as the product of: the applicable percent as specified in this section, the hospital's TPS divided by 100, and the linear exchange function slope.

We are codifying in our regulations at § 412.162 that the value-based incentive payment adjustment factor is determined by subtracting the applicable percent as specified in paragraph (d) of this section from the value-based incentive payment percentage and then adding that difference to one.

Finally, we are codifying in our regulations at § 412.160 a definition of linear exchange function. We previously finalized this definition in the Hospital Inpatient VBP Program final rule (76 FR 26531) as the means to translate a hospital's TPS into a value-based incentive payment percentage such that:

(1) each eligible hospital's value-based incentive payment percentage is based on its TPS; and

(2) the total amount of value-based incentive payments to all hospitals in a fiscal year is equal to the total amount available for value-based incentive payments in such fiscal year.

d. Timing of the Base Operating DRG Payment Amount Reduction and Value-Based Incentive Payment Adjustment for FY 2013 and Future Hospital VBP Program Years

The applicable percent reduction and the value-based incentive payment adjustment are distinct adjustments which we are required to make to base operating DRG payment amounts for eligible hospitals under the Hospital VBP Program. In this section, we outline our proposals for applying these adjustments to the base-operating DRG payment amounts.

In the Hospital Inpatient VBP Program final rule, for the FY 2013 Hospital VBP Program, we established that we would incorporate the value-based incentive payment adjustment into our claims processing system in January 2013, and that the adjustment would apply to all FY 2013 discharges, including those that occurred beginning on October 1, 2012 (76 FR 26536). Because of this January 2013 application of the value-based incentive payment adjustment, in the FY 2013 IPPS/LTCH PPS proposed

rule (77 FR 28075), we proposed that we would not apply the 1.00 percent applicable reduction to the base operating DRG payment amount for each discharge until we apply the value-based incentive payment adjustment factor. In other words, we would add the value-based incentive payment amount to the hospital's reduced base-operating DRG payment amount for each FY 2013 discharge at the same time that we apply the 1.00 percent reduction to the base operating DRG payment amount. The simultaneous application of the 1.00 percent reduction to the base-operating DRG payment amounts and the value-based incentive payment amount (if applicable, based on the hospital's TPS) would prevent hospitals from receiving a 1.00 percent reduction to their base operating DRG payment amounts before they receive their value-based incentive payment amount adjustment. Accordingly, under our proposal, beginning in January 2013, a hospital would receive a base operating DRG payment amount for each discharge occurring in FY 2013 that is the net result of the application of the 1.00 percent reduction and the application of the hospital's individual value-based incentive payment amount adjustment.

In FY 2014 and future years of the Hospital VBP Program, we proposed to apply both the applicable percent reduction and the value-based incentive payment amount adjustment to the base operating DRG payment amount for a discharge during the regular claim payment process, beginning in October of each fiscal year. These adjustments would be made simultaneously with respect to each discharge.

We invited public comment on this proposal.

Comment: Commenters supported the proposal to delay application of the reduction to the base-operating DRG payment amounts in FY 2013 until those reductions can be applied simultaneously with the value-based incentive payment adjustments. Commenters also supported the proposal to apply the applicable percent reduction and the value-based incentive payment adjustment factor to the base operating DRG payment amount simultaneously, beginning in January 2013, when the adjustments are incorporated into the claims processing system.

Response: We thank the commenters for their support of these proposals and we are adopting them as final.

After consideration of the public comments we received, we are finalizing our proposal to delay the application of the 1.00 percent applicable reduction to the base operating DRG payment amount for each discharge occurring in FY 2013 until we apply the value-based incentive payment adjustment factor. We are also finalizing our proposal that beginning with the incorporation of value-based incentive payment adjustments into the claims processing system in January 2013, a hospital would receive a base operating DRG payment amount for each discharge occurring in FY 2013 that is the net result of the application of the 1.00 percent reduction and the application of the hospital's individual value-based incentive payment amount adjustment. We are also finalizing our proposal that, beginning with October 1, 2013 discharges, we will simultaneously apply both the applicable percent reduction and the value-based incentive payment adjustment to the base operating DRG payment amount for each discharge during the regular claim payment process.

e. Process for Reducing the Base Operating DRG Payment Amount and Applying the Value-Based Incentive Payment Adjustment for FY 2013

In developing our proposal for FY 2013, we considered two different methodologies for applying the 1.00 percent reduction to the base operating DRG payment amount for each discharge, and for applying the value-based incentive payment adjustment to the reduced base operating DRG payment amount: (1) reprocessing the claims submitted prior to January 2013, which is when we expect to incorporate the value-based incentive payment adjustments into our claims processing system; and (2) modifying the exchange function slope in such a way as to redistribute the value-based incentive payment adjustments for discharges occurring prior to incorporating the adjustments into our claims processing system. Neither approach would require hospitals to resubmit claims.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28075), we proposed to reprocess the claims submitted by hospitals for discharges occurring between October 1, 2012 and such time as the value-based incentive payment adjustments are incorporated into the claims processing system. We believe that this approach is the most straightforward way to address the January implementation of FY 2013 value-based incentive payment adjustments. For the second methodology we considered, we would need to modify the exchange function slope, because adjustments would not have been made beginning on October 1, 2012, the start of FY 2013. As described in section VIII.C.5.c. of this preamble, calculation of the exchange function slope is based on the hospital's TPS and the estimated amount available for value-based incentive payments.

The total amount available to make value based incentive payments to eligible hospitals is equal to the total of their base-operating DRG payment reduction amounts, as estimated by the Secretary, according to section 1886(o)(7)(A) of the Act.

Under this approach, we would account for this delay in implementation of applicable percent reductions and value-based incentive payment adjustment factors by modifying the computed exchange function slope so that we could use it to calculate a value-based incentive payment adjustment factor for each hospital that would distribute the total amount available for value based incentive payments between January and September 30, 2013. We would modify the exchange function to accomplish this by multiplying its slope by the following fraction: the total number of days in the fiscal year / (divided by) the number of days between the date we incorporate adjustments and the end of the fiscal year. For example, if the date the value-based adjustment is incorporated into the system is January 15, then the number of days between January 15, 2013 and September 30, 2013 is 258. Therefore, we would multiply the exchange function slope by 365/258, in order to redistribute the value-based incentive payment adjustments that occur on or after January 15, 2013 in such a manner that they also account for discharges occurring between October 1, 2012 and January 15, 2013. For purpose of calculating the exchange function slope modification, we would assume that hospitals' base operating DRG payments are constant throughout the fiscal year (that is, DRG payments are not concentrated in the beginning or the end of the year, for example).

We believe that this alternative approach could cause confusion regarding payment amounts for discharges that occur between the beginning of the fiscal year and the implementation of the value-based incentive payment adjustments but are not billed until after the implementation of the value-based incentive payment adjustments. Those claims would be paid as though the applicable percent reduction and the value-based incentive payment adjustments were not in effect, because they would be based on date of discharge.

We invited public comment on our proposed approach to reprocess hospital inpatient claims that are billed between October 1, 2012 and such time as we are able to incorporate the value-based incentive payment adjustments into our claims processing system in January 2013. We recognize that hospitals would be responsible for maintaining their own internal accounting systems in order to accommodate the reprocessing of these claims in January 2013; therefore, we also invited public comment on the alternative approach described above of modifying the exchange function slope to redistribute the value-based incentive payment adjustments, or any other approaches which might minimize the administrative burden imposed upon hospitals.

Comment: The majority of commenters supported the proposal to reprocess claims, in order to account for the January 2013 implementation of FY 2013 value-based incentive payment adjustment factors, because they believed that the approach is the most straightforward and least burdensome to hospitals. Many of these commenters noted that reprocessing does pose some administrative burden to hospitals, and they requested that CMS perform a timely reprocess or even a dedicated one.

Response: We thank the commenters for their support of the proposal to reprocess claims in January 2013 and acknowledge the concern that this places an administrative burden on hospitals. We appreciate the importance of timely reprocessing hospital claims to reflect the adjustment. While we are unable to guarantee a dedicated reprocess for payment adjustments under the Hospital VBP Program, we will make every effort to reprocess claims as quickly as practicable.

Comment: Some commenters stated that they did not support our proposal to reprocess claims. A few of these commenters expressed a preference for settlement at cost report. One commenter stated that a lump sum adjustment would be preferable, that adjusting the value-based incentive payment adjustments across the remainder of the year would be next in order of preference, and that claims reprocessing would be the least preferred option, indicating that it places a burden on hospitals to track, validate, and reconcile claims, long after the services were furnished. This commenter expressed concern with the amount of time CMS might take to reprocess these claims, asking that it be completed no later than March 31, 2013, should this option be selected. Another commenter expressed preference for an adjustment to the linear exchange function slope, in order to distribute the payment adjustments across the remainder of the fiscal year, stating that this approach would alleviate financial, operational, and administrative challenges associated with reprocessing.

Response: We do not believe a lump sum adjustment or cost report settlement will be feasible, because neither of these adjustments would be reflected in Medicare claims history. Either a lump sum adjustment or the cost report settlement would be

made outside of the claims processing system. This would mean that the claim would appear in Medicare claims history to have been paid without any value-based incentive payment adjustment factor when, in reality, an adjustment would have been made outside of the claims system. Given that we use Medicare claims data for a number of programs and initiatives across the agency, we believe that reprocessing claims is the most straightforward approach and that it allows us to maintain an accurate claims history. Further, we do not wish to delay high-performing hospitals' receipt of their value-based incentive payment amounts or delay low-performing hospitals incurring payment reductions until the cost report is finalized. We believe that delaying the settlement of these value-based incentive payments until cost report settlement would add a degree of uncertainty to hospital payments, which might not be reconciled for several years.

We appreciate the comment that an adjustment to the linear exchange function might alleviate some administrative burden; however, we believe that such an adjustment might create confusion regarding the payment amounts made for discharges occurring prior to the January 2013 implementation of the value-based incentive payment adjustments but processed after the implementation. Further, as noted above, we are concerned that this result might create an inaccurate claims history that would impact other CMS programs for which this claims history is used. If we were to adjust claims paid after the January incorporation of value-based incentive payment adjustment factors into the claims processing system, then the claims history would show a portion of the year during which claims were not subject to any value-based incentive payment adjustments. The claims paid during the remainder of the year would then reflect an

adjustment that distributes incentives across less than a full fiscal year. The concentration of a fiscal year's worth of incentives across less than the full fiscal year might skew calculations done under other CMS programs that rely on Medicare claims data.

Comment: A few commenters expressed general concern that CMS would not have the value-based incentive payment adjustment factors for FY 2013 in place, in the claims processing system, until January 2013.

Response: As noted above, we finalized the January 2013 application of the value-based incentive payment adjustment factors, for discharges occurring in FY 2013, in the Hospital Inpatient VBP Program final rule (76 FR 26536). We acknowledge that this results in additional complexities; however, we previously finalized this policy in order to meet the statutory posting and notification deadlines of the Hospital VBP Program.

After consideration of the public comments we received, we are finalizing our proposal to reprocess the claims submitted by hospitals for discharges occurring between October 1, 2012 and the January 2013 incorporation of the value-based incentive payment adjustments into the claims processing system.

6. Review and Corrections Processes

a. Background

Section 1886(o)(10)(A)(i) of the Act requires that the Secretary make information available to the public regarding individual hospital performance in the Hospital VBP Program, including: (1) the performance of the hospital on each measure that applies to

the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the hospital's TPS. To comply with this requirement, we stated in the Hospital Inpatient VBP Program final rule that we intended to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the performance score with respect to each condition or procedure, for example, AMI, HF, PN, and SCIP), each hospital's domain-specific score, and each hospital's TPS on the Hospital Compare Web site (76 FR 26534 through 26536).

Section 1886(o)(10)(A)(ii) of the Act requires the Secretary to ensure that each hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to each hospital under section 1886(o)(10)(A)(i) of the Act prior to such information being made public. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74545), we finalized procedures that will enable hospitals to review and correct both the underlying data and measure rates for the clinical process of care measures and HCAHPS dimensions under the Hospital VBP Program (76 FR 74545 through 74547).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28076), we made additional proposals that will enable hospitals to review and correct their claims-based measure rates, as well as their condition-specific scores, domain-specific scores, and TPSs.

b. Review and Corrections Process for Claims-Based Measure Rates

We use claims/administrative data to calculate measure rates for measures that we have adopted for a number of pay for reporting and pay for performance programs, such

as the Hospital VBP Program. For claims-based measures used in the Hospital IQR Program, we currently provide hospitals with confidential reports containing the measure rate calculations and accompanying confidential detailed discharge-level information prior to making the rates available to the public. With respect to the claims-based measures we adopt for the Hospital VBP Program, we proposed to deliver the same type of confidential reports and accompanying confidential detailed discharge-level information for purposes of providing hospitals an opportunity to review and submit corrections for their claims-based measure rates under section 1886(o)(10)(A)(ii) of the Act.

The confidential reports would contain the claims-based measure rate calculations and would be accompanied by additional confidential discharge-level information based on the most recent administrative data available at the time we run the data for purposes of calculating the rates. As we discuss below, we proposed to create extracts of the data to be used for measure rate calculation purposes approximately 90 days after the last discharge date in the performance period for the measure. Our intent in providing the confidential reports and accompanying discharge-level data to hospitals is twofold: (1) to provide hospitals with an opportunity to review and submit corrections for the measure rates that we will make available to the public; and (2) to facilitate hospitals' quality improvement efforts with respect to the measures. The discharge-level information would contain data derived from claims and administrative data that were used in the calculation of the measure rates. Depending on the measure, this discharge level information might include data elements such as dates of admission, dates of discharge,

patient risk factors, primary and secondary diagnoses, procedures, dates of death, dates of service after discharge by the same or other providers/suppliers, and provider/supplier numbers. The confidential reports and accompanying discharge level data would be delivered to each hospital via its secure QualityNet account.

We proposed to provide hospitals a period of 30-days to review and submit corrections for the claims-based measure rates contained in their confidential reports. This 30-day period would begin the day hospitals' confidential reports and accompanying discharge-level data are posted to QualityNet. These measure rates will be used for performance scoring, value-based incentive payment amount calculations, and public reporting for the Hospital VBP Program. Based on our previous experience with public reporting of measures under the Hospital IQR Program, including the 30-day risk standardized mortality rates and the AHRQ Patient Safety Indicators, we believe this 30-day period will allow enough time for hospitals to review their data and notify us of suspected errors in the measure rate calculations, and for us to incorporate appropriate corrections to the calculations. During the review and correction period, hospitals should notify us of suspected errors using the technical assistance contact information provided in their confidential reports.

The review and correction process we proposed to adopt for the claims-based measure rates would not allow hospitals to submit corrections related to the underlying claims data we used to calculate the measure rates, or allow hospitals to add new claims to the performance period data set that we ran to calculate the rates. This is because it is necessary to take a static "snapshot" of the claims in order to perform the calculations.

For purposes of this Program, we would calculate the claims-based measures using claims and corrections to claims submitted by hospitals that were incorporated into our claims database during the approximately 90 day period following the last date of discharge to be included in the measure calculation.

We recognize that under our current timely claims filing policy, hospitals have up to one year from the date of discharge to submit a claim. However, in using claims and other administrative data to calculate measure rates for the Hospital VBP Program, we proposed to create data extracts using claims information as it exists in our Common Working File (CWF) approximately 90 days after the last discharge date in the performance period for the measures. For example, if the last discharge date in the performance period for a measure is June 30, 2011, we would create the data extraction on or about September 30, 2011 and use that data to calculate the measure rates for that performance period. Hospitals would then receive the measure rates in their confidential reports and accompanying data, and they would have an opportunity to review and submit corrections to those rates. As we stated above, hospitals would not be able to submit corrections to the underlying data that we extracted on or about September 30, 2011, and would also not be able to add claims to the data set. We would consider the underlying claims and administrative data to be complete for purposes of the Hospital VBP Program claims-based measure rate calculations at the conclusion of the approximately 90 day period following the last date of discharge used in the performance period.

We considered a number of factors in determining that an approximately 90 day "run-out" period is appropriate for purposes of calculating the claims-based measure rates. First, we seek to provide timely quality data to hospitals for the purpose of quality improvement, and to the public for the purpose of transparency. Next, we seek to make payment adjustments to hospitals as close in time to the applicable performance period as possible. Finally, we seek to have as complete a data set as possible, recognizing that hospitals have up to one year from the date of discharge to submit a claim under our timely claims filing policy.

After we run the data and create the data extract for purposes of calculating the measure rate for a claims-based measure, it takes several months to incorporate other data needed to complete the rate calculation (particularly in the case of a risk-adjusted and/or episode based measure). We then need to generate and check the rate calculations, as well as program, populate, and deliver the confidential reports and accompanying data to hospitals. We are also aware that hospitals would like to receive performance information under the Hospital VBP Program as close in time to the performance period as possible. If we were to wait to run the data for purposes of calculating the claims-based measure rates until at least 12 months after the last discharge date in the performance period, we would not, for operational reasons, be able to provide the measure rates to hospitals 18 to 24 months after the performance period ended. We believe that this would create an unacceptably long delay both for hospitals that are interested in receiving timely measure rate calculations for their own quality improvement efforts, and for us to (1) calculate TPSs for a program year and (2) publicly

report hospital performance on the Hospital Compare Web site. Therefore, we proposed to extract the data needed to calculate a claims-based measure rate approximately 90 days after the last discharge date for the measure's performance period so that we can best balance our need to provide timely program information to hospitals against the need to calculate the claims-based measures using as complete a data set as possible.

During the 30-day review and correction period, hospitals should notify us of suspected errors in our calculation of the measure rates using the technical support contacts provided in the hospital's confidential report. We would investigate the validity of each submitted correction and notify hospitals of the results. Should we confirm that we made an error in calculating one or more claims-based measure rates included in a hospital's confidential report, we would correct the calculation(s) and issue a new confidential report to the hospital. We proposed that once the 30-day review and corrections period has concluded, we would not accept any additional corrections submitted by a hospital.

We invited public comment on the proposed review and correction process for claims-based measure rates to be used in the Hospital VBP Program.

Comment: A number of commenters supported our proposals on review and correction of claims-based performance measure data.

Response: We thank commenters for their support.

Comment: Some commenters urged us to allow up to 60 days for hospitals to review and correct their claims-based measure data under the Hospital VBP Program,

noting that hospitals will receive discharge-level information on claims-based measures for the first time.

Response: We believe that the proposed 30 day review and correction period is adequate for reviewing Hospital VBP measure rates and performance scores. This 30 day time period is the same amount of time used in Hospital Compare measure rate previews, and this time period has proved to be adequate for hospitals to review their measure rates. We are also concerned about the delay that would result in making value-based incentive payments if we allowed hospitals 60 days to review and correct their claims-based measure data. We believe that we have a responsibility to provide hospitals with timely reimbursements, and allowing 60 days for review and corrections would unacceptably further delay our ability to make incentive payments under the Program. Our experience with delivering similar reports to hospitals on similar measures indicates that 30-days is sufficient time for hospitals to download their reports and verify the accuracy of the measure calculations and troubleshoot any suspected discrepancies with the help of our contractor. In light of the fact that we will be providing even more detailed information than we have previously provided to hospitals under the Hospital IQR Program, we believe that 30-days is sufficient time for hospitals to review and submit corrections to the claims-based measure rates that will be used in the Hospital VBP Program.

After consideration of the public comments we received, we are finalizing the claims-based measure rate review and correction process as proposed for FY 2014 and all subsequent payment determinations.

c. Review and Correction Process for Condition-Specific Scores, Domain-Specific Scores and Total Performance Scores

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28077), we proposed to adopt a review and corrections process that will enable hospitals to review and submit corrections with respect to their performance on each condition (the condition-specific score), their performance on each domain (the domain-specific score) and their TPSs. Under this proposed process, we would provide each hospital with a TPS Report (this would be a different report than the hospital confidential report and accompanying data described above, and the reports described in previous rules that will enable hospitals to review and correct their chart-abstracted and HCAHPS measure data). A hospital would have 30 days from the date we post the report on its QualityNet account to review the TPS Report and submit any necessary corrections to us via QualityNet. This proposed requirement will enable us to evaluate corrections requests and provide decisions on those requests in a timely manner. As discussed further below, we also proposed that the submission of a correction through this process be a prerequisite to a hospital being able to submit an appeal of the calculation of its performance assessment with respect to the performance standards and/or its TPS under section 1886(o)(11)(A) of the Act.

Hospitals would not be able to use this proposed review and correction process to ask us to reconsider a hospital's eligibility under section 1886(o)(1)(C) of the Act to participate in the Hospital VBP Program for a fiscal year. However, we sought public comment on whether our determination regarding a hospital's eligibility should be subject to correction.

We believe that this proposed review and corrections process will ensure that hospitals are able to fully and fairly review their condition-specific scores, domain-specific scores, and TPS. We invited public comment on this proposal. We note that we anticipate posting FY 2013 hospital performance information on Hospital Compare in April 2013. We proposed to codify the process for posting hospital-specific information under the Hospital VBP Program in our regulations at 42 CFR 412.163.

We view the review and corrections process as separate and distinct from the appeals process. Each process is aimed at allowing hospitals to seek certain reconsiderations from CMS. The review and corrections process is aimed at correcting data that will be made public on the Hospital Compare Web site, while the appeals process allows hospitals to seek reconsideration for errors that may have been introduced during the TPS calculation that may affect hospitals' payments.

Comment: Many commenters urged us to allow up to 60 days for hospitals to review and correct their TPSs under the Hospital VBP Program.

Response: As discussed above, we are concerned about the delay in making value-based incentive payments to hospitals that would result if we allowed hospitals 60 days to review and correct their TPSs. The proposed 30 day review and correction period is the same length of time that we have long allowed hospitals to preview the data to be made public under the Hospital IQR Program, and we believe that this time period has proven to be adequate for hospitals to review their measure rates. We believe that we have a responsibility to provide hospitals with timely reimbursements, and allowing

60 days for review and corrections of TPSs would, in our view, unacceptably further delay incentive payments under the Hospital VBP Program.

After consideration of the public comments we received, we are finalizing our proposals on review and corrections as proposed. We are also codifying these policies at 42 CFR 412.163.

7. Appeal Process under the Hospital VBP Program

a. Background

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A) of the Act) and the hospital performance score (section 1886(o)(5) of the Act).

Under section 1886(o)(11)(B) of the Act, there is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount; (2) the determination of the amount of funding available for the value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act; (3) the establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act; (4) the measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act; (5) the methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital

performance scores and the calculation of such scores; or (6) the validation methodology specified in section 1886(b)(3)(B)(viii)(XI) of the Act.

b. Appeal Process

We solicited public comments on the general structure and procedures we should consider when developing an appeals process for the Hospital VBP Program in the Hospital Inpatient VBP Program proposed rule (76 FR 2484). We took these comments into consideration when we developed the proposed appeals process that appears below. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28077), we proposed to implement an administrative appeals process that provides hospitals with the opportunity to appeal the calculation of their performance assessment with respect to the performance standards, as well as their TPS.

We proposed to codify this proposed appeals process and the limitations on administrative and judicial review in our regulations at 42 CFR 412.167.[132]

Under our proposed appeals process, if a hospital is seeking to appeal a calculation of the TPS, measure/dimension score, condition-specific score, domain specific score, or measure rate/data for which the hospital could have submitted a correction during the review and correction process we have both previously finalized (with respect to chart-abstracted and HCAHPS data) and proposed to adopt in this proposed rule, we would require that the hospital first submit a correction to that calculation, and receive an adverse determination from us, as part of that process before the hospital could challenge it under the appeals process. We proposed to adopt this

[132] We inadvertently also proposed to include regulation text on the limitations on review at 42 CFR 412.162(e).

requirement because we believe that we will be able to resolve many hospital claims through the review and corrections process, and thus eliminate the need for an appeal. To the extent that a hospital seeks to appeal a calculation that was the subject of a correction request, we proposed that the deadline for the hospital to submit an appeal under section 1886(o)(11)(A) of the Act would be 30 days from the date the we informed the hospital through QualityNet of our decision on the correction request. For any other appeals requests, we proposed that hospitals have up to 30 days after the conclusion of the review and corrections period specified above to submit an appeal. We sought public comment on the appropriateness of this proposed appeals timeline and whether we should consider any other possible deadlines.

We proposed that all appeals be submitted through QualityNet and that they contain the following information:

- Hospital's CMS Certification Number (CCN)
- Hospital Name
- Hospital's basis for requesting an appeal. This must identify the hospital's specific reason(s) for appealing the hospital's TPS or performance assessment with respect to the performance standards.
- CEO contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box).
- QualityNet System Administrator contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box).

Consistent with sections 1886(o)(11)(A) and (B) of the Act, we proposed that hospitals would be able to submit an appeal on the following issues:

- CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;
- Whether the achievement/improvement points were calculated correctly;
- Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;
- Whether CMS correctly calculated the domain scores, including the normalization calculation;
- Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;
- Whether CMS calculated the HCAHPS consistency points correctly;
- Whether the correct domain scores were used to calculate the TPS;
- Whether each domain was weighted properly;
- Whether the weighted domain scores were properly summed to arrive at the TPS; and
- Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

We invited public comment on this proposed administrative appeal process.

Comment: Commenters generally expressed support for CMS' proposed appeals process for the Hospital VBP Program. Some commenters requested additional detail on CMS' timeframe for resolving appeals.

Response: We thank the commenters for their support. We regret that we are not able to provide further detail on a timeframe for resolving appeals requests at this time. The Hospital VBP Program is new, and we therefore have no basis on which to estimate the number or magnitude of appeals requests that we will need to review. We intend to resolve all appeals requests under the Hospital VBP Program as quickly as possible given available resources.

Comment: Some commenters opposed CMS' proposed appeals process, arguing that, despite their best efforts, hospitals miss errors during their own internal accuracy reviews and do not believe that the proposed timeframe provides hospitals the ability to fully review their scoring reports. Commenters argued that hospitals should have every opportunity to correct mistakes once they are identified, even if hospitals identify those mistakes after the review and corrections process.

Response: We remind commenters that they have ample opportunity to review and correct patient level HCAHPS and process of care measure data submission prior to quarterly data submission deadline as part of our review and correction process. We also believe that the proposed limitation on the appeals process encourages hospitals to review their score reports as thoroughly as possible in order to ensure that we make accurate, timely value-based incentive payments through this program.

After consideration of the public comments we received, we are finalizing the appeals process for the Hospital VBP Program as proposed. We are also codifying this process and the limitations on review in our regulations at 42 CFR 412.167.

8. Measures for the FY 2015 Hospital VBP Program

a. Relationship Between the National Strategy and the Hospital VBP Program

Section 399HH of the Public Health Service Act, as added and amended by sections 3011 and 10302 of the Affordable Care Act, requires the Secretary to establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health. The Secretary published the "National Strategy for Quality Improvement in Health Care" on March 21, 2011. The strategy is available at: http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf.

We believe we can incorporate the goals of the National Quality Strategy into our policies under the Hospital VBP Program. We view the strategy as an important driver in revamping how Medicare services are paid for, moving increasingly towards rewarding hospitals that deliver better outcomes in health and health care at lower cost to the beneficiaries and communities they serve. Over time, the strategy is also helping us align the goals for quality measurement and improvement in hospitals with those of other providers and suppliers in the health system, promoting shared accountability across care settings for beneficiary care and quality improvement.

We believe that, given the availability of endorsed measures and the need to balance the number and scope of the measures against the burden on participating hospitals, as well as ensuring that the Hospital VBP Program's measure set reflects our quality improvement priorities, the Hospital VBP Program measures should as fully as possible reflect the six measurement domains that arise from the National Quality Strategy's six priorities: Clinical Care; Person- and Caregiver-Centered Experience and

Outcomes; Safety; Efficiency and Cost Reduction; Care Coordination; and Community/Population Health. We believe that measure sets should generally rely on a mix of standards, outcome, process of care measures, and patient-reported measures including measures of care transitions, patient experience, and changes in patient functional status, with an emphasis on measurement as close to the patient-centered outcome of interest as possible. We took all of these factors into consideration when developing our measure proposals for the FY 2015 Hospital VBP Program.

In addition, we believe that measure sets should evolve to include a focused set of measures that reflect the most important areas of service and quality improvement for hospitals as well as a core set of measure concepts that align quality improvement objectives across all provider types and settings.

b. FY 2015 Measures

In the Hospital Inpatient VBP Program final rule (76 FR 26496 through 26497), we adopted a policy under which we would examine whether any clinical process of care measures that were otherwise eligible for inclusion in a Hospital VBP Program measure set were topped-out, and thus, should be excluded because measuring hospital performance on a topped-out measure would have no meaningful effect on a hospital's TPS. Our methodology for evaluating whether a measure is topped-out focuses on two criteria: (1) National measure data show statistically indistinguishable performance levels at the 75^{th} and 90^{th} percentiles, and (2) National measure data show a truncated coefficient of variation (TCV) less than 0.10.

We analyzed the clinical process of care measures that we believe are eligible for the FY 2015 Hospital VBP Program based on their prior inclusion in the Hospital IQR Program and posting on Hospital Compare for "topped out" status, and concluded that one of the candidate measures for the FY 2015 Program – SCIP-Inf-10: Surgery Patients with Perioperative Temperature Management – is now "topped-out." Therefore, we did not propose to include this measure in the FY 2015 Hospital VBP Program.

We welcomed public comments on whether any other existing Hospital VBP measures may be "topped out" and should therefore be considered for removal from the proposed measure set. We also noted that we do not believe it is appropriate at this time to test or re-test proposed outcome measures for "topped-out" status because such measures allow CMS to reward hospitals for high-quality outcomes, which is a central aim of quality improvement efforts in the health care system. We further believe that these measures are critical to providing patients with better care and believe it is important to hold hospitals accountable for the clinical outcomes captured by these measures. We invited public comments on this policy, including whether we should examine the proposed outcome measure set for "topped-out" status at this time.

Comment: A number of commenters supported our continued exclusion of "topped-out" measures from the Hospital VBP Program.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to remove SCIP-Inf-10: Surgery Patients with Perioperative Temperature Management in the FY 2015 Hospital VBP Program because it is topped-out.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28079), for the FY 2015 Hospital VBP Program, we proposed to retain 12 of the 13 clinical process of care measures that we have adopted for the FY 2014 Hospital VBP Program. We proposed to remove SCIP-VTE-1 from the FY 2015 measure set because this measure is very similar to another measure we have adopted for the Program (SCIP-VTE-2) but, in our view, is not as closely linked to better surgical outcomes because it assesses the ordering of VTE prophylaxis, as opposed to the patient's actual receipt of such prophylaxis within 24 hours of surgery. We also note that, during a recent maintenance review of SCIP-VTE-1, the NQF concluded that it would no longer endorse this measure, and we proposed in this proposed rule to remove the measure from the Hospital IQR Program beginning with the FY 2015 payment determination. Therefore, we also proposed to remove SCIP-VTE-1 from the Hospital VBP Program measure set beginning with the FY 2015 Hospital VBP Program. We note that in the future, we anticipate proposing to adopt surgical outcome measures, including one or more measures that assess complications arising from VTE prophylaxis medications, first into the Hospital IQR Program and then into the Hospital VBP Program.

We proposed to adopt one additional clinical process of care measure – AMI-10: Statin Prescribed at Discharge. This measure has been specified under the Hospital IQR Program for the FY 2013 payment determination (75 FR 50200). AMI-10 measure data were posted on the Hospital Compare Web site on January 26, 2012, so as discussed further below, we proposed a 9-month performance period for this measure for FY 2015. We intend to align the performance period for AMI-10 with the other clinical process

measures' performance period in future years. The measure is NQF-endorsed (#0639) and we did not find it to be "topped-out" when we examined the list of candidate measures as described above. We also note that current American College of Cardiology (ACC)/American Heart Association (AHA) guidelines place a strong emphasis on the initiation or maintenance of statin drugs for patients hospitalized with AMI, particularly those with LDL-cholesterol levels at or above 100 mg/dL. Therefore, we believe that this measure is appropriate for use in the Hospital VBP Program.

However, after examining the most recently-available data, we have concluded that the AMI-10 measure meets our definition of "topped-out." Therefore, we are not finalizing this measure for the FY 2015 Hospital VBP Program.

For the Patient Experience of Care domain, we proposed to retain the eight dimensions of the HCAHPS survey that we adopted for the FY 2013 and FY 2014 Hospital VBP Program. We believe that the 8 HCAHPS dimensions finalized for the FY 2013 and FY 2014 Hospital VBP Programs are well-understood by hospitals and the public and capture important aspects of the patient's experience in the acute care environment.

For the Outcome domain, we proposed to retain the three 30-day mortality measures that we finalized for the FY 2014 Hospital VBP Program. As described above, we continue to believe that these measures are important to quality improvement efforts because outcome measures allow us to reward hospitals for high-quality outcomes, which is a central aim of quality improvement efforts in the health care system. We further believe that these measures are critical to providing patients with better care and believe

it is important to hold hospitals accountable for the clinical outcomes captured by these measures. We also proposed to adopt two additional outcome measures -- PSI-90, the AHRQ PSI composite measure, and the CLABSI: Central Line-Associated Blood Stream Infection measure--for the Outcome domain.

We initially adopted the CLABSI measure for the FY 2013 Hospital IQR Program in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50200 through 50202) and refer readers to that final rule for further discussion of the measure. CLABSI is a HAI measure that assesses the rate of laboratory-confirmed cases of bloodstream infection or clinical sepsis among ICU patients. This measure was first NQF-endorsed in 2004, and adopted by the HQA in 2007. The measure can be stratified by the type of ICU and is aggregated to the hospital level by the NHSN. We first posted hospital performance on this measure on Hospital Compare on January 26, 2012.

We believe that adoption of the CLABSI measure for the Hospital VBP Program is consistent with the intention captured in the Hospital VBP Program's statutory requirement that we consider measures of HAIs for the FY 2013 Hospital VBP Program's measure set. This measure was also included in the HHS Action Plan to Prevent HAIs, which is referenced in section 1886(o)(2)(B)(i)(I)(ee) of the Act.

We initially adopted the AHRQ PSI composite measure (PSI-90) for the FY 2010 Hospital IQR Program in the FY 2009 IPPS/LTCH PPS final rule (73 FR 48602 through 48603) and refer readers to that final rule for further discussion of that measure. PSI-90 is a composite measure of patient safety indicators developed and maintained by AHRQ and measure data were posted on Hospital Compare on October 14, 2011. We believe

that its use in the Hospital VBP Program is appropriate in order to encourage hospitals to take all possible steps to avoid threats to patient safety that may occur in the acute care environment.

For the Efficiency domain, we proposed to adopt one new measure: the Medicare Spending per Beneficiary measure. The proposed measure is inclusive of all Part A and Part B payments from 3 days prior to a subsection (d) hospital admission through 30 days post discharge with certain exclusions. It is risk adjusted for age and severity of illness, and the included payments are standardized to remove differences attributable to geographic payment adjustments and other payment factors. We submitted the measure to the NQF for endorsement on July 2, 2012.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627) for a detailed description of the measure. Additional information on the measure, including a detailed specification document can be found at: http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996. This measure has been specified under the Hospital IQR Program, and performance data was posted on the Hospital Compare Web site on April 21, 2012. As discussed further below, we proposed that the performance period for this measure for the FY 2015 Hospital VBP Program would begin on May 1, 2013, which will be more than one year after the performance data was publicly posted. Further, section 1886(o)(2)(B)(ii) of the Act requires us to ensure that measures selected for the Hospital VBP Program include measures of efficiency, including measures of Medicare

spending per beneficiary, for FY 2014 or a subsequent fiscal year. We believe that this proposed measure fulfills that requirement.

The proposed FY 2015 Hospital VBP Program measures appear below:

Proposed Quality Measures for FY 2015 Hospital VBP Program	
Clinical Process of Care Measures	
Measure ID	Description
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival
AMI-10	Statin Prescribed at Discharge
HF-1	Discharge Instructions
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2
SCIP-Card-2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery
Patient Experience Measures	
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems Survey
Outcome Measures	
AHRQ PSI composite	Complication/patient safety for selected indicators (composite)
CLABSI	Central Line-Associated Blood Stream Infection
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate
MORT-30-HF	Heart Failure (HF) 30-day mortality rate
MORT-30-PN	Pneumonia (PN) 30-day mortality rate
Efficiency Measures	
MSPB-1	Medicare Spending per Beneficiary

*Proposed dimensions of the HCAHPS survey for use in the FY 2015 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment,

Discharge Information and Overall Rating of Hospital. These are the same dimensions of the HCAHPS survey that have been finalized for prior Hospital VBP Program years.

We invited public comment on the proposed measure set for the FY 2015 Hospital VBP Program.

Comment: Some commenters asked that CMS seek the MAP's evaluation of stroke measures for possible inclusion in future Hospital VBP Program years, arguing that such measures are strongly aligned with the Hospital VBP Program's goals of rewarding better care value and patient outcomes. Other commenters suggested that CMS consider adopting pain assessment measures for the Hospital VBP Program.

Response: We thank commenters for the suggestions. We will consider adopting additional measures for the Hospital VBP Program as they become available under the statutory requirements, as they align with the National Quality Strategy, and as they fit within our other quality improvement priorities.

Comment: Many commenters applauded the clinical process of care measure proposals for the FY 2015 Hospital VBP Program. Other commenters suggested that CMS should move away from chart-abstracted measures for future program years in favor of more robust measures of quality that impose less reporting burden on hospitals.

Response: We thank the commenters that supported the clinical process of care measure proposals. With regard to the suggestion that we move away from using chart-abstracted measures in the future, we are aware of the burden that chart abstraction imposes on hospitals and intend to move the Hospital VBP measure set towards measures of outcomes and efficiency, rather than clinical processes, which we believe represent the

next steps in quality measurement and will provide better incentives to hospitals to manage care quality and contain costs.

Comment: Commenters generally supported the proposal to remove SCIP-VTE-1 from the Hospital VBP Program, citing agreement with CMS' rationale that the SCIP-VTE-2 measure is more closely linked to outcomes than SCIP-VTE-1.

Response: We thank commenters for their support.

Comment: Some commenters objected to further use of the PN-3b measure (blood cultures performed in the Emergency Department prior to initial antibiotic received in the hospital) in the Hospital VBP Program, arguing that the measure is not directly linked to improved patient outcomes for pneumonia patients. Commenters also noted that NQF is considering withdrawing its endorsement of this measure.

Response: To the extent that the NQF issues updated guidance with respect to the PN-3b measure, we will take that guidance into consideration as we determine whether the measure remains appropriate for the Hospital VBP Program. In the meantime, we continue to believe that the PN-3b measure should remain in the Hospital VBP Program measure set because it captures important clinical quality information. Given the threat of antibiotic resistance, we believe that blood cultures prior to antibiotic administration remains an important point for quality improvement in the hospital setting.

Comment: Some commenters argued that the SCIP-Card-2 measure has undergone major changes for discharges beginning January 1, 2012. Commenters argued that the changes to the measure's specifications are significant and that the measure should not be used for value-based purchasing. Commenters also called on CMS to

adopt a transparent process to indicate when a VBP measure has changed and to ensure that changes do not arbitrarily affect hospitals' scores.

Response: We disagree with commenters' assertion that the changes made to the SCIP-Card-2 measure's specifications are significant enough to warrant the measure's exclusion from the Program. The specifications change extended the perioperative window in order to measure hospitals' continued administration of beta blockers for surgery patients on those drugs prior to arrival. While we understand that this change occurred during the FY 2013 Program's performance period, we do not believe that change to be so significant as to fundamentally alter the measure. We further note that NQF did not consider the change substantive during its maintenance review. We view this change as a necessary improvement to the measure's specifications to ensure that the measure aligns with best clinical practices and the highest quality standards.

We intend to closely monitor changes to the Hospital VBP Program, including the effects of updates to measures, and should we find that such changes warrant revisions to our scoring methodology, we will address the issue in future rulemaking.

Comment: Some commenters opposed our proposal to adopt HF-1 for the FY 2015 Program, noting that MAP recommended its removal. Other commenters argued that we should not adopt SCIP-Inf-2, as the Hospital IQR Program is adopting a surgical site infection outcome measure.

Response: We view HF-1 as an important measure of care coordination and therefore do not believe it appropriate to remove the measure from the Hospital VBP measure set at this time. We note that MAP recommended removing the HF-1 measure

because the measure has not been recommended for continued NQF endorsement. If the NQF issues further guidance with respect to HF-1, we will take that guidance into consideration as we evaluate whether it is appropriate to retain HF-1 in the measure set.

While we are aware that the Hospital IQR Program is adopting a Surgical Site Infection (SSI) measure collected through the National Health Safety Network (NHSN), we may not consider that measure for the Hospital VBP Program until such time as it meets the requirements specified in section 1886(o)(2) of the Act. We therefore believe it is appropriate to continue to include SCIP-Inf-2 in the Hospital VBP Program measure set at this time.

Comment: Some commenters requested that we clarify that the Regulatory Impact Analysis included in the proposed rule correctly omitted the SCIP-Inf-10 measure, which we stated is "topped-out."

Response: We thank commenters for raising this matter. While the proposed rule referred to the SCIP-Inf-10 measure in its description of the Regulatory Impact Analysis, the measure was properly omitted in the calculations that appear in the Regulatory Impact Analysis.

Comment: Some commenters expressed concern about further use of the HCAHPS survey in the Hospital VBP Program, arguing that the survey is biased against urban and safety-net hospitals. Commenters suggested that the "degree of quietness" item is unfair to urban hospitals, as is the survey's policy of not adjusting results for very low-income patients. Other commenters argued that HCAHPS scores vary systematically

based on factors unrelated to quality of care and urged CMS to account for those variables in HCAHPS scoring.

Response: We have examined the association between safety net status and the Patient Experience of Care (HCAHPS) domain score in the Hospital VBP Program. We analyzed Patient Experience of Care scores during the Hospital VBP Program Dry Run period (Baseline Period: April - December 2008; Performance Period: April to December 2010), both overall and among urban hospitals.

Although we do not have an official definition or designation of "safety net" hospital, safety net status typically entails one or more of three criteria: high Medicaid share; high proportion of uncompensated patients; and high county-associated poverty rate. During the Hospital VBP Program Dry Run, 28 hospitals (7 of them urban) met all three criteria, 157 hospitals (83 of them urban) met two of the three criteria, 625 hospitals (391 urban) met one of the three criteria, and 2,219 hospitals (1,718 urban) met none of the three criteria.

In general, during the Hospital VBP Program Dry Run, after all HCAHPS adjustments are applied (patient mix and survey mode), safety net hospitals perform similarly to other hospitals. For example, 24 percent of the hospitals that meet any of the three safety net criteria (198/810) scored in the top quartile of Hospital VBP Patient Experience of Care domain (versus 25 percent (550/2219) of hospitals that met none of the safety net criteria). For urban hospitals, the figures are 110/481 safety net hospitals (23 percent) vs. 454/1718 other hospitals (26 percent). If we consider only those hospitals that meet two of the three safety net criteria, then 36/185 safety net hospitals (20

percent) and 12/90 urban safety net hospitals (13 percent) are in the top quartile (with 5 of these 12 in the top decile).

The HCAHPS patient mix adjustment model controls for patient characteristics not under the control of the hospital that directly impact response tendencies. It also controls for socioeconomic status of the patient population through education, which is a well-accepted method for controlling for socioeconomic status, in particular, in the elderly population. Other characteristics, such as hospital characteristics or geographic location, are not included in the adjustment models because controlling for hospital characteristics would mask potential quality differences across different types of hospitals.

Comment: Some commenters strongly supported the inclusion of the Medicare Spending per Beneficiary measure in the FY 2015 Hospital VBP Program. These commenters noted that cost information is valuable when combined with other quality measures, in assisting patients, purchasers, and policymakers in identifying value in healthcare. Some commenters suggested that the Medicare Spending per Beneficiary measure's inclusion in the Hospital VBP Program not be further delayed, citing their belief that it was important to Congress, because it is the only measure specifically required for inclusion in the Hospital VBP Program.

Response: We thank the commenters for their support and we agree that the Medicare Spending per Beneficiary measure is an important first step toward identifying value in healthcare. Further, we believe that the Medicare Spending per Beneficiary measure provides an incentive for hospitals to build stronger relationships with and better

understand the providers and suppliers that furnish care for their patients before and after an acute care hospitalization.

Comment: Some commenters supported the inclusion of the Medicare Spending per Beneficiary measure in the Hospital VBP Program as a first efficiency measure and encouraged CMS to work toward building a more robust efficiency measure set and to focus on efficiency measures that are connected to clinical process and outcomes.

Response: We appreciate these comments and acknowledge the potential for building a more robust Efficiency domain in the Hospital VBP Program. We will consider these comments as we evaluate whether to propose to adopt additional efficiency measures in the Hospital VBP Program.

Comment: Some commenters commended CMS for its efforts to develop a spending measure but suggested that the Medicare Spending per Beneficiary measure requires further development before it should be included in the Hospital VBP Program.

Response: We appreciate that the Medicare Spending per Beneficiary measure is new to hospitals, but we disagree that the measure is not fully developed. This measure was developed and tested by CMS with the help of expert contractors. We originally described the measure in depth in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25896 through 258997). We considered all public comments received on the measure and revised it accordingly. We publicly posted detailed specifications on February 1, 2012. We also invited public comment on the measure during a National Provider Call held in February 2012. Subsequently, we have conducted extensive

additional testing on the measure, in preparation for the July 2, 2012 submission to the NQF for endorsement.

Comment: Some commenters expressed concern with the Medicare Spending per Beneficiary measure in general. A few of those commenters stated that the Medicare Spending per Beneficiary measure was a measure of cost, not efficiency. One commenter expressed general concern with rewarding or penalizing providers based on expenditures per patient. A few commenters stated that the measure should be delayed until other value-based purchasing programs establish parallel incentives. A few commenters suggested that the measure should assess not only cost, but also quality and expressed concern that a cost-only measure might have the unintended consequences of incentivizing cost reduction at the expense of quality or access to care. One commenter stated that smaller hospitals could be unfairly disadvantaged due to referrals occurring during the 30 days post discharge, and one commenter stated that the measure could unfairly disadvantage urban hospitals serving large populations of dual-eligible beneficiaries. One commenter requested that CMS post ICD-10 measure specifications in the final rule.

Response: For the purposes of inclusion of the Medicare Spending per Beneficiary measure in the Efficiency domain, we define "efficiency" in the sense of "cost efficiency." This definition is consistent with existing approaches to measuring cost in the healthcare setting (Pacific Business Group on Health. Hospital Cost Efficiency Measurement: Methodological Approaches. January 2006, available at http://www.pbgh.org/storage/documents/reports/PBGHHospEfficiencyMeas_01-

2006_22p.pdf). Efficiency refers to the relative cost of clinical resources used to achieve a measured level of quality; as such, the Medicare Spending per Beneficiary measure gauges efficiency by calculating hospitals' relative costs to Medicare after adjusting for case mix differences and other factors.

We also agree that it is beneficial to view a cost measure in light of other quality measures. As we stated in the FY 2012 IPPS/LTCH PPS final rule, for purposes of the Hospital VBP Program, we will weight and combine the Efficiency domain with the other domain scores, in order to calculate each hospital's TPS. This procedure for calculating a hospital's TPS ensures that Medicare spending per beneficiary makes up only a portion of the TPS and that the remainder is based on hospitals' performance on the other measures (76 FR 51622). We further emphasize that section 1886(o)(2)(B)(ii) of the Act expressly requires the inclusion of "measures of Medicare spending per beneficiary" in the Hospital VBP Program. We do not believe that the Medicare Spending per Beneficiary measure itself should assess both cost and quality. We believe that a distinct measure of cost, independent of quality, enables us to identify hospitals involved in the provision of high quality care at a lower cost to Medicare.

With regard to some commenters' suggestions that the implementation of the Medicare Spending per Beneficiary measure should be delayed until parallel incentives are established under other CMS programs, we disagree. While we acknowledge the value in provision of consistent incentives, we believe that the prompt implementation of this measure is an important step to incentivizing care coordination, improving more effective post acute care delivery and follow up, and reducing unnecessary services and

preventable readmissions for Medicare beneficiaries. We will work with other incentive programs within CMS in an attempt to align future incentives to the extent possible.

We acknowledge that a hospital with fewer discharges during the performance period could see its measure performance more notably impacted by a high-cost episode. We note that although the measure is reliable using a minimum of 10 cases, we proposed a minimum of 25 cases and sought comment on a minimum of 50. Further, we exclude high-cost outlier episodes from this measure, so that these types of high cost cases will not unduly affect a hospital's Medicare Spending per Beneficiary measure performance. We also do not believe that the measure unfairly disadvantages urban hospitals serving dual-eligible beneficiaries. We have included an adjustment for severity of illness during the 90 days preceding the Medicare Spending per Beneficiary episode, in order to capture chronic conditions that may be experienced by any Medicare beneficiaries. Further, as we stated in the FY 2012 IPPS/LTCH PPS final rule, we do not believe that a socioeconomic risk adjustment factor is appropriate. This policy is consistent with the NQF's stated position on not adjusting for potential demographic (sex or race) or socioeconomic factors. Because an adjustment for dual-eligibility could be considered a proxy for socioeconomic status, we are not adjusting for this factor.

With regard to the request that we include ICD-10 measure specifications in this final rule, we are unable to accommodate this request. We do not currently have ICD-10 specifications for the Medicare Spending per Beneficiary measure, but to the extent that future implementation of ICD-10 affects the measure specifications already publicly posted, we will provide updated specifications to the public as soon as possible.

Comment: Several commenters submitted comments related to the post-discharge window in the Medicare Spending per Beneficiary measure. Some commenters expressed concern that the care provided to Medicare beneficiaries during the 30 days post hospital discharge is outside of hospitals' control, with one noting that follow-up care may be provided in a geographically distant location, relative to a transplant center. One commenter stated that a 30-day post-discharge period may be insufficient to capture long term savings achieved through the provision of technologies with higher upfront cost. A few commenters stated that a 30-day post discharge window was too long.

One commenter stated that the length of the post discharge window could, in some cases, be longer than 30 days because the total cost of the care that started within the 30 day period, but extended longer than 30 days, would be captured in the measure. This commenter suggested that this fact precludes hospitals from being able to compare their performance with other hospitals. One commenter suggested that planned admissions to other facilities should be excluded, and one commenter suggested that the measure should be limited to services related to the reason for original index admission. One commenter expressed concern with the inclusion of readmissions in this measure, suggesting that hospitals could be penalized twice for them.

Response: We do not believe that the care furnished to beneficiaries after they are discharged from an acute care hospital is wholly outside of the hospital's control. As we stated in the FY 2012 IPPS/LTCH PPS final rule, we believe that hospitals that provide quality inpatient care, conduct appropriate discharge planning, and work with providers and suppliers on appropriate follow-up care will realize efficiencies and perform well on

the measure, because the Medicare beneficiaries they serve will have a reduced need for excessive post-discharge services (76 FR 51621). We believe that hospitals can work effectively to improve care coordination, even if the post-discharge care is furnished in a geographically distant location. We finalized a 30-day post discharge period for the Medicare Spending per Beneficiary measure under the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule. This post discharge window is consistent with other agency initiatives, including the post-discharge period that applies to the readmission measures under the Hospital IQR Program and the Hospital Readmissions Reduction Program (76 FR 51619). As we indicated in that final rule, we will consider extending the length of the post-discharge period in future rulemaking, as suggested by one commenter, as both we and hospitals gain experience with the measure.

We recognize that the measure might capture Medicare payments for services initiated during the 30 days following discharge and continuing beyond them, but we do not believe that this is a disadvantage to any particular hospital. These payments represent actual costs to Medicare incurred during the Medicare Spending per Beneficiary episode surrounding a hospitalization, and we do not believe it would be appropriate to sever payments made under prospective payment systems into smaller units that are not what Medicare actually paid. We also disagree that inclusion of payments for services extending beyond the 30 day post-discharge window precludes meaningful comparison between hospitals, as all hospitals are subject to the same methodology in calculating their Medicare Spending per Beneficiary amounts and comparing them to the national median.

We disagree that planned admissions to other facilities should be excluded from the Medicare Spending per Beneficiary measure, because we seek to incentivize planning for appropriate and efficient post-discharge care through the use of this measure. With regard to the suggestion that services unrelated to the index admission should be excluded from the Medicare Spending per Beneficiary measure, we acknowledge that unforeseen events which are unrelated to the hospital stay could occur. As we stated in the FY 2012 IPPS/LTCH PPS final rule, this facet of the measure is consistent with the all cause readmission measure CMS is finalizing for the Hospital IQR Program and that determinations of the degree of relatedness of each subsequent hospital stay to an initial hospitalization could be subjective (76 FR 51621). We continue to believe that attributing all services provided during the episode is the best way to encourage quality inpatient care, care coordination, and care transitions. As we noted in that final rule, all hospitals will be subject to the same method of calculation of their Medicare spending per beneficiary amounts, as compared to the median Medicare spending per beneficiary amount across all hospitals, so we do not believe that inclusion of services which could be determined to be unrelated to the index admission will notably disadvantage any individual hospital (76 FR 51621).

With regard to the comment that hospitals could be doubly penalized by the inclusion of readmissions in this measure, we reiterate, as stated in the FY 2012 IPPS/LTCH PPS final rule, that we believe the Medicare payments made for readmissions must be attributable to the index hospital stay, in order: to fully capture Medicare spending relative to a hospital stay; to encourage the provision of

comprehensive inpatient care, discharge planning, and follow-up; and to strengthen incentives to reduce readmissions (76 FR 51621). The Medicare spending per beneficiary measure is not a measure of readmission rates, but rather is a measure of total Medicare spending per beneficiary relative to a hospital stay.

Comment: Several commenters expressed views related to the risk adjustment methodology for the Medicare Spending per Beneficiary measure. One commenter expressed support for the methodology. Some commenters suggested that the risk adjustment methodology was not sufficient and should include adjustments for factors including comorbidities, severity of illness, age, sex, race, socioeconomic factors, concurrent treatments, transplant status, education level, ambulation status, functional status, and range of motion. One commenter suggested that the measure should be adjusted for differences in patients treated in an academic medical center versus those treated in community hospitals. One commenter suggested that the risk adjustment methodology should use a hierarchical, rather than a linear regression.

Response: We agree that the Medicare Spending per Beneficiary measure should be adjusted for comorbidities, severity of illness, and age. Accordingly, we are utilizing the hierarchical condition categories (HCCs) applied to conditions billed during the 90 days preceding the Medicare Spending per Beneficiary episode, the beneficiaries' age, and their institutional status, to risk adjust the expected spending during the episode. We believe that concurrent treatments and transplant status will be captured in the expected spending for Medicare beneficiaries with the same HCCs.

As we indicated in the FY 2012 IPPS/LTCH PPS final rule, we disagree with the comments that risk-adjustment for the Medicare Spending per Beneficiary measure should include further adjustment for socioeconomic factors, beneficiary sex, or beneficiary race. Consistent with NQF's position on not adjusting for potential demographic (sex or race) or socioeconomic factors, we believe that the best adjustment for a payment measure is based on the beneficiaries' underlying health status, not demographic or socioeconomic factors. (76 FR 51624). In order to minimize the burden on hospitals, we have finalized the Medicare Spending per Beneficiary measure as a claims-based measure (76 FR 51622). As such, we would be unable to apply an adjustment for ambulation status, functional status, or range of motion. With regard to the use of a hierarchical regression, we note that the HCC categories are calculated in a hierarchical fashion. The risk adjustment methodology also allows for differing relationships between comorbidities and different MS-DRG admission diagnoses, with the understanding that a given comorbidity may affect a given MS-DRG more or less than another MS-DRG. As also stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624), we intend to analyze the risk-adjustment methodology, as we gain experience with this measure, to evaluate whether it could be further refined.

Comment: Some commenters were opposed to the inclusion of the Medicare Spending per Beneficiary measure in the Hospital VBP Program for FY 2015 because they stated that hospitals had been given insufficient time to become familiar with the measure. These commenters noted that the measure was posted on Hospital Compare in April 2012, stating that this allowed them less than one calendar quarter to become

familiar with the measure. One commenter added that hospitals have only an early understanding about how hospitals might make an impact on the cost without affecting quality. A few commenters stated that the Medicare Spending per Beneficiary measure rates were difficult to interpret.

Response: The Medicare Spending per Beneficiary measure data was added to the Hospital Compare Web site on April 19, 2012, after the measure was finalized for inclusion in the Hospital IQR Program through notice and comment rulemaking. We note that this posting followed a 30-day data preview in February 2012, during which we hosted a National Provider Call as well as accepted public comments via email. The proposed performance period for this measure would begin more than a full year after the April 2012 data posting. We provided information on how to interpret the Medicare Spending per Beneficiary measure data on Hospital Compare, and we remain cognizant of the measure's complexity. We will make every attempt to respond to inquiries and further clarify to the extent necessary how the measure is calculated as we move forward in utilizing this measure. When viewed in conjunction with other quality measures, the Medicare Spending per Beneficiary measure enables the public to recognize hospitals involved in providing high-quality care at a lower cost to Medicare.

Comment: Some commenters were opposed to the inclusion of the Medicare Spending per Beneficiary measure in the Hospital VBP Program, because they believed that CMS had not provided hospitals with sufficient data to understand or improve their performance on the measure. Some of these commenters stated that CMS had provided only information regarding whether the hospitals did better than, worse than, or the same

as the national average, and some stated that hospitals would appreciate the raw data so that they could validate the calculations.

Response: We disagree with the commenters who stated that we did not provide hospitals with specific information to enable them to understand or improve their Medicare Spending per Beneficiary measure performance. During the February 2012 data preview period, hospitals were provided with an index admission file that detailed every inpatient admission at the hospital during the performance period and whether or not it was counted as an index admission for the Medicare Spending per Beneficiary measure; a beneficiary risk score file, which identified the beneficiaries whose hospitalizations were counted as index admissions, their index admission DRG, and data regarding health status based on the beneficiary's claims history in the 90 days prior to the start of an episode; and an episode file, which contains information on the care provided during the stay as well as what type of care was provided in the episode. The episode file also provided the hospitals with the top five providers of both inpatient and outpatient services, as defined by actual Medicare dollars paid, so that the hospitals could work to better coordinate care. We note that although we have made the risk adjustment methodology available, we are unable to provide the raw data used for risk adjustment, as that would entail providing every single claim line submitted during the 90 days preceding the episode and throughout the episode, for every beneficiary hospitalized nationwide during the performance period. This amount of data would be unusable to most of the public and could have privacy implications.

Comment: Several commenters expressed their views regarding the data provided to the public with regard to the Medicare Spending per Beneficiary measure. One commenter stated that CMS had provided ample opportunity for public comment. Some commenters expressed concern that CMS had provided data only to hospitals through confidential reports, so hospitals were unable to compare their performance to other hospitals, and others requested a public use file that would allow outside organizations to verify calculations, analyze potential unintended consequences, or assist hospitals in identifying opportunities for hospitals to reduce spending.

Response: We appreciate the public interest in data regarding the Medicare Spending per Beneficiary measure. We note that some information could only be provided directly to hospitals, through confidential reports, because it contains Medicare beneficiaries' personally identifiable information. That level of data was only provided to the hospitals that treated the beneficiaries during the period of performance. In response to the request for data, we have posted a file on Hospital Compare that provides data on the makeup of the average Medicare Spending per Beneficiary episodes at the individual hospital, state, and national levels. The file is entitled "MSPB_Spending_Breakdowns_by_Claim_Type_051510-021411.csv," and it can be accessed at: http://hospitalcompare.hhs.gov/Data/spending-per-hospital-patient.aspx. We have also published an additional file entitled, "MSPB_Spending_Breakdowns_by_Claim_Type_051510-021411_File_Description.docx" which provides a detailed explanation of the data fields contained in the "MSPB_Spending_Breakdowns_by_Claim_Type_051510-021411.csv"

file. This file can be accessed in the "downloads" section of the Hospital VBP Web site at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/Hospital-Value-Based-Purchasing/. We believe that the provision of these files satisfies the public's need for data while protecting beneficiary privacy.

Comment: Several comments expressed views regarding the reliability of the Medicare spending per beneficiary measure. Commenters stated that reliability testing was not published and should be before the measure is finalized.

Response: We appreciate the value of reliability analyses for the Medicare Spending per Beneficiary measure, as it is a new measure type for the Hospital VBP Program. We proposed to include the Medicare Spending per Beneficiary measure in the Hospital VBP Program for FY 2015, based on our belief that it would be reliable. This belief was based not only on the nature of the measure, in that it captures almost all discharges during the performance period and is calculated using payment amounts obtained from Medicare claims data, but also on a body of published research and historical NQF findings related to claims-based resource use measures. Because the Medicare Spending per Beneficiary measure is not condition-specific, but captures nearly all discharges from eligible hospitals during a performance period, most hospitals were expected to have a large sample size of Medicare Spending per Beneficiary episodes. Larger sample sizes increase the reliability of the measure.

There is also published research that indicates that spending for an episode of care varies "greatly" among hospitals (N Engl J Med. 2008; 359: 3-5) and measures for which

there is a larger inter-hospital variability are more likely to be reliable. Other studies, such as the one conducted by Jha and colleagues, also found statistically significant differences in the cost of care among hospitals using a predictive cost model (Health Aff. 2009; 28(3): 897-906), and another study found significant variation in Medicare spending per discharge for five common conditions (Healthcare Financial Management Association. Data Trends. Mar 2011. Available at http://www.ahd.com/news/HFM_DataTrends_2011_March.pdf). Furthermore, MedPAC found that measures of spending per beneficiary were an appropriate means of assessing variation in cost and that "much of the variation [remaining] after removing the effects of input price adjusters is attributable to the quantity of services beneficiaries use." The study showed that even with aggregation at the county level, only 87.3 percent of beneficiaries nationally are between 85 percent and 115 percent of average cost per beneficiary, even after adjusting for health status, participation in Medicare Parts A and B, and payment to hospitals that reflect hospital costs for providing uncompensated care to the poor and teaching hospital costs for graduate medical education. After all such adjustments, the standard deviation at the beneficiary level was greater than 10 percent of the average cost per beneficiary (MedPAC. Report to Congress: Variation and Innovation in Medicare, Jun 2003). While these studies do not explicitly test the reliability of a beneficiary-level episode-based cost measure, they clearly establish significant variation in spending per beneficiary and show that provider choices drive that part of that variation.

In addition to this research, the NQF has found other resource use measures that are based on Medicare claims data, such as all-cause readmission measure (NQF # 1789), to be highly reliable. For the all-cause readmission measure, "reliability and validity [at the data element level and at the measured score level] was generally received as adequate by the steering committee" (NQF: 2012 Proc. Feb 2012, available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70455). Further, in a memorandum to the NQF Board of Directors, the NQF's Senior Vice President for Performance Measures report noted that the majority of NQF committee members stated that the Hospital-wide All Cause Readmission Measure was highly reliable (Burston, 2012: Appeal of Hospital-wide All Cause Readmission Measure, 95pp. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71398). To further confirm our expectation that the Medicare Spending per Beneficiary measure is sufficiently reliable for inclusion in the Hospital VBP Program, we elected to obtain an analysis similar to that performed for certain other Hospital VBP measures. That analysis concluded that the Medicare Spending per Beneficiary measure has an overall reliability of 0.951 with a minimum number of 10 cases. The overall reliability of the Medicare Spending per Beneficiary Measure increases by 0.0002 when the minimum number of episodes increases from 10 to 25. The reliability analysis may be accessed publicly in the "Downloads" section of our Hospital VBP Web page, located at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/hospital-value-based-purchasing/index.html?redirect=/Hospital-Value-Based-Purchasing/

Comment: One commenter noted that the MAP identified measures of cost as a high-priority gap area for the Hospital VBP Program and strongly supported the measure's direction, in its February 2012 Final Report to the Department of Health & Human Services. Some commenters suggested that CMS should not finalize the measure until it is endorsed by the NQF, and some said that the measure must go through the NQF endorsement process. Many of these commenters also noted that that the MAP did not support inclusion of the Medicare Spending per Beneficiary measure at the time of its report.

Response: We appreciate the value of the NQF's endorsement of performance measures. We also agree with the commenter's assessment that the MAP "strongly" supported the measure's direction pending additional specification and testing. We have since made the measure specifications public and allowed comment through a National Provider Call held in February 2012. In the FY 2013 IPPS/LTCH PPS proposed rule, we expressed our intent to submit the Medicare Spending per Beneficiary measure to the NQF for endorsement consideration, and we did so on July 2, 2012. We disagree with the commenters who contended that the measure must go through the NQF endorsement process before it may be included in the Hospital VBP Program and note that we were only required by statute to give due consideration to any measures of Medicare spending per beneficiary currently endorsed by the NQF or any other consensus organizations

under section 1886(b)(3)(B)(viii)(IX) of the Act. We have met that requirement and have also submitted the measure to the NQF for consideration for endorsement.

Comment: Some commenters argued that the proposed AHRQ PSI composite measure is not sufficiently reliable to distinguish differences in patient safety among health care institutions. Other commenters suggested that this type of safety measure is not appropriate for use in a payment program like the Hospital VBP Program. Some commenters argued that the measure calculation is too complex for hospitals and their vendors to attempt to replicate, and is therefore difficult as a focus of quality improvement.

Response: We believe that the proposed AHRQ PSI composite measure is sufficiently reliable for purposes of the Hospital VBP Program when using the minimum number of cases as proposed. We believe that one principal contributor to measure reliability is measure denominator size. While reliability will vary for individual hospitals based on the denominator size that applies to each hospital, we are finalizing a minimum number of cases for this measure that we believe is sufficiently reliable and appropriately balances our priorities of including hospitals in the Program and excluding hospitals from a measure when their performance on that measure may not be meaningfully captured.

We also believe that adopting the AHRQ PSI composite measure, with the minimum number of cases specified by the measure steward, provides strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration for quality improvement. We further believe that

adopting the minimum number of cases as proposed enables those incentives to be extended to as many hospitals as possible, thus ensuring that as many patients as possible will benefit should hospitals take steps to improve their performance on the measure.

Further, we are particularly concerned about the effects that not finalizing the AHRQ PSI composite might have on hospitals' quality performance. We believe that the PSI measure, as a composite measure of patient safety, appropriately encourages robust hospital attention to patient safety events. As we have stated in prior rulemaking, we believe that the Hospital VBP Program exists to drive quality improvement in the acute inpatient setting, and we believe strongly that measures of patient safety such as the AHRQ PSI measure and the CLABSI measure are important metrics on which hospitals should focus their quality improvement efforts.

Finally, while we are sympathetic to commenters' concerns about the composite measure's complexity, we note that the measure is composed of underlying safety indicators on which hospitals may focus their attention. We encourage hospitals that are unsure how to improve their performance on the AHRQ PSI measure or on any other measure finalized for the Hospital VBP Program to contact their QIO for assistance.

Comment: Two commenters assumed that because CMS proposed the removal of several individual AHRQ PSI measures from the Hospital IQR Program, we would also remove these indicators from the calculation of the AHRQ PSI-90 Composite measure for both Hospital IQR and the Hospital VBP Programs. Furthermore, these commenters believed that the statutory display requirement for the AHRQ PSI-90 Composite has not

been met because CMS did not display data for all eight of the individual AHRQ indicators that are used in the composite.

Response: We wish to clarify that our removal of several individual AHRQ indicators from the Hospital IQR Program does not in any way change the composition of the AHRQ PSI-90 composite measure for either the Hospital IQR or Hospital VBP Programs. No changes have been proposed for the AHRQ PSI-90 composite for the Hospital IQR or Hospital VBP Programs. We adopted and displayed the NQF-endorsed AHRQ PSI-90 Composite measure for the Hospital IQR Program (NQF#531) which is comprised of the following individual indicators: PSI-03, PSI-06, PSI-07, PSI-08, PSI-12, PSI-13, PSI-14, and PSI-15. We will continue to use/display this NQF-endorsed version of the PSI composite for the Hospital VBP Program.

Regarding the 1 year display requirement for the PSI-composite for the Hospital VBP Program, we have proposed to use the AHRQ PSI-90 Composite calculation in its totality for Hospital VBP Program scoring. We displayed this composite score in its totality on Hospital Compare beginning October 2011. Therefore, the PSI-90 Composite meets the display requirement for use in the Hospital VBP Program regardless of how many individual AHRQ indicators were displayed.

Comment: Some commenters opposed our proposal to adopt the CLABSI measure for the FY 2015 Hospital VBP Program, arguing that the measure should be validated before its use in the Hospital VBP Program. Other commenters argued that the relatively limited CLABSI data posted on Hospital Compare in early 2012 did not meet the requirement for public display prior to the measure's use in the Hospital VBP

Program. Some commenters suggested that it is not appropriate to adopt the CLABSI measure for both HAC payment policy and under the Hospital VBP Program. Some commenters argued that CMS should not include HAC measures in the Hospital VBP Program.

Response: We do not believe that we should wait until after the measure is validated before adopting it for the Hospital VBP Program. The CLABSI measure captures important information about infections that present substantial harm to patients. We believe that measuring and rewarding hospitals on their work at curbing CLABSI incidents is vital to rewarding the provision of high-quality health care, which is the central point of the Hospital VBP Program.

We believe that baseline and performance period CLABSI data are sufficiently reliable for purposes of the Hospital VBP Program. At least 20 State health departments validated CLABSI data reported to the NHSN during the baseline period, which gives us some assurance that the data is accurate. We also believe that our CLABSI minimum case threshold of at least one expected CLABSI event in the performance period (discussed more fully below) contributes to this measure's reliability, since we exclude hospitals with the lowest measure reliability from receiving a measure score. Our Hospital IQR Program CLABSI validation process starting with January 2012 CLABSI events was finalized through rulemaking (76 FR 51646 through 51648) to ensure data accuracy during the performance period. We believe that commenters may have erroneously concluded that CMS is adopting identical quality measures in two separate programs – in this case, the Hospital VBP Program, and HAC payment policy under

section 1886(d)(4)(D) of the Act. We do not believe this to be the case. HAC measures are based on Medicare claims and capture only the Medicare population, while the CLABSI measure that we have proposed to adopt for the FY 2015 Hospital VBP Program is a surveillance measure reported to the NHSN and captures non-Medicare patients as well. We view the measures for each program as complementary and believe that adoption of these measures in each program should indicate to hospitals the high priority that we place on curbing infections and the harm the represent to patients.

We disagree with commenters' assertion that the measure data posted on Hospital Compare did not meet the statutory requirement for public display under the Hospital VBP Program. Section 1886(o)(2)(C)(i) of the Act prohibits the Secretary from selecting a measure for the Hospital VBP Program with respect to a performance period unless that measure has been specified under the Hospital IQR Program and included on Hospital Compare for at least one year prior to the beginning of the performance period. We posted CLABSI data on Hospital Compare in January 2012 in satisfaction of that requirement.

We believe that current Hospital Compare data provides a broad national snapshot of CLABSI performance. Although the initial January 2012 posting of Hospital Compare data included only 1 quarter of CLABSI information, we expect the number of hospitals for which data is posted on Hospital Compare to increase to the majority. In the most recent May 2012 posting, we posted over 1,500 hospitals' CLABSI data on the Hospital Compare Web site. This posting included January through June 2012 CLABSI data. An additional 500 hospitals submitted reports that they had insufficient intensive care unit

(ICU) beds, and were not required in the Hospital IQR Program to submit CLABSI data. These hospitals did not treat a sufficient number of patients eligible to be included in the CLABSI measure. This measure exclusion, coupled with the large number of hospitals that are reporting CLABSI data, indicates broad understanding of the measure and sufficient data for public reporting.

In addition, as described further below, because we believe that including more data in the CLABSI measure calculations will alleviate commenters' concerns about the relatively small number of hospitals that reported on the measure initially, we will finalize a 12-month baseline period for the CLABSI measure for FY 2015 (this is discussed more fully below). By including all available data from CY 2011 in the resulting performance standards calculations, we believe we can ensure that the finalized performance standards accurately reflect national performance benchmarks.

Comment: Some commenters expressed support for CMS' proposals to adopt the AHRQ patient safety composite measure and the CLABSI measure.

Response: We thank commenters for their support.

Comment: Some commenters asked CMS to wait before adopting the CLABSI measure that includes both ICU and non-ICU patients.

Response: We believe that this measure supports making care safer, one of the National Quality Strategy's goals. We intend to solicit comments from the MAP and solicit comment on the expanded measure in future rulemaking.

Comment: Some commenters supported CMS' proposal to include mortality measures in the FY2015 Hospital VBP Program, though commenters also suggested that

CMS consider additional risk-adjustment to include socioeconomic status and clinical factors.

Response: We thank commenters for their support. We believe the existing risk-adjustment methodology is sufficient. These measures were endorsed by the National Quality Forum, and the NQF extensively reviewed the risk adjustment methodology as part of their overall review. The 30-day mortality measures are currently risk-adjusted to include clinical factors, and we believe that risk adjustment model to be well-understood by hospitals and sufficiently robust for quality measurement. The Hierarchical Condition Category (HCC) grouping of clinical conditions and hospital case-mix are used for risk adjustment. The HCC model makes use of all physician and hospital encounter diagnoses and was designed to predict a beneficiary's expenditures based on the total clinical profile represented by all of his/her assigned HCCs. Additionally, there are several exclusions to the mortality measures, such as enrollment in a hospice program. We refer commenters to the extensive documentation of the mortality measure methodology at http://www.qualitynet.org.

Comment: Some commenters expressed strong opposition to further use of the 30-day mortality measures in the Hospital VBP Program, arguing that the measures are unreliable and should be the subject of a validity study. Some commenters also argued that the risk adjustment process applied to these measures is insufficient. Commenters also requested that we pursue a validation study of the mortality measures as soon as possible.

Response: We believe that the three 30-day mortality measures are sufficiently reliable for inclusion in the Hospital VBP Program. One principal contributor to measure reliability is measure denominator size, and the reliability of a measure is going to vary for individual hospitals, based on the denominator size that applies to each hospital. Our proposed FY 2015 minimum case threshold increase from 10 to 25 cases for the mortality measures improves reliability by excluding an additional estimated 376 to 682 hospitals in FY 2015 with the lowest number of cases in the measure denominators and, thus, lowest level of reliable measure scores. This analysis was performed subsequent to the reliability analysis posted on the CMS Web page https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf in February 2012. Our proposed FY 2016 expansion of the performance period to 21 months also improves reliability by increasing the number of cases in the mortality measure denominator. We believe that the previously finalized FY 2014 Hospital VBP mortality measures are sufficiently reliable, since the 12 month performance period is expected to increase the denominator counts for most hospitals, relative to the 9 month FY 2015 mortality measure performance period.

We believe that our increase in the minimum number of cases for the mortality measures for FY 2015 improves overall reliability, since we excluded hospitals with the lowest reliability from receiving a score on the mortality measures. We proposed the 25 case minimum for each of the three 30-day mortality measures because we recognize that each of these measures are risk adjusted to estimate differences in hospital patient

case mix. Our process of care measures included in the Hospital VBP program do not utilize risk adjustment estimation techniques, and we believe that our proposal to increase the minimum case threshold to 25 cases incorporates the increased reliability necessary for the three mortality measures using risk adjustment estimation techniques. We believe that our 25 case minimum threshold is also supported by the central limit theorem, a commonly used statistical theorem used in sampling theory and statistical estimation. According to Rice's Mathematical Statistics and Data Analysis (2^{nd} edition, 1995), this theorem states that under certain conditions, the mean of a sufficiently large number of independent random variables, each with a finite mean and variance, will be approximately normally distributed. For these mortality measures, a 25 case minimum threshold for should be sufficient to create an approximate normal distribution of hospital TPSs. We believe that the distribution of mortality measures is sufficiently reliable for inclusion in the program, based on this information and the relatively small contribution of the mortality measures to the total performance score. We also proposed to set the the Outcome domain weight at 30 percent for the FY 2015 program so that the total performance score continues to be normally distributed and reliable with the inclusion of the mortality measures. We also view the TPS's reliability is an important factor when considering performance periods, minimum numbers of cases and measures, and other policies for the Hospital VBP Program, as the TPS is the basis for value-based incentive payments.

We also weighed our policy goal to link payment to patient outcomes for the vast majority of hospitals in our proposal to include the 3 mortality measures with a 25 case

minimum. For the FY 2015 proposed 9 month performance period and 25 case threshold, we estimate that about 1,566 hospitals would be included for the AMI 30-day mortality measure, 2,514 hospital would be included for the HF 30-day mortality measure, and 2,690 hospitals would be included for the PN 30-day mortality measure. Increasing the minimum case threshold would dramatically decrease the number of hospitals receiving a score for these measures, and would dramatically reduce the impact on patient health outcomes that the 3 mortality measures promote. We further believe that the 3 mortality measures are valid through their very strong link to patient health outcomes. The National Quality Forum endorsed these measures and one fundamental criterion in their assessment was a demonstrated link to patient health outcomes. We believe that the inclusion of mortality measures improves the Total Performance Score's validity by adding measures with relatively high correlation with patient outcomes. We further believe that these measures, which capture outcomes data, enable us to provide incentives to hospitals focusing on a broader picture of health care quality, rather than simply rewarding hospitals for completing clinical processes.

Comment: Some commenters suggested that we consider additional HAC measures for the Hospital VBP Program, including CAUTI and vascular catheter-associated infection. Commenters urged us to retain the HAC measures that we suspended in the CY 2012 OPPS/ASC final rule with comment period for the FY 2014 Hospital VBP Program and suggested that we consider additional HAI measures for the FY 2015 VBP Program.

Response: We thank commenters for these suggestions. As stated above, we will consider additional measures for the Hospital VBP Program as they become available under the requirements set forth in section 1886(o)(2) of the Act and if they are consistent with the National Quality Strategy and the agency's other quality improvement priorities.

After consideration of the public comments we received, we are finalizing the FY 2015 Hospital VBP Program measure set as proposed, with the exception, as described further above, of AMI-10, which we have concluded is "topped-out."

c. General Process for Hospital VBP Program Measure Adoption for Future Program Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28080), in order to facilitate measure adoption for the Hospital VBP Program for future years, as well as further align the Hospital VBP Program with the Hospital IQR Program, we proposed to re-adopt measures from the prior program year for each successive program year, unless proposed and finalized otherwise (for example, because one or more of the clinical process of care measures is topped-out). We intend to continue monitoring Hospital VBP measures for topped-out status and will propose to remove topped-out measures from the program as appropriate in future rulemaking. We will therefore generally re-adopt the prior program year's measure set unless we propose to add or remove measures through rulemaking and in response to public comments. However, under this policy, once measures are finalized, we would not separately re-propose them for each program year. We invited public comments on this proposal.

Comment: Some commenters supported the proposal to re-adopt Hospital VBP measures automatically for each program year, noting that the policy will give stability and predictability to the program while still affording CMS flexibility to make needed changes.

Response: We agree and thank commenters for their support.

Comment: Some commenters opposed the proposal to re-adopt measures for future program years unless CMS proposes to remove them. Commenters suggested that new measures may make older measures redundant or unnecessary, and argued that stakeholders should be able to comment on the entire measure set annually.

Response: We intend to re-evaluate the entire Hospital VBP measure set each year, and to propose to remove any measures that we conclude would be redundant or unnecessary due to the addition of other, newer measures. We also intend to solicit comments on an annual basis on the entire measure set, including both newly proposed and previously finalized measures, and we will consider and respond to all of these comments. We view the proposal to automatically re-adopt measures as a way to ensure consistency across Hospital VBP Program years. This proposal also seeks to assist hospitals in their planning and quality improvement efforts through more advanced notice about Hospital VBP measures to be included in future program years.

After consideration of the public comments we received, we are finalizing our policy enabling automatic re-adoption of quality measures from prior program years as proposed.

9. Measures and Domains for the FY 2016 Hospital VBP Program

a. FY 2016 Measures

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28080), we proposed to retain the three 30-day mortality measures that were finalized for the FY 2014 Hospital VBP Program, and which we are finalizing for the FY 2015 Hospital VBP Program, for the FY 2016 Hospital VBP Program. We also proposed to retain PSI-90, which is the AHRQ PSI composite measure that we are finalizing for the FY 2015 Hospital VBP Program, for the FY 2016 Hospital VBP Program. By proposing to adopt these measures now, we believe we will be able to adopt a longer performance period and collect more data for performance scoring than would be possible if we waited to make this proposal until the FY 2014 IPPS/LTCH PPS proposed rule. We also proposed to adopt these measures at this time because we recognize that under section 1886(o)(3)(C) of the Act, we must establish and announce performance standards not later than 60 days prior to the beginning of the performance period for the fiscal year involved. Accordingly, we proposed that the performance period for these measures would begin October 1, 2012, for purposes of the FY 2016 Hospital VBP Program. Because we are finalizing our proposal above to automatically re-adopt measures from year to year, the other proposed FY 2015 measures will also become part of the FY 2016 measure set (with the exception of the CLABSI measure) unless we propose otherwise in future rulemaking. We also anticipate adopting additional measures for the FY 2016 Hospital VBP Program in future rulemaking.

The proposed FY 2016 Hospital VBP Program 30-day mortality measures and AHRQ PSI composite measure are shown below:

Proposed Outcome Measures for FY 2016 Hospital VBP Program	
Measure ID	**Description**
AHRQ PSI composite	Complication/patient safety for selected indicators (composite)
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate
MORT-30-HF	Heart Failure (HF) 30-day mortality rate
MORT-30-PN	Pneumonia (PN) 30-day mortality rate

We did not propose to adopt the CLABSI measure for the FY 2016 Hospital VBP Program at this time, but stated that we may propose it in future rulemaking.

We invited public comment on these proposals.

Comment: Some commenters urged us to clarify whether CMS will propose to adopt the CLABSI measure for the FY 2016 Hospital VBP Program.

Response: We anticipate proposing to adopt CLABSI for the FY 2016 Hospital VBP Program.

Comment: Some commenters urged CMS to exclude patients identified as needing only hospice or palliative care from Hospital VBP Program calculations, arguing that inconsistent access to these services may result in unfair penalties to hospitals in areas without those services.

Response: As patients needing hospice or palliative care will still require resources from hospitals, we do not believe it would be appropriate to exclude them from Hospital VBP Program calculations, nor do we believe it would be consistent with

measure specifications. We intend to monitor the effects of the Hospital VBP Program on care quality in the acute inpatient setting and will examine this issue in the future.

After consideration of the public comments we received, we are finalizing our proposal to include the 30-day mortality measures, AHRQ PSI composite measure, and other measures finalized for the FY 2015 Hospital VBP measure set (with the exception of the CLABSI measure) in the FY 2016 measure set. As stated above, we might propose in future rulemaking to adopt additional measures beginning with the FY 2016 Hospital VBP Program.

b. Quality Measure Domains for the FY 2016 Hospital VBP Program

Currently, measure domains are defined by the measure type rather than by measure function. At the time of the Hospital VBP Program's development, we believed this type of measure classification, which was included in the 2007 Report to Congress, was appropriate for the program based on its clarity and simplicity compared to alternative scoring models. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26513 through 26514) for further discussion of our decision to finalize the Three-Domain Performance Scoring Model for the Hospital VBP Program with appropriate modifications for additional domains as necessary. The FY 2014 Hospital VBP Program's domains are clinical process of care, outcomes, and patient experience of care. The FY 2015 Hospital VBP Program's proposed domains are clinical process of care, outcomes, patient experience of care, and efficiency.

We strive to align quality measurement and value-based purchasing efforts with the National Quality Strategy and across programs. Value-based purchasing programs in

particular allow us to link the National Quality Strategy with Medicare reimbursements to providers and suppliers on a national scale. Given this objective, as well as our objective to focus quality measurement on the patient-centered outcome of interest to the extent possible, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28081), we proposed to reclassify the Hospital VBP measures into domains based on the six priorities of the National Quality Strategy, beginning with the FY 2016 Hospital VBP Program. We made this proposal in this proposed rule to ensure that we have ample time to consider all public comments and finalize any policies in advance of the FY 2016 program year.

We proposed that the following six domains serve as a framework for measurement and TPS calculations for the Hospital VBP Program beginning with the FY 2016 program year: Clinical Care; Person- and Caregiver-Centered Experience and Outcomes; Safety; Efficiency and Cost Reduction; Care Coordination; and Community/Population Health.

To illustrate how CMS would classify measures into the proposed new domains, we offered the following example using the proposed FY 2015 Hospital VBP measure set:

Proposed FY 2015 measures	**Proposed FY 2016 domain**	**Proposed FY 2015 domain**
HF-1 Discharge Instructions	Care Coordination	Clinical Process of Care
AMI-10 Statin Prescribed at Discharge	Clinical Care	Clinical Process of Care
AMI-7a Fibrinolytic Agent Received Within 30 Minutes of Hospital Arrival	Clinical Care	Clinical Process of Care

Proposed FY 2015 measures	Proposed FY 2016 domain	Proposed FY 2015 domain
AMI-8a Primary PCI Received Within 90 Minutes of Hospital Arrival	Clinical Care	Clinical Process of Care
Mortality-30-AMI: Acute Myocardial Infarction (AMI) 30-day Mortality Rate	Clinical Care	Outcomes
Mortality-30-HF: Heart Failure (HF) 30-day Mortality Rate	Clinical Care	Outcomes
Mortality-30-PN: Pneumonia (PN) 30-Day Mortality Rate	Clinical Care	Outcomes
PN-3b Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	Clinical Care	Clinical Process of Care
PN-6 Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients	Clinical Care	Clinical Process of Care
SCIP Card-2 Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period	Clinical Care	Clinical Process of Care
SCIP-Inf-01 Prophylactic antibiotic received within 1 hour prior to surgical incision	Clinical Care	Clinical Process of Care
SCIP-Inf-02 Prophylactic antibiotic selection for surgical patients	Clinical Care	Clinical Process of Care
SCIP-Inf-03 Prophylactic antibiotics discontinued with 24 hours after surgery end time	Clinical Care	Clinical Process of Care
SCIP-Inf-04 Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	Clinical Care	Clinical Process of Care
SCIP-VTE-2 Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	Clinical Care	Clinical Process of Care
Medicare spending per beneficiary	Efficiency and Cost Reduction	Efficiency

Proposed FY 2015 measures	Proposed FY 2016 domain	Proposed FY 2015 domain
HCAHPS - Hospital Consumer Assessment of Healthcare Providers and Systems Survey	Person- and Caregiver-Centered Experience and Outcomes	Patient Experience of Care
Central Line-Associated Blood Stream Infection (CLABSI)	Safety	Outcome
PSI 90 Complication/Patient Safety for Selected Indicators (Composite)	Safety	Outcome

We acknowledge that some of the measures noted above could appropriately be placed in more than one domain because the quality improvement characteristics they seek to measure, especially for outcome measures, are multifaceted. We believe that the measure classification by domain should reflect the primary measurement objective and the type of quality improvement goal the measure seeks to capture. For example, although a reduction in CLABSIs may reflect improved clinical care, we believe that it better reflects an improvement in patient safety because such infections often cause harm to patients.

We proposed that the TPS would continue to be determined by aggregating each hospital's scores across all domains. A hospital's score on each domain would also continue to be calculated based on the hospital's score on each measure within the domain, which is based on the higher of its achievement or improvement during the applicable performance period.

We welcomed public comment on our proposal to regroup the Hospital VBP Program's quality measures into six domains that better reflect the National Quality Strategy, beginning with the FY 2016 Hospital VBP Program.

We also solicited comments on how to properly weight the domains in FY 2016. We believe that domain weighting should primarily balance two factors. First, it should reflect our concept of quality as it relates to the National Quality Strategy and the most critical needs for quality improvement in caring for beneficiaries. Second, it should reflect the relative depth and maturity of measures in each domain. For example, although improvement in the proposed Care Coordination domain is a priority, we would want to take into consideration whether the care coordination measures available for inclusion in that domain in a particular year capture multiple aspects of care coordination. If we did not believe that the measures within a domain captured enough aspects of care, we would consider proposing a relatively lower weight for the domain. We anticipate that the domain weights will evolve over time as the measure set changes.

We also recognize that the current domain weighting system allows us to place higher value on measures closer to the patient-centered outcome of interest by grouping outcome measures into a single domain. In the proposed domain reclassification, the 30-day mortality measures would be grouped with process measures. Although we anticipate that the measure set will evolve over time to be more focused on outcomes, the current measure set continues to emphasize clinical processes. We sought public comment on whether CMS should continue to group all outcome measures in a single domain. In addition, we sought public comment on the implications of and alternatives to

the proposed approach of including both clinical process of care measures and outcome measures in the proposed Clinical Care domain under the proposed domain reclassification.

Comment: Some commenters expressed support for our proposal to realign the Hospital VBP measure scoring domains around the priorities articulated in the National Quality Strategy.

Response: We thank commenters for their support.

Comment: Some commenters expressed concerns about the proposed domain reclassification for FY 2016, suggesting that the proposed structure could dilute hospitals' focus on outcome measures. Commenters preferred that outcome measures continue to be grouped together and given substantial domain weight to reflect the relatively greater importance of outcomes to patients and taxpayers. Other commenters were concerned about adopting domains based on the National Quality Strategy with relatively few measures.

Response: We understand the commenters' concern and agree that the Hospital VBP Program should, over time, focus its measure set on measures of outcomes and efficiency rather than clinical processes. We intend to continue shifting the focus of the Hospital VBP Program's measure set from clinical processes to measures of outcomes and efficiency, and will consider the commenters' concerns about diluting hospitals' focus on outcome measures in the future.

We are also concerned about adopting domains with relatively few measures, but we note that such a policy serves to focus hospitals' attention on the measures captured in

such domains. As noted above, we finalized the FY 2015 Program's Efficiency domain with one measure, which we believe shows the relative importance of efficiency in the health care sector.

Comment: Some commenters urged CMS to proceed cautiously in reclassifying Hospital VBP measure scoring domains for the FY 2016 Hospital VBP Program. Some commenters suggested that the National Quality Strategy's priorities are more appropriate for Accountable Care Organizations or as guiding principles for quality rather than as quality domains. Commenters suggested that CMS allow Hospital VBP Program scoring previews before completing any domain reclassification in order to allow hospitals to evaluate the impact on their scores. Some commenters also suggested that CMS wait until hospitals have actual experience with the Hospital VBP Program before fundamentally reshaping its structure.

Response: We thank commenters for their input. We will consider the feasibility of providing hospitals with scoring previews in the future. As we are not finalizing this domain reclassification at this time, we believe we are meeting commenters' request that we wait until hospitals have actual experience with the Program before reshaping it. We will consider re-proposing this domain reclassification when we have more information to evaluate hospitals' performance under the Program.

After consideration of the public comments we received, we are not finalizing our proposal to reclassify the Hospital VBP measures into domains based on the six priorities of the National Quality Strategy in FY 2016. We will maintain the existing four-domain

structure in FY 2016. We will consider these comments should we address this issue again in future rulemaking.

10. Performance Periods and Baseline Periods for the FY 2015 Hospital VBP Program

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program for a fiscal year that begins and ends prior to the beginning of such fiscal year.

a. Clinical Process of Care Domain Performance Period and Baseline Period for FY 2015

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74534), for the FY 2014 Hospital VBP Program, we finalized a 9-month (3-quarter) performance period from April 1, 2012 through December 31, 2012 for the clinical process of care domain measures.

As we stated in that final rule with comment period, adopting a 3-quarter performance period for this domain for the FY 2014 Hospital VBP Program would enable us to consider adopting a 12-month performance period for this domain for FY 2015. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28082), we proposed to adopt CY 2013 (January 1, 2013 through December 31, 2013) as the performance period for all but one of the clinical process of care domain measures for the FY 2015 Hospital VBP Program. This proposed performance period for FY 2015 would begin immediately after the end of the FY 2014 performance period and will enable us to begin to make value-based incentive payments to hospitals beginning October 1, 2014. A 12-month performance period would also give us more data on which to score hospital

performance, which is an important goal both for CMS and for stakeholders. We also note that a 12-month performance period is consistent with the periods used for the Hospital IQR Program.

However, as noted above, AMI-10 measure data were posted on Hospital Compare on January 26, 2012. Therefore, we stated that we did not believe we could begin a performance period for this measure on January 1, 2013, which would align with the proposed performance period for all other clinical process of care measures. We considered the most appropriate way to include this measure in the FY 2015 Hospital VBP Program and concluded that we should propose a 9-month performance period from April 1, 2013 through December 31, 2013. As we have stated for prior program years, we believe that a 9-month performance period provides sufficiently reliable quality measure data for clinical process of care measures. We also stated that we intend to align the AMI-10 measure's performance period with all other clinical process measures for future program years.

As we explained in the Hospital Inpatient VBP Program final rule (76 FR 26511), we believe that baseline data should be used from a comparable prior period for purposes of calculating the performance standards. However, we also strive to balance that belief with our desire to use the most recently-available data in order to calculate performance standards, as we believe that more recent data more closely reflects current performance on measures. Therefore, we proposed to adopt CY 2011 (January 1, 2011 through December 31, 2011) as the baseline period for all but one of the Clinical Process of Care domain measures for the FY 2015 Hospital VBP Program. As noted above, we proposed

to adopt a 9-month performance period for the AMI-10 measure. In accordance with our preference for adopting a comparable prior period for purposes of calculating the performance standards, we proposed to adopt a 9-month baseline period of April 1, 2011 through December 31, 2011 for the AMI-10 measure.

We welcomed public comment on these proposals.

Comment: Commenters generally supported CMS' clinical process of care performance period proposals for the FY 2015 Hospital VBP Program, including proposing to use a full calendar year for most clinical process measures and a slightly shorter performance period for AMI-10 consistent with its posting date on Hospital Compare.

Response: We thank commenters for their support. However, as described further above, because we have concluded that AMI-10 is "topped-out," we are not finalizing that measure for the Hospital VBP Program.

After consideration of the public comments we received, we are finalizing the FY 2015 performance period and baseline period for the Clinical Process of Care domain as proposed, with the exception of the proposed periods for the AMI-10 measure.

b. Patient Experience of Care Domain Performance Period and Baseline Period for FY 2015

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74534), for the FY 2014 Hospital VBP Program, we finalized a 9-month (3-quarter) performance period from April 1, 2012 through December 31, 2012 for the Patient Experience of Care domain measure.

As we stated in that final rule with comment period, adopting a 3-quarter performance period for this domain for the FY 2014 Hospital VBP Program would enable us to consider adopting a 12-month performance period for this domain for FY 2015. Consistent with our goal of adopting a full 12-month period for this domain in order to collect a larger amount of HCAHPS survey data compared to a 9-month period, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28083) we proposed to adopt CY 2013 (January 1, 2013 through December 31, 2013) as the performance period for the Patient Experience of Care domain measure for the FY 2015 Hospital VBP Program. This proposed performance period for FY 2015 would begin immediately after the end of the FY 2014 performance period and would enable us to begin making value-based incentive payments to hospitals beginning on October 1, 2014. We also note that a 12-month performance period is consistent with the periods used for the Hospital IQR Program.

As we explained in the Hospital Inpatient VBP Program final rule (76 FR 26511), we believe that baseline data should be used from a comparable prior period for purposes of calculating the performance standards. Therefore, we proposed to adopt CY 2011 (January 1, 2011 through December 31, 2011) as the baseline period for the Patient Experience of Care domain measure for the FY 2015 Hospital VBP Program.

We welcomed public comment on these proposals.

Comment: Commenters generally supported the proposal to adopt 12-month baseline and performance periods for the Patient Experience of Care Domain for the FY 2015 Hospital VBP Program.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing the FY 2015 Patient Experience of Care performance period and baseline period as proposed.

c. Efficiency Domain Measure Performance Period and Baseline Period for FY 2015

We posted performance data for the Medicare Spending Per Beneficiary measure on Hospital Compare on April 21, 2012. We therefore concluded that the earliest we could begin a performance period for FY 2015 is one year from the date on which the data was posted. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28083), we proposed an end date of December 31, 2013 for this measure's performance period. This end date is consistent with the end dates proposed for the Clinical Process of Care domain and for the HCAHPS measure in the Patient Experience of Care domain.

In the interest of maintaining consistency across domains, to the extent possible, and in order to ensure that data have been posted for at least 1 year prior to the beginning of the measure performance period, we proposed to adopt an 8-month performance period (May 1, 2013 through December 31, 2013) for the Medicare spending per beneficiary measure for the FY 2015 Hospital VBP Program. We believe this proposed performance period enables us to collect as much measure data as possible and the time necessary to process claims and incorporate measure data into Hospital VBP Program scores. We further proposed to adopt a corresponding prior period (May 1, 2011 through December 31, 2011) as the baseline period for purposes of calculating the performance standards. This proposed baseline period would be consistent with the baseline period

proposed for other Hospital VBP Program measures in that it precedes the performance period by two years.

We welcomed public comment on the proposed FY 2015 performance and baseline period for the Medicare spending per beneficiary measure.

Comment: Some commenters argued that the proposed performance period for the Medicare Spending per Beneficiary measure is not long enough to produce reliable data on which to base performance scores.

Response: We disagree. We believe that the proposed performance period will enable us to make robust comparisons of hospitals' spending levels, which we note are important considerations for quality improvement. As described in the FY 2013 IPPS/LTCH PPS proposed rule, we conducted an independent analysis of the minimum number of cases necessary for hospitals to receive a reliable score on the Medicare Spending per Beneficiary measure (77 FR 28089-90), and we believe that the 25 case minimum finalized below appropriately ensures that hospitals are being compared using reliable measure data. In addition, in order to confirm our expectation that the Medicare Spending per Beneficiary measure would be reliable, an expectation that was based on the large number of discharges included in the measure and the body of literature supporting the ability of cost measures to assess variability between hospitals, we have conducted comprehensive reliability testing of the measure. As discussed in section VIII.C.8.b of this preamble, that analysis found the measure to be reliable with a minimum of 10 cases. We discuss and finalize our minimum case number for the Medicare Spending per Beneficiary measure in section VIII.C.14.c. of this preamble.

After consideration of the public comments we received, we are finalizing the FY 2015 performance period for the Medicare Spending per Beneficiary measure as proposed.

d. Outcome Domain Performance Periods for FY 2015

(1) Mortality Measures

In the Hospital Inpatient VBP Program final rule (76 FR 26495), we finalized a 12-month performance period (July 1, 2011 – June 30, 2012) for the Outcome domain for the FY 2014 Hospital VBP Program. We also finalized a comparable prior period as the baseline period (July 1, 2009 through June 30, 2010) for purposes of calculating improvement points as well as the performance standards.

Due to the lengthy time needed for us to compile certain claims-based measure data at the individual hospital level and calculate the measure rates and scores (discussed more fully in section VIII.C.6.b. of this preamble in the context of our review and corrections proposal for claims-based measures), we must conclude the performance period for the mortality and AHRQ PSI measures for FY 2015 by June 30, 2013.

We are concerned about the difficulty that varied performance periods impose on participating hospitals. While we believe the public recognizes the need for different performance periods due to varied measure types and collection methods, we strive to propose performance periods that are as consistent as possible from one program year to the next. We believe this consistency is important for all hospitals that are working to improve the quality of care they provide to Medicare beneficiaries and to the entirety of the patient population. However, we are also aware that the Hospital VBP statute

requires that we establish and announce performance standards for Hospital VBP measures at least 60 days in advance of the performance period. Because we proposed to adopt these measures for FY 2015 in the FY 2013 IPPS/LTCH PPS proposed rule, which will not be effective until 60 days after it is finalized, we did not believe we could propose a performance period for these measures beginning earlier than October 1, 2012.

We note that this proposed performance period is less than 12 months, which may raise seasonality concerns with regard to these measures. We note further that we examined the independent analysis of these measures' reliability provided by Mathematica Policy Research, entitled, "Reporting Period and Reliability of AHRQ, CMS 30-day and HAC Quality Measures – Revised," which is available on our Web site (http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf), and which concluded that the measures may not achieve total reliability for all hospitals for reporting periods as short as 6 months. However, we believe that holding all hospitals accountable using the same period will fairly alleviate those concerns, particularly because these measures are risk-adjusted using a methodology that does not penalize hospitals for poor performance on the measure without a relatively larger sample size. As described further below, while we are concerned about these measures' reliability when adopting a performance period of less than 12 months, we believe that increasing the required minimum number of cases will assure sufficient reliability for these measures for value-based purchasing. Based on our stated objective to include outcome measures in the Hospital VBP Program, we believe that the proposed 9-month

performance period for these measures will produce sufficiently reliable results for hospitals.

Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28083), we proposed to adopt a 9-month performance period for the three 30-day mortality measures for FY 2015 from October 1, 2012 through June 30, 2013. We further proposed a comparable baseline period from October 1, 2010 through June 30, 2011.

We welcomed public comment on our proposal to adopt a performance period for the proposed FY 2015 mortality measures that runs from October 1, 2012 through June 30, 2013, and a baseline period that runs from October 1, 2010, through June 30, 2011.

Comment: Many commenters expressed concern about the proposed performance period for mortality measures, arguing that the proposed period is too short to provide reliable measure scores on which to base TPSs. Commenters noted that a statistical report released by CMS concluded that the mortality measures do not appear to be reliable even with up to 24 months of performance information.

Response: As stated above, we believe that holding all hospitals accountable using the same time period alleviates any significant concerns about seasonal variation in measure performance. We believe that our proposal is responsive to concerns about outcome measure reliability. Our proposals are designed to increase overall reliability of these measures, and exclude hospitals with the most unreliable measure rates from receiving a score in the outcome domain. We also considered the improved validity resulting from outcome measures that include a higher correlation with patient outcomes,

relative to process of care measures. As stated previously, we assessed measure reliability, TPS reliability and validity, and alignment with our policy goal to reduce cost and improve patient health outcomes when we developed our proposals.

Comment: Some commenters expressed concern about the proposed performance periods, suggesting that CMS should wait until it can adopt 12-month performance and baseline periods before adopting measures into the Hospital VBP Program. Commenters argued that 12-month performance periods represent the minimum length that CMS should consider finalizing.

Response: While we are also concerned about requiring hospitals to improve on quality metrics during varied performance periods, as stated above, we believe the proposed performance periods enable us to adopt robust quality measures covering important clinical topics as quickly as possible, thereby encouraging hospitals to improve their performance on the measures. We believe that the Hospital VBP Program's shifting focus from measures of clinical processes to outcome and efficiency measures rightly ensures that hospitals consider how to improve every aspect of the care provided to Medicare beneficiaries, an aim that we achieve by adopting new measures into the Hospital VBP Program as soon as possible.

After consideration of the public comments we received, we are finalizing the FY 2015 performance period and baseline period for the 30-day mortality measures as proposed.

(2) AHRQ PSI Composite Measure

We posted hospital performance data on the AHRQ PSI composite measure on Hospital Compare on October 14, 2011. Based on that posting date, we believe the earliest we could begin a performance period for FY 2015 is October 14, 2012. As discussed above, we must conclude the performance period for certain claims-based measures by June 30, 2013 in order to allow sufficient time to calculate the measure rates and scores. We note that we did not specify which measures' performance period we must end by June 30, 2013 in the proposed rule; we intended to refer specifically to the mortality measures and the AHRQ PSI composite measure.

Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28084), we proposed to adopt a nearly 9-month performance period (October 15, 2012 through June 30, 2013) for the AHRQ PSI composite measure for FY 2015. We believe that this performance period will provide us with sufficiently reliable data on which to base hospitals' scores. We further proposed to adopt a comparable prior period from October 15, 2010 through June 30, 2011 as the baseline period for purposes of calculating the performance standards.

While we would prefer to adopt a performance period longer than nearly 9-months in order to provide the most reliable measure data possible, we believe that the proposed period enables us to ensure that this measure, which assesses hospital performance on the critical topic of patient safety, is included in hospitals' FY 2015 TPSs and, therefore, will become a focus of quality improvement efforts. We note further that we examined the independent analysis of this measure's reliability provided by

Mathematica Policy Research, entitled, "Reporting Period and Reliability of AHRQ, CMS 30-day and HAC Quality Measures – Revised," which is available on our Web site (http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf), and which concluded that the AHRQ PSI composite measure achieves moderate reliability for the majority of hospitals for reporting periods of 6 months or longer. Based on our objective to include patient safety measures in the Hospital VBP Program, we believe that the proposed nearly 9-month performance period for this measure will produce reliable results for hospitals.

We welcomed public comment on these proposals.

Comment: Many commenters opposed the proposed performance period for the AHRQ PSI composite measure, arguing that CMS' standard for reliability testing for the measure is not sufficient for a payment program. Some commenters urged CMS to review measure reliability at 0.9 or higher to ensure that value-based incentive payments have high reliability rates.

Response: As described above, we believe that the AHRQ PSI composite measure is sufficiently reliable for purposes of the Hospital VBP program. The median reliability level of this measure is estimated to be 0.7 for a 9 month performance period. In our measure selection and performance period assessment, we also assessed the validity of the measure through its correlation with patient health outcomes, and the reliability of the TPS as indicative of hospital performance. We do not believe that focusing on the individual measure's reliability, to the exclusion of its contribution to the

reliability of the TPS, is the sole criterion for assessing the appropriateness of adopting measures to the Hospital VBP Program. We note that the AHRQ PSI composite measure is a measure of patient safety, a critical topic for quality measurement and improvement, and we believe strongly that adopting this measure for the Hospital VBP Program will ensure that hospitals focus on the topic of patient safety when working towards quality improvement.

We do not believe that commenters' suggestion of adopting 0.9 as the standard for measure reliability to the exclusion of other criteria is advisable. We further note that we assess quality measures for adoption in the Hospital VBP Program in many ways, including reliability, the number of hospitals receiving a score on the measure, the measure topic, and alignment with quality priorities.

After consideration of the public comments we received, we are finalizing the FY 2015 performance period and baseline period for the AHRQ PSI composite measure as proposed.

(3) CLABSI Measure

We posted CLABSI measure data on Hospital Compare on January 26, 2012. Pursuant to our commitment to post measure data on Hospital Compare at least one year prior to the beginning of a performance period for the Hospital VBP Program, the earliest we can begin a performance period for this measure is January 26, 2013. Because, as described above, we believe this measure captures important patient safety data, in this case related to infections that present the possibility of significant harm to hospitalized patients, we believe it is appropriate to adopt the measure as soon as possible for as

lengthy a performance period as possible. Adopting an approximately 11-month performance period for this measure will not, in our view, appreciably harm the measure's statistical reliability for purposes of value-based purchasing scoring, particularly because (as described below) we also proposed to adopt the measure steward's criteria for minimum number of cases to receive a measure score.

Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28084), we proposed to adopt an approximately 11-month performance period for the CLABSI measure from January 26, 2013 through December 31, 2013 with a comparable baseline period of January 26, 2011 through December 31, 2011 for purposes of calculating the performance standards.

We welcomed public comment on these proposals.

Comment: Many commenters were concerned about the proposed performance period for the CLABSI measure. Commenters were specifically concerned about the quality of CLABSI data that is being reported publicly, as they argued that less than 25 percent of hospitals met the minimum case threshold for reporting on Hospital Compare during the first quarter of public reporting. Commenters asserted that the relatively small sample is not representative of hospitals around the country.

Response: We understand commenters' concerns about the robustness of the CLABSI measure data. However, we believe that the best way to address these concerns is to include as much data from as many participating hospitals as possible. While the January 2011 Hospital Compare display included data for a relatively small number of hospitals, approximately 2,300 hospitals reporting CLABSI data were suppressed on the

January 2011 Hospital Compare due to insufficient volume of reported data. In total, over 2,600 hospitals submitted CLABSI data during the first quarter 2011 to the NHSN to comply with our Hospital IQR Program reporting requirement. An additional 600 hospitals reported to CMS that they did not treat a sufficient volume of ICU patients, and were not required to report CLABSI data to CMS. We also note that the May 2012 display of Hospital Compare included over 1,500 hospitals' CLABSI data, an increase of over 1,000 hospitals from the January posting. We anticipate the number of hospitals posted on Hospital Compare will increase to over 2,000 hospitals when we collect 12 months of CLABSI data. We do not believe it is appropriate to drop January 2011 reported data because we believe that the increased reliability using a12 month performance period and we believe that any sampling bias that may have been introduced by the relatively small number of reporting hospitals in the first quarter is eliminated by adopting a 12-month baseline period and including as many hospitals as possible. We believe that adopting a 12-month baseline period enables us to calculate performance standards that fully and fairly reflect national performance on the CLABSI measure without including the effects of seasonal variation.

We also wish to provide hospitals with baseline performance period data as soon as feasible to promote hospital quality improvement efforts. We anticipate that hospitals will also see their 12 month baseline performance period CLABSI data on Hospital Compare by January 2013. These same data are posted on Hospital Compare as part of our Hospital IQR program. We expect to provide Hospital Compare preview reports containing this information to hospitals during fall 2012 calendar year.

In addition, CDC advised us that CLABSI measure data may not be easily disaggregated to incident day, but rather, may only be reduced to incident month. For that reason, we are finalizing that instead of beginning the performance period for the CLABSI measure for FY 2015 with January 26, 2013 events, the performance period will begin with February 1, 2013 events.

After consideration of the public comments we received, we are finalizing an FY 2015 performance period for the CLABSI measure of February 1, 2013 through December 31, 2013 infection event data, with a baseline period of January 1, 2011 through December 31, 2011 infection event data.

The final performance and baseline periods for all of the FY 2015 measures appear below:

Domain	Baseline period	Performance period
Clinical Process of Care	January 1, 2011 – December 31, 2011	January 1, 2013 – December 31, 2013
Patient Experience of Care	January 1, 2011 – December 31, 2011	January 1, 2013 – December 31, 2013
Outcome ● Mortality ● AHRQ PSI ● CLABSI	● October 1, 2010 – June 30, 2011 ● October 15, 2010 – June 30, 2011 ● January 1, 2011 – December 31, 2011	● October 1, 2012 – June 30, 2013 ● October 15, 2012 – June 30, 2013 ● February 1, 2013 – December 31, 2013
Efficiency ● Medicare Spending Per Beneficiary-1	● May 1, 2011 – December 31, 2011	● May 1, 2013 – December 31, 2013

e. Performance Periods for FY 2016 Measures

In order to provide relatively more reliable data for the three proposed 30-day mortality measures and the AHRQ PSI composite measure, we considered how we could adopt a 24-month performance period for the FY 2016 Hospital VBP Program. We do not believe it is feasible to do so at this time given the statutory requirement that we establish and announce performance standards at least 60 days in advance of the applicable performance period. However, we intend to propose to adopt a 24-month performance period for these measures as soon as is practicable and will consider a 24-month performance period in future rulemaking.

Given the time constraints associated with the annual IPPS/LTCH PPS rulemaking schedule, we believe that the longest performance period we can propose for FY 2016 at this time is 21 months. We believe that this performance period will provide relatively more reliable measure data and will enable us to consider adopting a 24-month performance period in the future.

Therefore in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28084), we proposed to adopt a 21-month performance period for the three proposed 30-day mortality measures and the AHRQ PSI composite measure for the FY 2016 Hospital VBP Program, from October 1, 2012 through July 30, 2014. We further proposed a baseline period of October 1, 2010 through July 30, 2011, for purposes of calculating performance standards and measuring improvement. We note that this baseline period is identical to the proposed baseline period for these measures for FY 2015. We also note that this baseline period is shorter than the proposed performance period. We believe it is

appropriate to use the most recently-available data to calculate performance standards and are concerned about the possibility of using data from several years prior to the performance period for performance standards. However, we sought public comment on whether we should adopt a 24-month baseline period.

We welcomed public comment on this proposal. We also sought comments on the possibility of adopting a "rolling" 2-year performance period for certain claims-based measures during which we would score hospitals using 24 months of data. As an example, under such a policy for mortality measures, hospitals could be scored for the FY 2018 Hospital VBP Program using data from the performance periods for FY 2017 (while not yet proposed, one possibility for that year could be July 1, 2013 through June 30, 2015). For subsequent fiscal years, we would drop the oldest 12 months of data from that period and add the next 12 months. The performance period for the FY 2019 Hospital VBP Program under that policy could be July 1, 2014 through June 30, 2016.

Comment: Many commenters applauded CMS' proposal to move towards a 24-month performance period for outcome measures in the future. However, some commenters argued that CMS should not finalize shorter performance periods for these measures in the interim, citing reliability concerns.

Response: We thank commenters for their support. We believe that our proposal is responsive to concerns about outcome measure reliability, since we proposed a 21 month FY 2016 performance period and a 25 case minimum threshold for including mortality measures for the FY 2015 Hospital VBP Program. Both proposals are designed to increase the overall reliability of these measures. We also considered the improved

validity resulting from more outcome measures that include a higher correlation with patient outcomes, relative to process of care measures. As stated previously, we assessed measure reliability, TPS reliability and validity, and alignment with our policy goal to reduce cost and improve patient health outcomes when we developed our proposals. We disagree that we should exclude these measures from the TPS until we can adopt lengthier performance periods. We believe that scoring hospitals on these measures, even with relatively shorter performance periods, ensures that the topics covered by these measures remain important components of hospitals' quality improvement efforts.

Comment: Some commenters opposed the proposal to adopt longer performance periods for certain measures in FY 2016. Commenters argued that the varied performance periods are confusing for hospitals, and that using longer timeframes results in hospitals being held accountable for old data.

Response: We understand commenters' concerns about the varied performance periods finalized for the Hospital VBP Program and about using relatively older data. However, we make every effort to communicate with hospitals about the time periods during which their performance will be assessed. We will continue to work to notify hospitals about the measures, performance periods, performance standards, and other components of the Hospital VBP Program.

We view the use of relatively older data as a necessary component of the Hospital VBP Program given the current state of quality measurement. Many measures in the Hospital VBP Program are claims-based, which often require more time to compile and calculate, and require relatively longer performance periods than other types of measures

to maximize reliability. While this may result in hospitals' being held accountable for data from prior fiscal years, we do not believe this policy to be avoidable at this time.

After consideration of the public comments we received, we are finalizing the FY 2016 performance period and baseline period for the 30-day mortality measures as proposed. However, based on the AHRQ PSI measure's posting on Hospital Compare on October 14, 2011, we do not believe we can finalize a performance period for that measure beginning on October 1, 2012. Based on the date of the posting, we believe that the longest performance period we could adopt would run from October 15, 2012 to June 30, 2014, with a corresponding baseline period from 2 years prior.

The table below displays the final performance periods and baseline periods for the FY 2016 mortality and AHRQ PSI composite measures.

Measure	**Baseline period**	**Performance period**
Mortality	October 1, 2010 – June 30, 2011	October 1, 2012 – June 30, 2014
AHRQ PSI	October 15, 2010 – June 30, 2011	October 15, 2012 – June 30, 2014

11. Performance Standards for the Hospital VBP Program for FY 2015 and FY 2016

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established and announced not later than 60 days before the beginning of the

performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. Achievement and improvement standards are discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513). In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28085), we proposed to codify this for performance standards in our regulations at § 412.165.

b. Performance Standards for the FY 2015 Hospital VBP Program Measures

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28085), we proposed to establish performance standards that apply to the FY 2015 Hospital VBP Program using the same methodologies that we previously adopted for the FY 2013 and FY 2014 Hospital VBP Programs. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for a detailed discussion of the methodology we adopted for the clinical process of care, patient experience of care, and outcome measures, and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) for a discussion of the methodology we adopted for the Medicare spending per beneficiary measure.

We continue to believe that the finalized methodology for calculating performance standards is appropriate for the Hospital VBP Program given that the

Program remains relatively new to hospitals and the public. The proposed performance standards for the clinical process, outcome, and Medicare spending per beneficiary measures appear in the first table below, while the proposed performance standards for the patient experience of care (HCAHPS survey) measure appears in the second table below. We note that the performance standards displayed below represent estimates based on the most recently-available data; we are updating the standards in this final rule. We also note that the performance standards for the CLABSI measure and the AHRQ PSI composite measure are calculated with lower values representing better performance, in contrast to other measures, on which higher values indicate better performance. We note further that we inadvertently omitted the benchmark for the AMI-10 measure and the achievement threshold and benchmark for the HF-1 measure in the proposed rule. We corrected those omissions in the FY 2013 IPPS/LTCH PPS proposed rule correction notice (77 FR 34327 through 34328) and the corrected table appears below.

Proposed Performance Standards for the FY 2015 Hospital VBP Program Clinical Process of Care and Outcome Domains, and the Medicare Spending Per Beneficiary Measure [Corrected]			
Clinical Process of Care Measures			
Measure ID	**Description**	**Achievement Threshold**	**Benchmark**
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.72727	1.00000
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.92857	1.00000
AMI-10	Statin Prescribed at Discharge	0.90474	1.00000
HF-1	Discharge Instructions	0.92090	1.00000
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	0.97129	1.00000
PN-6	Initial Antibiotic Selection for CAP	0.93671	0.99832

Proposed Performance Standards for the FY 2015 Hospital VBP Program Clinical Process of Care and Outcome Domains, and the Medicare Spending Per Beneficiary Measure [Corrected]			
	in Immunocompetent Patient		
SCIP-Card-2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period	0.95122	1.00000
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.97872	1.00000
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	0.97882	1.00000
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.96154	0.99905
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.94799	0.99824
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2	0.93333	1.00000
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery	0.94118	0.99938
Outcome Measures			
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	0.8477	0.8673
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate	0.8861	0.9042
MORT-30-PN	Pneumonia (PN) 30-Day Mortality Rate	0.8818	0.9021
PSI-90	Patient safety for selected indicators (composite)	0.4006	0.2754
CLABSI	Central Line-Associated Blood Stream Infection	0.442	0.000
Efficiency Measures			
MSPB-1	Medicare Spending per Beneficiary	Median Medicare spending per beneficiary ratio across all hospitals during the performance period	Mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals during the performance period

Proposed Performance Standards for the FY 2015 Hospital VBP Program Patient Experience of Care Domain			
HCAHPS Survey Dimension	**Floor**	**Achievement Threshold**	**Benchmark**
Communication with Nurses	49.22%	76.28%	85.56%
Communication with Doctors	57.31%	79.61%	88.72%
Responsiveness of Hospital Staff	34.83%	62.75%	78.59%
Pain Management	43.05%	69.24%	78.24%
Communication about Medicines	28.11%	60.46%	71.72%
Hospital Cleanliness & Quietness	40.35%	63.79%	78.46%
Discharge Information	55.10%	83.29%	89.60%
Overall Rating of Hospital	29.26%	67.73%	83.13%

We welcomed public comment on these proposed performance standards.

Comment: Some commenters noted that the performance standards table in the FY 2013 IPPS/LTCH PPS proposed rule omitted the achievement thresholds and benchmarks for HF-1 and AMI-10.

Response: We thank commenters for their attention to this matter. As noted above, we published the proposed performance standards values for those two measures in the FY 2013 IPPS/LTCH PPS proposed rule correction notice (77 FR 34327 through 34328).

Comment: Some commenters expressed support for the proposed performance standards for FY 2015.

Response: We thank commenters for their support.

Comment: Some commenters noted a slight decline in the Clinical Process of Care performance standards for the FY 2015 Program compared to the finalized standards for FY 2014. Commenters suggested that CMS should analyze these differences and ascertain whether this decline was the result of a true decline in quality

performance or other factors. Other commenters urged CMS to monitor the Hospital VBP Program closely, particularly as the first year of full implementation looms, to ensure that the program's goals are met and that no unintended consequences result.

Response: We thank commenters for their input. We intend to monitor hospitals' performance under the Hospital VBP Program closely, with particular attention to changes in hospitals' quality performance over time.

Comment: Some commenters argued that CMS should display the numerical values of the performance standards for the Medicare Spending per Beneficiary measure rather than the descriptions ("Median Medicare spending per beneficiary ratio across all hospitals during the performance period" and "Mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals during the performance period"). These commenters did not support the methodology for calculating Medicare Spending per Beneficiary performance standards because those numerical values were not provided.

Response: We disagree. We finalized the methodology we would use to assess hospital performance on the Medicare Spending per Beneficiary measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51655) and believe that we have met the requirement to notify hospitals of the performance standards. We will provide the numerical equivalents when they are available, after the conclusion of the performance period. Further, the Medicare Spending per Beneficiary measure is constructed as a measure of costs attributable to patient care during the specified episode of care. We do not believe it is helpful for hospitals to be compared against performance standards constructed from

baseline period data, on this payment-based measure, given potential changes in Medicare payment policy, changes in market forces, and changes in utilization practices. The national median Medicare Spending per Beneficiary ratio will be 1.0, because it is the ratio of the hospital's score to the national median.

For hospitals' information, we are providing historical benchmark and achievement threshold information during the period May 15, 2010–February 14, 2011. For hospitals' information, we are providing historical benchmark and achievement threshold information during the period May 15, 2010–February 14, 2011, in addition to the measure rates for this period, which were displayed on Hospital Compare on April 19, 2012. During this historical performance period, this median ratio was associated with a Medicare Spending per Beneficiary amount of $17,988.04. Hospitals were given this national median Medicare Spending per Beneficiary amount on a Hospital Open Door Forum. We would also like to provide hospitals with the amount that corresponds to what would have been the benchmark for the measure, were this an actual Hospital VBP performance period. The benchmark Medicare Spending per Beneficiary ratio, or mean of the lowest decile, was 0.806. This ratio corresponds to a Medicare Spending per Beneficiary amount of $14,495.

After consideration of the public comments we received, we are finalizing the FY 2015 performance standards. As described further above, we are not finalizing performance standards for AMI-10 because we are not including it in the FY 2015 measure set.

The final performance standards for the clinical process, outcome, and Medicare spending per beneficiary measures appear in the first table below, while the final performance standards for the patient experience of care (HCAHPS survey) measure appears in the second table below.

Final Performance Standards for the FY 2015 Hospital VBP Program Clinical Process of Care, Outcome, and Efficiency Domains			
Clinical Process of Care Measures			
Measure ID	**Description**	**Achievement Threshold**	**Benchmark**
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.80000	1.00000
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.95349	1.00000
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	0.94118	1.00000
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.97783	1.00000
SCIP-Card-2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period	0.95918	1.00000
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.97175	1.00000
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	0.98639	1.00000
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.98637	1.00000
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.97494	1.00000
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2	0.95798	0.99767
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes	0.94891	0.99991

Final Performance Standards for the FY 2015 Hospital VBP Program Clinical Process of Care, Outcome, and Efficiency Domains			
	Within 24 Hours Prior to Surgery to 24 Hours After Surgery		
Outcome Measures			
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	0.847472	0.862371
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate	0.881510	0.900315
MORT-30-PN	Pneumonia (PN) 30-Day Mortality Rate	0.882651	0.904181
PSI-90	Patient safety for selected indicators (composite)	0.622879	0.451792
CLABSI	Central Line-Associated Blood Stream Infection	0.437	0.000
Efficiency Measures			
MSPB-1	Medicare Spending per Beneficiary	Median Medicare spending per beneficiary ratio across all hospitals during the performance period	Mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals during the performance period

Final Performance Standards for the FY 2015 Hospital VBP Program Patient Experience of Care Domain			
HCAHPS Survey Dimension	**Floor**	**Achievement Threshold**	**Benchmark**
Communication with Nurses	47.77%	76.56%	85.70%
Communication with Doctors	55.62%	79.88%	88.79%
Responsiveness of Hospital Staff	35.10%	63.17%	79.06%
Pain Management	43.58%	69.46%	78.17%
Communication about Medicines	35.48%	60.89%	71.85%
Hospital Cleanliness & Quietness	41.94%	64.07%	78.90%
Discharge Information	57.67%	83.54%	89.72%
Overall Rating of Hospital	32.82%	67.96%	83.44%

We are also aware that once the ICD-10-CM/PCS coding transition is completed, we will be faced with comparing hospitals' performance from baseline periods coded

using ICD-9-CM with performance periods coded using ICD-10-CM/PCS. We note that constructing performance standards from such baseline periods could produce unforeseen consequences for quality measurement and performance scoring. Therefore, we sought comments on how to fairly compare hospitals' performance on quality measures when captured in different coding sets.

Comment: Some commenters expressed concern about how to measure hospitals' performance when measures or coding sets change. Commenters argued that it would be unfair to compare hospitals' performance using ICD-9-CM in the baseline period and ICD-10-CM/PCS in the performance period. Commenters urged us to re-run the data using the same coding set for both periods in order to ensure fair comparisons.

Response: We thank commenters for their input. We will consider these comments in future rulemaking and closely monitor future measure specification updates incorporating ICD-10 codes into our future measure proposals. We will also closely monitor how measure rates change following ICD-10 adoption in our future performance standards and measure proposals.

c. Performance Standards for FY 2016 Hospital VBP Program Measures

As described further above, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28086), we proposed to adopt the three 30-day mortality measures and the AHRQ PSI composite measure for the FY 2016 Hospital VBP Program. We also proposed to adopt performance standards for these measures based on the proposed baseline periods outlined above. Proposed performance standards for these measures appear in the table below. We noted that the performance standards displayed below represent estimates

based on the most recently-available data, and stated that we would update the standards in this final rule. We also note that the performance standards for the AHRQ PSI composite measure are calculated with lower values representing better performance, in contrast to the mortality measures, on which higher values indicate better performance.

Proposed Performance Standards for FY 2016 Hospital VBP Programs Outcome Domain: Mortality/PSI Composite Measures			
Outcome Measures			
Measure ID	**Description**	**Achievement Threshold**	**Benchmark**
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.8477	0.8673
MORT-30-HF	Heart Failure (HF) 30-day mortality rate	0.8861	0.9042
MORT-30-PN	Pneumonia (PN) 30-day mortality rate	0.8818	0.9021
PSI-90	Patient safety for selected indicators (composite)	0.4006	0.2754

Comment: Many commenters expressed general opposition to the proposed performance standards for the FY 2016 Program based on their opposition to further adoption of the proposed measures for that program year.

Response: We responded to comments opposing the adoption of these measures above and are finalizing our adoption of those measures. We do not interpret the comments as objecting specifically to the proposed FY 2016 performance standards if we finalized the measures themselves.

After consideration of the public comments we received, we are finalizing the FY 2016 performance standards as proposed. Set out below are the final performance standards for the three 30-day mortality measures and the AHRQ PSI composite measure.

Final Performance Standards for FY 2016 Hospital VBP Programs Outcome Domain: Mortality/PSI Composite Measures			
Outcome Measures			
Measure ID	**Description**	**Achievement Threshold**	**Benchmark**
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.847472	0.862371
MORT-30-HF	Heart Failure (HF) 30-day mortality rate	0.881510	0.900315
MORT-30-PN	Pneumonia (PN) 30-day mortality rate	0.882651	0.904181
PSI-90	Patient safety for selected indicators (composite)	0.622879	0.451792

d. Adopting Performance Periods and Standards for Future Program Years

For prior program years, with the exception of the Hospital Inpatient VBP Program proposed and final rules, we have proposed and finalized policies for the Hospital VBP Program in the IPPS/LTCH PPS and OPPS/ASC regulations. However, we do not believe these two rulemaking vehicles are ideally suited for additional Hospital VBP proposals. While we are aware that it is convenient for the public when additional proposals are made in a relatively limited number of rulemaking vehicles, we are concerned about the limitations that these regulations' schedules place on our ability to propose and finalize quality measures, performance periods, and performance standards in a timely manner.

In order to facilitate quality measure adoption for the Hospital VBP Program and ensure that hospitals are kept fully aware of the performance standards to which we intend to hold them accountable and the performance periods during which their performance will be measured, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28087), we proposed to update performance periods and performance standards

for future program years via notice on our Web site or another publicly-available Web site. We would establish future performance standards for the clinical process of care, outcome, and patient experience of care measures using the same methodology that we first finalized in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26513). We would establish future performance standards for the Medicare spending per beneficiary measure using the same methodology that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656). In the case of other types of measures whose scoring would not be appropriately described by the methodologies outlined above, we intend to propose and finalize additional scoring methodologies.

We believe that this proposal will enable us to adopt measures representing the best in medical practice into the Hospital VBP Program more quickly and will allow us to establish and announce performance standards and performance periods when necessary outside the annual IPPS/LTCH PPS and OPPS/ASC rulemaking schedules. We believe this flexibility is especially necessary as the Hospital VBP Program continues to evolve and incorporate new types of quality measures.

We welcomed public comment on this proposal.

Comment: Many commenters expressed support for the proposal to adopt performance standards and performance periods for future program years via notice on the CMS Web site or other publicly-available forum.

Response: We thank commenters for their support.

Comment: Some commenters expressed opposition to the proposal to adopt performance periods and performance standards outside of the rulemaking process.

Commenters argued that the annual IPPS rulemaking process is the most transparent, understood venue for hospitals to track changes to Medicare's programs.

Response: We believe that adopting performance periods and performance standards outside the rulemaking process provides us with more flexibility than the annual rulemaking processes allow. We intend to consider fully any comments we receive on the Hospital VBP Program each year, and we do not believe that finalizing this policy precludes stakeholders from providing valuable input for our consideration.

Comment: Some commenters were concerned about CMS' proposal to adopt performance periods and performance standards outside the rulemaking process as they believed that stakeholders would no longer be able to comment on the proposals.

Response: As stated above, we intend to consider fully any public comments we receive on the Hospital VBP Program when developing our policies for future program years. Since we would be updating performance standards and performance periods under this policy, not changing the underlying finalized methodology in either case, we believe this policy provides us additional flexibility without compromising the public's ability to provide input.

We also believe that our proposal would improve quality because it would enable us to use more recent baseline information for the performance standard calculations. Currently, we are only able to use the most recent data available at the time we issue the IPPS/LTCH PPS proposed and final rules. This proposal would allow us to use more current data extracts because we would not be limited by the rulemaking calendar when posting performance standards.

Comment: To the extent that CMS uses rulemaking to adopt requirements for the Hospital VBP Program in the future, some commenters urged us to use a stand-alone regulation, as was done with the Program's initial rulemaking. Commenters suggested that the proposal and finalization of new policies in the IPPS and OPPS rules has been confusing for hospitals and other stakeholders.

Response: We believe that hospitals and the public are well aware of the annual IPPS and OPPS rulemaking schedules, though we understand that including Hospital VBP proposals in both IPPS and OPPS rules may have been confusing. We believe it is appropriate to update the Hospital VBP Program, which generally applies to IPPS hospitals, in the annual IPPS rule as necessary because hospitals are generally aware of that regulation and monitor it closely. However, we reserve the right to adopt Hospital VBP policies in other rulemaking vehicles as necessary.

After consideration of the public comments we received, we are finalizing our proposal to adopt performance standards and performance periods via notice on our Web site or another publicly-available Web site.

12. FY 2015 Hospital VBP Program Scoring Methodology

a. General Hospital VBP Program Scoring Methodology

In the Hospital Inpatient VBP Program final rule, we adopted a methodology for scoring clinical process of care, patient experience of care, and outcome measures. As noted in that rule, this methodology outlines an approach that we believe is well understood by patient advocates, hospitals, and other stakeholders because it was developed during a lengthy process that involved extensive stakeholder input, and was

based on a scoring methodology we presented in a report to Congress. We also noted in that final rule that we had conducted extensive additional research on a number of other important methodology issues to ensure a high level of confidence in the scoring methodology (76 FR 26514). In addition, we believe that, for reasons of simplicity, transparency, and consistency, it is important to score hospitals using the same general methodology each year, with appropriate modifications to accommodate new domains and measures. We finalized a scoring methodology for the Medicare spending per beneficiary measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28087), for the FY 2015 Hospital VBP Program, we proposed to use these same scoring methodologies to score hospital performance. We believe these scoring methodologies continue to appropriately capture hospital quality as reflected by the finalized quality measure sets. We also note that re-adopting the finalized scoring methodology from prior program years represents the simplest and most consistent policy for providers and the public.

Comment: Some commenters suggested that CMS should consider suspending any further changes to the Hospital VBP Program for at least two years in order to allow hospitals to implement quality improvement policies. Other commenters argued that the Hospital VBP Program is challenging to hospitals due to the burden of chart abstraction. Commenters argued that preparing for new measures requires substantial work by hospital staff, and further suggested that the complicated calculations involved in

Hospital VBP Program payments could be simplified by adding measure scores together and calculating confidence intervals.

Response: We do not believe it would be appropriate to suspend further changes to the Hospital VBP Program at this time. While we are aware that chart abstraction is a burden to hospitals, we note that, because the Hospital VBP Program is built on the quality measures already adopted for the Hospital IQR Program, the Hospital VBP Program in this regard does not impose an additional reporting burden on hospitals.

We note further that the finalized Hospital VBP Program scoring methodology is based on research dating back to the 2007 Report to Congress, as further described in the Hospital Inpatient VBP Program final rule (76 FR 26493). We do not believe that simply adding measure scores together and calculating confidence intervals fully and fairly represents hospitals' performance on quality measures, nor does it enable objective comparisons between hospitals' scores.

Comment: Some commenters argued that the Hospital VBP Program TPS should be risk-adjusted to account for the challenges faced by urban safety-net hospitals, including the increased follow-up and post-discharge care required by beneficiaries living in poverty and with limited access to care. Commenters noted that patients who choose urban safety-net hospitals are sicker than typical hospitals patients and more complicated to treat.

Response: We intend to monitor closely the effects of the Hospital VBP Program on hospitals, including any systemic disparities that may result. We note that many of the finalized measures for the Hospital VBP Program are risk-adjusted, but we do not believe

it is appropriate to separately risk-adjust hospitals' TPSs at this time. We believe the TPS, as calculated according to the finalized scoring methodology, is sufficiently reliable for purposes of awarding value-based incentive payments under the Hospital VBP Program.

Comment: Some commenters urged CMS to analyze Hospital VBP Program scores to determine whether events such as tropical storms Irene and Lee had any effect on hospitals' scores. Commenters noted that the storms interrupted many services provided by hospitals, including data collection, and argued that hospitals should not be penalized for effects resulting from those extreme weather events.

Response: As stated above, we intend to closely monitor the impact of the Hospital VBP Program on hospitals. We do not believe that the Hospital VBP Program requires an additional mechanism for disaster waivers than is provided in the Hospital IQR Program. We encourage hospitals in areas affected by tropical storms Irene and Lee, or other types of natural disasters, to seek disaster extensions or waivers under the Hospital IQR Program. Hospitals waived from Hospital IQR Program data reporting during applicable Hospital VBP performance periods and not meeting Hospital VBP minimum case, measure, and domain thresholds would be excluded from the applicable Hospital VBP Program year and would not be subject to the base operating DRG payment amount reduction for that fiscal year.

Comment: Some commenters argued that the Hospital VBP Program should also apply to Medicare Advantage (MA) beneficiaries in order to reward quality provided by hospitals more fully. Other commenters specifically argued that the AHRQ PSI

composite measure should capture both fee-for-service and Medicare Advantage beneficiaries.

Response: The Hospital VBP Program would apply to MA beneficiaries in cases in which the hospital did not have an agreement governing payment with the MA organization, as the hospital would be entitled, under section 1866(a)(1)(O) of the Act to the same payment from the MA organization as it would receive from us if the beneficiary were not enrolled in a MA plan. In the case of a hospital that does have an agreement governing payment with the MA organization, that agreement would govern the payment amount, and it would be up to the parties to that agreement whether to take the Hospital VBP Program into account in establishing payment amounts.

With respect to whether the AHRQ PSI composite measure should capture MA beneficiaries, based on the methodology currently used to collect this measure (it is claims-based), data involving MA beneficiaries would not be captured because claims for those beneficiaries' services are handled by their MA plans.

After consideration of the public comments we received, we are finalizing the scoring methodology for the FY 2015 Hospital VBP Program as proposed.

b. Domain Weighting for the FY 2015 Hospital VBP Program for Hospitals That Receive a Score on All Four Domains

As we stated in the Hospital Inpatient VBP Program final rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care, and functional status measures (for example, measures assessing physical and mental

capacity, capability, well-being and improvement). We took these considerations into account when developing the domain weighting proposal outlined below.

As discussed above, we proposed to add the Efficiency domain to the Hospital VBP Program beginning with the FY 2015 Hospital VBP Program. Therefore, we proposed the following domain weights for the FY 2015 Hospital VBP Program for hospitals that receive a score on all four proposed domains:

Proposed Domain Weights for the FY 2015 Hospital VBP Program for Hospitals Receiving a Score on All Proposed Domains	
Domain	**Weight**
Clinical Process of Care	20 percent
Patient Experience of Care	30 percent
Outcome	30 percent
Efficiency	20 percent

We believe this domain weighting appropriately reflects our priorities for quality improvement in the inpatient hospital setting and aligns with the National Quality Strategy's priorities. We believe that the proposed domain weighting will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient experience. We note that the proposed domain weighting places the strongest relative emphasis on outcomes and the patient experience, which we view as two critical components of quality improvement in the inpatient hospital setting. We further note that the proposed domain weighting, for the first time, incorporates a measure of efficiency and continues to provide substantial weight to clinical processes. We welcomed public comment on this proposed weighting methodology.

Comment: Some commenters supported the proposed domain weighting for FY 2015, arguing that it represents an appropriate balance between quality and efficiency domains.

Response: We thank commenters for their support.

Comment: Some commenters opposed the proposed domain weighting for FY 2015, arguing that the proposed outcome measures and the Medicare Spending per Beneficiary measure should not be included in the Hospital VBP Program and should therefore not be given any domain weight. Other commenters specifically opposed the proposed weighting for the Efficiency domain, arguing that 20 percent is too high for a domain containing one measure and suggesting that placing such weight on a spending measure may result in unintended consequences for patient care.

Response: We appreciate the comment, but disagree for several reasons. Since first implementing the Hospital VBP Program, we have signaled our intent to move the Program from measures of clinical processes to measures of outcomes and efficiency. We signaled this intention because we believe that outcome and efficiency measures provide the most direct incentives for hospitals to improve their quality performance in ways that are directly applicable to patients. Further, efficiency measures provide additional incentives for hospitals to control costs, which is an important goal for the Medicare program and for the health system at large. We do not believe that lowering the domain weighting proposed for outcome or efficiency measures will sufficiently encourage hospitals to strive for improvements in the quality of care provided to Medicare beneficiaries and to all of their patients. As we explain in more detail in

responses to comments above, we believe that it is appropriate to include the 30-day mortality measures and the Medicare spending per beneficiary measure in the Hospital VBP Program.

Comment: Some commenters called on CMS to revisit our finalized domain weighting for FY 2014.

Response: We do not believe it is appropriate to revisit the details of the finalized FY 2014 Hospital VBP Program at this time. We have strived to provide hospitals as many details about each program year as far in advance of the applicable performance periods as possible. We do not believe it would be equitable to hospitals that strove to improve their quality performance on FY 2014 measures during the FY 2014 performance periods to change the finalized FY 2014 domain weights.

Comment: Some commenters noted the drop in weighting for clinical process of care measures over program years. Other commenters argued that clinical processes should receive more weight than outcomes until broader risk adjustment is perfected.

Response: As stated above, we signaled our intention to move the Hospital VBP Program from its initial focus on measures of clinical processes, which are not risk adjusted, towards measures of outcomes and efficiency. Shifting the program's focus would necessarily mean reducing the domain weighting for the Clinical Process of Care domain over time. We believe that this reduction is appropriate given the need for quality improvement efforts to more closely include measures of outcomes and efficiency.

We do not believe that further risk adjustment to the finalized outcome measures is appropriate at this time. As described further above, the mortality measures currently use the Hierarchical Condition Category (HCC) grouping of clinical conditions and hospital case-mix for risk adjustment. The HCC model makes use of all physician and hospital encounter diagnoses and was designed to predict a beneficiary's expenditures based on the total clinical profile represented by all of his/her assigned HCCs. Additionally, there are several exclusions to the mortality measures, such as enrollment in a hospice program. We refer commenters to the extensive documentation of the mortality measure methodology at http://www.qualitynet.org. However, as we have described above, we intend to monitor the effects of the Hospital VBP Program on hospitals and will propose other programmatic changes as necessary.

Comment: Some commenters expressed concerns with the weighting of the Patient Experience of Care domain, arguing that patients' severity of illness negatively affects their HCAHPS scores. A few commenters mentioned a Cleveland Clinic analysis that shows a greater than expected impact of severity of illness on HCAHPS scores.

Response: We adjust the HCAHPS data for patient characteristics that are not under the control of the hospital and that may affect patient reports of hospital experiences. The goal of adjusting for patient-mix is to estimate how different hospitals would be rated if they all provided care to comparable groups of patients. In developing the HCAHPS patient-mix adjustment (PMA) model, we sought important and statistically significant predictors of patients' HCAHPS ratings that also vary meaningfully across hospitals (O'Malley et al., 2005). The PMA model includes self-reported health status,

education, service line (medical, surgical, or maternity care), age, response percentile order (also known as "relative lag time," which is based on the time between discharge and survey completion), service by linear age interactions, and primary language other than English.

With respect to a Cleveland Clinic analysis mentioned by a few commenters that shows a greater than expected impact of severity of illness on HCAHPS scores, our understanding is that this analysis does not examine associations between those patient characteristics and HCAHPS scores after standard CAHPS PMA is applied, which would be expected to remove most or all of that association. We also note that this study is not based on national data.

We are aware of no data suggesting that patient characteristics result in bias in the HCAHPS patient-mix adjusted data used in the Hospital VBP Program. We therefore do not believe that the proposed weighting for the Patient Experience of Care domain is too high or penalizes hospitals with relatively sicker patients.

Comment: Some commenters supported the proposed Efficiency domain weight of 20 percent, and two commenters suggested that CMS consider increasing it to 30 percent over time. One commenter supported a 30 percent weight for the Efficiency domain at the outset. Some commenters suggested that 20 percent was too high, because the measure is the sole measure in an Efficiency domain or because the commenters do not support inclusion of the Medicare Spending per Beneficiary measure in the Hospital VBP Program for FY 2015. These commenters suggested that the Efficiency domain be excluded or given a weight of no more than 5 percent.

Response: We appreciate the comments in support of an initial weight of 20 percent for the Efficiency domain. We will consider increasing the domain weight for future years, as hospitals gain experience with the domain and build stronger relationships with the providers and suppliers who care for their patients before and after hospitalization to maintain high quality while controlling costs. We disagree with the commenters who stated that a 20 percent Efficiency domain weight is too high. We believe that attributing significant weight to this domain is critical to ensuring that hospitals make efforts to provide effective care on an inpatient basis and build stronger relationships with the providers and suppliers who care for their patients before and after the hospitalization.

Comment: Some commenters argued that the changing domain weights over time make it difficult to evaluate a hospital's performance over time.

Response: While we are aware that direct comparisons between program years become more difficult with the changes we have proposed in domain weights over time, we believe that such changes are necessary to continue shifting the program from its initial focus on clinical processes and the patient experience to accommodate outcome and efficiency measures as well.

After consideration of the public comments we received, are finalizing the FY 2015 domain weighting as proposed. The final domain weights are set out below.

Final Domain Weights for the FY 2015 Hospital VBP Program for Hospitals Receiving a Score on All Proposed Domains	
Domain	**Weight**
Clinical Process of Care	20 percent

Final Domain Weights for the FY 2015 Hospital VBP Program for Hospitals Receiving a Score on All Proposed Domains	
Domain	**Weight**
Patient Experience of Care	30 percent
Outcome	30 percent
Efficiency	20 percent

c. Domain Weighting for Hospitals Receiving Scores on Fewer than Four Domains

In prior program years, we finalized a policy that hospitals must have received domain scores on all finalized domains in order to receive a TPS. However, since the Hospital VBP Program has evolved from its initial two domains to an expanded measure set with four quality domains, we considered whether it was appropriate to continue this policy.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28088), as described further below, we proposed a higher minimum number of cases for the three 30-day mortality measures for FY 2015 than was finalized for the FY 2014 Hospital VBP Program in order to improve these measures' reliability given the relatively shorter proposed performance period described above. However, we are concerned that the relatively higher minimum number of cases could result in a substantially larger number of hospitals being excluded from the Hospital VBP Program. We believe that we should make a concerted effort to include as many hospitals as possible in the Program in order to offer quality incentives to as many hospitals as possible and encourage quality improvement as broadly as possible throughout the health care system while maintaining our focus on measure and scoring reliability.

Therefore, we proposed that, for the FY 2015 Hospital VBP Program and subsequent fiscal years, hospitals with sufficient data to receive at least two domain scores (that is, sufficient cases and measures to receive a domain score on at least two domains) will receive a TPS. We also proposed that, for hospitals with at least two domain scores, TPSs would be reweighted proportionately to the scored domains to ensure that the TPS is still scored out of a possible 100 points and that the relative weights for the scored domains remain equivalent to the weighting outlined above. We believe that this proposal allows us to include relatively more hospitals in the Hospital VBP Program while continuing to focus on reliably scoring hospitals on their quality measure performance.

We welcomed public comment on this proposal.

Comment: Some commenters supported the proposal to provide a TPS to hospitals with sufficient data in at least two domains rather than requiring that hospitals receive a score in all four domains to receive a TPS. Commenters acknowledged CMS' effort to ensure that as many hospitals as possible participate in the Hospital VBP Program and suggested that CMS monitor the effects of this proposed change on included and excluded hospitals.

Response: We thank commenters for their support. We intend to closely monitor this policy's effects on hospitals' scores.

Comment: Some commenters expressed concerns about the proposal to provide hospitals with TPSs for FY 2015 if they receive domain scores on at least 2 of the 4

domains. Commenters were concerned that low-volume hospitals could be penalized under this policy and noted that comparing hospitals' TPSs would become more difficult.

Response: We disagree with the commenters' characterization of our proposal. By enabling hospitals to receive a TPS with domain scores on just two domains out of four, we believe we are allowing low-volume hospitals to participate more broadly in the Hospital VBP Program than they might have otherwise. We note that the Hospital VBP Program's incentive payments depend entirely on the relative distribution of TPSs. Therefore, we believe that comparisons between hospitals' scores are incomplete without the full context provided by national TPS information and corresponding value-based incentive payment information. We acknowledge that comparisons among hospitals with different numbers of domain scores may become more difficult, but we view this compromise as necessary in order to ensure broad participation in the program by hospitals.

After consideration of the public comments we received, we are finalizing our policy to provide a TPS to hospitals receiving domain scores on at least 2 of the 4 finalized domains for the FY 2015 Hospital VBP Program.

13. Applicability of the Hospital VBP Program to Hospitals

a. Background

Section 1886(o)(1)(C) of the Act specifies how the Hospital VBP Program applies to hospitals. Specifically, the term "hospital" is defined under section 1886(o)(1)(C)(i) of the Act as a "subsection (d) hospital (as defined in section 1886(d)(1)(B [of the Act]))." Section 1886(o)(1)(C)(ii) of the Act sets forth a list of exclusions to the definition of the

term “hospital” with respect to a fiscal year, including a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program), a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients, a hospital for which there are not a minimum number of measures that apply to the hospital for the applicable performance period for the fiscal year, and a hospital for which there are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In addition, section 1886(o)(1)(C)(iv) of the Act states that in the case of a hospital that is paid under section 1814(b)(3) of the Act, the Secretary may exempt the hospital from the Hospital VBP Program if the State submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program. We interpret the reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the “waiver” specified by section 1814(b)(3) of the Act, would have been paid under the IPPS.

b. Exemption Request Process for Maryland Hospitals

Acute care hospitals located in the State of Maryland are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26530), we finalized our policy that the Hospital VBP Program would apply to acute care hospitals

located in the State of Maryland unless the Secretary exercises discretion pursuant to section 1886(o)(1)(C)(iv) of the Act. We also finalized a procedure for the State to submit a report pursuant to section 1886(o)(1)(C)(iv) of the Act in a timeframe that would allow it to be received no later than October 1, 2011, which is the beginning of the fiscal year prior to FY 2013.

We received an FY 2013 exemption request from the Maryland Health Services Cost Review Commission on September 30, 2011 and the Secretary approved the exemption request in December 2011. This request included a discussion on how the State program achieved or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program. When evaluating the Maryland Health Services Cost Review Commission's request, we considered the relevant health outcomes for the State's hospitals as described in the Maryland Health Services Cost Review Commission's request and noted that they achieve or surpass the current national results for Hospital VBP FY 2013 clinical process of care and HCAHPS dimensions. We also assessed closely-related clinical outcomes as measured by quality data reported through the Hospital IQR Program. For the FY 2013 Hospital VBP Program, however, we did not assess the criterion "cost savings" as required by the statute, as the FY 2013 Hospital VBP Program does not use any efficiency measures and is a budget-neutral program pursuant to section 1886(o)(7)(A) of the Act. Maryland hospitals are therefore exempt from the FY 2013 Hospital VBP Program.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28088), beginning with the FY 2014 Hospital VBP Program, we proposed to adopt a new procedure for submission of the report in order for a hospital within the State to be exempt from the Hospital VBP Program. Under this proposed procedure, if the State seeks an exemption with respect to a particular program year, it would need to submit a report that meets the requirements of section 1886(o)(1)(C)(iv) of the Act in a timeframe that allows it to be received by the Secretary on or before November 15 prior to the effective fiscal year (for example, the report seeking an exemption from the FY 2014 Hospital VBP Program would have to be received by the Secretary no later than November 15, 2012). We anticipate notifying the State, as well as each hospital for which the State has requested an exemption, of our decision whether to grant the request no later than 90 days following the exemption request deadline.

We will evaluate each exemption request to see if the State has demonstrated that it has implemented a similar program for participating hospitals that achieves or surpasses the measured results in terms of patient health outcomes and cost savings relative to the Hospital VBP Program.

We welcomed public comment on our proposals.

Comment: Some commenters asked that we clarify that the exemption request process for hospitals paid under section 1814(b)(3) of the Act will apply to all such hospitals within a State, rather than to requesting hospitals.

Response: Future exemptions, if requested by the Maryland Health Services Cost Review Commission and granted by the Secretary, would apply to all hospitals paid under section 1814(b)(3) of the Act.

We proposed to codify the applicability of the Hospital VBP Program to hospitals paid under section 1814(b)(3) of the Act in 42 CFR 412.162(d). We did not receive any comments on the specific regulatory text that we proposed. We are finalizing this provision with minor revisions in a new 42 CFR 412.161(b). We are also codifying at 42 CFR 412.161(a) that the Hospital VBP Program applies to hospitals, as that term is defined in our regulations at § 412.160.

After consideration of the public comments we received, we are finalizing our exemption request process as proposed.

14. Minimum Numbers of Cases and Measures for the FY 2015 Hospital VBP Program

a. Background

Section 1886(o)(1)(C)(ii)(III) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year. Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531), we finalized minimum numbers of 10 cases and 4 measures in the Clinical Process of

Care domain and 100 completed HCAHPS surveys for the Patient Experience of Care domain. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74534), we finalized a minimum number of 10 cases for the three 30-day mortality measures. We also finalized a minimum number of 2 measures with respect to the Outcome domain. In both rules, we finalized a policy that hospitals must have sufficient cases and measures in all domains in order to receive a TPS.

b. Minimum Numbers of Cases and Measures for the FY 2015 Outcome Domain

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28089), as described further above, we proposed a 9-month performance period for the three 30-day mortality measures for the FY 2015 Hospital VBP Program. We have reassessed the previously finalized 10 case minimum threshold for the three 30-day mortality measures (76 FR 74533 through 74534), as well as reexamined the independent analyses by Brandeis University and Mathematica Policy Research, when considering these three measures' proposed addition. We recognize that the proposed 9-month performance period for these measures, in combination with a minimum number of 25 cases per measure, would increase the number of hospitals with insufficient cases on the measure to several hundred hospitals, based on past information.

In order to ensure that the mortality measure scores remain sufficiently reliable, we proposed to adopt a 25-case minimum for the three 30-day mortality measures for FY 2015. We believe that this proposal will ensure relatively more reliable measure data than could be obtained with the 10-case minimum that was previously finalized for FY 2014 given the relatively shorter proposed performance period in FY 2015. As

described above, while this may result in fewer hospitals receiving scores on the mortality measures, we have proposed to reallocate domain weighting for hospitals with fewer domain scores than the total number of finalized domains. By doing so, we believe we are appropriately allowing as many hospitals as possible to participate in the Hospital VBP Program while also ensuring reliable quality measure and quality domain data.

We note that this proposed minimum number of cases is higher than has been finalized for other types of measures such as clinical process of care measures. However, we note that clinical process of care measures are not risk-adjusted and are not outcome-based. Because those measures do not require statistical adjustment to estimate hospital-specific differences in case mix, we believe that the relatively smaller case minimum is acceptable for clinical process of care measures.

For the AHRQ PSI composite measure, we proposed to adopt AHRQ's methodology, which uses three cases for any of the underlying indicators as a case minimum. For the CLABSI measure, we proposed to adopt CDC's minimum case criteria, which calculates a standardized infection ratio for a hospital on the CLABSI measure if the hospital has 1 predicted infection during the applicable period. We believe that the measure stewards' methodologies for constructing reliable measure data are most appropriate for use in the Hospital VBP Program. Further information on these measures may be found on the QualityNet Web site.

In the CY 2012 OPPS/ASC final rule with comment period we concluded, based on an independent analysis, that the minimum number of measures that a hospital must report in order to receive a score on the Outcome domain is two measures. We continue

to believe that this minimum number is appropriate for the expanded Outcome domain because adding measure scores beyond the minimum number of measures has the effect of enhancing the domain score's reliability. For that reason, we proposed to adopt it for the FY 2015 Hospital VBP Program.

We welcomed public comment on these proposals.

Comment: Many commenters expressed support for the proposal to raise the minimum number of cases for mortality measures to 25, though some expressed concern that this proposed minimum may not be reliable enough for performance scoring.

Response: We thank commenters for their support. We believe that the higher minimum number of cases provides sufficiently reliable mortality measure data for performance scoring. We believe that our proposal is responsive to concerns about outcome measure reliability, since we proposed a 21 month FY 2016 performance period and a 25 case minimum threshold for including mortality measures in the FY 2015 Hospital VBP Program. Both proposals are designed to increase the overall reliability of these measures, and exclude hospitals with the most unreliable measure rates from receiving measure scores. As stated previously, we assessed measure reliability, TPS reliability and validity, and alignment with our policy goal to reduce cost and improve patient health outcomes in our proposals.

Comment: Some commenters opposed the proposed minimum numbers of cases and measures for the AHRQ PSI composite and CLABSI measures, arguing that the measures are unreliable at the proposed numbers of cases.

Response: We disagree. As stated above, we believe that the AHRQ PSI measure is sufficiently reliable for the purposes of the Hospital VBP Program. Our proposal is responsive to concerns about outcome measure reliability, since we proposed a nearly 21 month FY 2016 performance period to include the AHRQ PSI composite measure in the FY 2016 TPS. That proposal is designed to increase overall reliability of the measure and to exclude hospitals with the most unreliable measure rates from FY 2016 TPSs. We also considered the improved validity resulting from more outcome measures that include a higher correlation with patient outcomes, relative to process of care measures. As stated previously, we assessed measure reliability, TPS reliability and validity, and alignment with our policy goal to reduce cost and improve patient health outcomes in our proposals. As we stated further above, we strive to improve both validity of the TPS through improved correlation with patient health outcomes, and its reliability to accurately incentivize health outcomes, patient experience of care, and reduced cost. We also considered both validity and reliability is of the TPS, in addition to alignment with policy goals to improve patient outcomes, as well as of the individual measure reliability contributing to the TPS. We also believe that adopting the minimum numbers of cases specified by the measure stewards in the case of the AHRQ PSI and CLABSI measures is both fully transparent and fair, as hospitals may apply their current experience with these measures to their use in the Hospital VBP Program.

After consideration of the public comments we received, we are finalizing the minimum numbers of cases for outcome measures as proposed.

c. Medicare Spending Per Beneficiary Measure Case Minimum

As required by section 1886(o)(1)(C)(iii) of the Act, we obtained an independent analysis to help us determine the appropriate minimum number of cases for the Medicare spending per beneficiary measure. For this measure, we proposed to interpret the term "case" in section 1886(o)(1)(C)(ii)(IV) of the Act as a Medicare spending per beneficiary episode. A Medicare spending per beneficiary episode is inclusive of all Part A and Part B payments from 3 days prior to a subsection (d) hospital admission through 30 days post discharge with certain adjustments and exclusions. The independent analysis examines the tradeoff between increasing the minimum number of episodes, which shrinks the confidence interval; and reducing the minimum number of episodes, which widens the confidence interval but enables more hospitals to receive a Medicare spending per beneficiary measure score. Because the distribution of Medicare spending per beneficiary episodes is skewed towards higher cost episodes, creating confidence intervals using statistical techniques that assume spending is normally and symmetrically distributed will not accurately describe the likelihood a hospital's true efficiency level falls within the confidence interval bounds.

To account for these statistical issues, the independent analysis uses a simulation-based ("non-parametric bootstrap") methodology to measure how the confidence interval of the Medicare spending per beneficiary measure changes when the minimum episode threshold increases. Medicare spending per beneficiary is measured for an "average" hospital, where the "average" hospital case is considered one with a Medicare spending per beneficiary episode distribution that mimics that of the entire

population of Medicare spending per beneficiary episodes. This methodology simulates the process of randomly drawing Medicare spending per beneficiary episodes from the population, and thus approximates the actual shape of the Medicare spending per beneficiary measure distribution from which confidence intervals are determined. By repeatedly calculating (in this case, 10,000 times for each minimum episode threshold) a Medicare spending per beneficiary measure for this simulated hospital under differing assumptions on the number of episodes observed, one can create a confidence interval for the Medicare spending per beneficiary measure of this "average" hospital. The upper and lower bounds of the 95 percent confidence interval indicates that 95 percent of the time, the hospital's Medicare spending per beneficiary measure will fall within this range when the minimum number of cases (the minimum episode threshold) is set at different levels. As the minimum episode threshold increases, the width of the confidence interval becomes narrower, but the number of hospitals receiving a Medicare spending per beneficiary measure score decreases.

In developing our proposal, we considered two options for setting the minimum number of cases for the Medicare spending per beneficiary measure: (1) setting the minimum number of cases at 25; and, (2) setting the minimum number of cases at 50.

We focused on these minimums because we believe that either of them provides a sufficiently narrow range at the 95 percent confidence interval. The independent analysis concludes that if the minimum number of cases is set at 25, then 95 percent of the time a hospital with an average underlying efficiency level (that is, 1.0) would receive a Medicare spending per beneficiary measure score between 0.81 and 1.23. Further, a

minimum number of 25 cases would enable 97.8 percent of hospitals to receive a Medicare spending per beneficiary measure score, based on historical data. The analysis also showed that the alternative minimum of 50 cases would result in a 95 percent confidence interval range of 0.86 to 1.16 and would enable 95.9 percent of hospitals to receive a Medicare spending per beneficiary measure score, based on historical data.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28090), after considering the options outlined above, we proposed to use 25 as the minimum number of cases required in order to receive a score for the Medicare spending per beneficiary measure. We believe that using a minimum number of 25 cases achieves an appropriate balance of our interest in allowing the maximum possible number of hospitals the opportunity to receive a score on the Medicare spending per beneficiary measure and maintaining a sufficiently narrow range for the 95 percent confidence interval. Additionally, although we proposed to use a minimum of 25 cases for the Medicare spending per beneficiary measure, we also sought comment on whether using a minimum of 50 cases better reaches our goal of maintaining a meaningful measure of Medicare spending across hospitals.

Comment: A few commenters stated that they were unable to meaningfully comment on the proposed minimum number of cases, because there was not a reliability study posted. Some commenters pointed to the reliability of the mortality measures, suggesting that 100 cases may not be a high enough minimum for a claims-based measure.

Response: In addition to the minimum number of cases analysis described above, we have obtained a more robust reliability analysis, in order to confirm our expectation that the Medicare Spending per Beneficiary measure would be reliable. As noted above, the analysis found the Medicare Spending per Beneficiary measure to have a reliability of 0.951, with a minimum of 10 cases, and an increase in reliability of 0.0002 when the minimum number of episodes increases from 10 to 25. Because we believe this analysis supports our expectation that a minimum number of 10 cases for the measure would be sufficient, we are confident that the minimum number of 25 cases proposed will produce sufficient measure reliability. The analysis may be accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/Hospital-Value-Based-Purchasing/, in the "Downloads" section.

Comment: Many commenters urged CMS to begin the legislatively-required demonstrations on value-based purchasing for hospitals not meeting the minimum numbers of cases and measures and for Critical Access Hospitals as soon as possible.

Response: We plan to begin those demonstrations when possible within our resource constraints.

After consideration of the public comments we received, we are finalizing our minimum number of cases for the Medicare Spending per Beneficiary measure as proposed.

15. Immediate Jeopardy Citations

Under section 1886(o)(1)(C)(ii)(II) of the Act, a hospital is excluded from the Hospital VBP Program if it has been cited by the Secretary during the performance period for deficiencies that pose immediate jeopardy to the health or safety of patients. In the Hospital Inpatient VBP Program final rule (76 FR 26528 through 26530), we finalized our interpretation of this provision to mean that any hospital that we cite through the Medicare State Survey and Certification process for deficiencies during the performance period that pose immediate jeopardy to patients will be excluded from the Hospital VBP Program for the fiscal year. We also finalized our proposal to use the definition of the term "immediate jeopardy" that appears in 42 CFR 489.3.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28090), in proposed § 412.160, we proposed to define "immediate jeopardy" in the same way as that term is defined in 42 CFR Part 489, which governs provider agreements and supplier approval. We believe that the language in section 1886(o)(1)(C)(ii)(II) of the Act referring to a hospital having been "cited" for deficiencies posing an immediate jeopardy is a reference to the process by which CMS, through agreements with State survey agencies, surveys or inspects hospitals for compliance with the hospital CoPs at 42 CFR Part 482 or Emergency Medical Treatment and Labor Act (EMTALA) regulations at § 489.24, and issues deficiency citations for non-compliance with Federal health, safety and quality standards. The survey process is governed by provisions found in 42 CFR Part 488, Survey, Certification and Enforcement Procedures. Further, provisions at 42 CFR Part 489, Provider Agreements and Supplier Approval, define the term "immediate jeopardy"

at § 489.3; authorize us at § 489.53(a)(3) to terminate the Medicare provider agreement for the hospital's failure to meet the CoP; authorize us at § 489.53(b) to terminate the Medicare provider agreement of a hospital that fails to meet the EMTALA regulatory requirements; and provide at § 489.53(d)(2)(i) for a shortened advance notice to the public of the termination when a hospital with an emergency department is in violation of EMTALA requirements and the violation poses immediate jeopardy. Therefore, we believe that the term "immediate jeopardy" should be defined in our Hospital VBP Program regulations in the same manner as it is defined for the purpose of survey, certification, enforcement, and termination procedures.

In proposed § 412.160, we proposed to define the phrase "cited for deficiencies that pose immediate jeopardy." We proposed a definition in order to avoid potential ambiguities about the terms "cited" and "deficiencies." There are several ways in which a hospital might be found to have an immediate jeopardy situation. Appendix Q of the State Operations Manual (SOM), Pub. No. 100-07, provides guidance to the State survey agencies on our policies concerning the identification and citation of immediate jeopardy and subsequent enforcement actions. A common way in which an immediate jeopardy situation is identified is when a surveyor or team of surveyors is in the process of conducting a survey of compliance with the Medicare CoP at the hospital and accurately identifies those situations which immediately jeopardize the health and safety of patients. Surveyors may be expected, according to State protocols, to consult immediately with their supervisors before declaring an immediate jeopardy, and in cases involving hospitals deemed to meet the CoP based on their accreditation, the State must first

consult with the CMS Regional Office (RO). In the case of EMTALA surveys, only the CMS Regional Office may determine, after reviewing the State Survey Agency's report, whether there was an EMTALA violation and, if so, whether it constituted an immediate jeopardy.

Once an immediate jeopardy situation is declared, the hospital's management is informed and expected to take steps to remove the immediate jeopardy, preferably before the survey team concludes the on-site portion of its survey. If the hospital does not remove the immediate jeopardy while the survey team is on-site, it has 23 days to submit an acceptable plan of correction and have an onsite follow-up survey to confirm removal. If the hospital fails to remove the immediate jeopardy in a timely manner, we may terminate the hospital's Medicare provider agreement. There are also situations where a survey team does not declare an immediate jeopardy while on-site, but a subsequent supervisory or CMS RO review of the survey team's findings identifies an immediate jeopardy situation that should have been declared. In such cases, the hospital is promptly advised of the immediate jeopardy and given 23 days to submit an acceptable plan of correction and have an onsite follow-up survey to confirm removal of the immediate jeopardy. It can also happen that a supervisory or CMS RO review will conclude that the survey documentation does not support a finding of an immediate jeopardy, and in such cases no official immediate jeopardy citation will be issued.

We note that removal of an immediate jeopardy is not necessarily the same as correction of the hospital's noncompliance deficiencies. Removal may be accomplished

by an interim measure while the hospital works to create a systematic and permanent correction of its deficient practices.

The Form CMS-2567, Statement of Deficiencies and Plan of Correction, is issued after each survey of a hospital, even if only to indicate that no deficiencies were found during the survey (SOM Section 2728 and SOM Exhibit 7A, Principles of Documentation, Principle #1). The CMS-2567 form constitutes the official notice to a healthcare facility of the survey findings. Statements made by surveyors to the facility while they are on-site are always preliminary in nature. After surveyors have exited the facility, they prepare the Form CMS-2567 based on their observations and survey documentation. Their draft Form CMS-2567 is then subjected to a supervisory review and, in the case of hospitals that are deemed to meet the CoP via accreditation and are being cited for serious noncompliance (that is, condition-level or immediate jeopardy citation), to a CMS RO review. The Form CMS-2567 is not considered final until it is transmitted to the healthcare facility, either by the State survey agency or, in certain cases, the CMS RO.

In the case of a survey where an immediate jeopardy situation was found, the Form CMS-2567 must state that the facility was found to have immediate jeopardy. This is the case regardless of whether the immediate jeopardy was removed while the survey team was still on-site at the facility, although on-site removal will be noted if it occurred. Furthermore, it is standard survey practice to cite on the Form CMS-2567 all noncompliance deficiencies identified during a survey even when the healthcare facility corrects those deficiencies after they have been identified by a surveyor, but before the

survey team exits the facility (SOM Exhibit 7A, Principles of Documentation, Principle #4).

We considered whether it would be reasonable to treat only those hospitals that failed to remove immediate jeopardy while a survey team was still on-site as having been "cited for an immediate jeopardy" solely for the purposes of the Hospital VBP Program. However, we concluded that this would not be equitable, since there are cases where an immediate jeopardy is identified after the survey team has left the hospital through a supervisory or CMS RO review, as described above. We also concluded this approach would not be consistent with the statutory requirement given that the Form CMS-2567 is the official notice to a healthcare facility of deficiencies found during a survey and in light of the fact that CMS includes references to the identification of an immediate jeopardy on the CMS-2567, regardless of when or if it was removed by the facility. We have, therefore, concluded that "citation" of an immediate jeopardy within the context of the Hospital VBP Program means the identification of an immediate jeopardy noted on the CMS-2567 that is issued to the hospital after a survey.

We also note that section 1886(o)(1)(C)(ii)(II) of the Act refers to the citation of plural "deficiencies" that pose immediate jeopardy and that this requires interpretation of its application to the Hospital VBP Program. We use an Automated Survey Processing Environment (ASPEN) system to catalog deficient practices identified during a survey and to generate the CMS-2567 that is issued to the hospital after the survey. To facilitate processing in the ASPEN system, we have subdivided the regulations applicable to each type of certified healthcare facility into specific "tags," each one of which has

corresponding interpretive guidelines in the applicable appendix of the SOM. Hospital tags are found in Appendix A. The ASPEN system also differentiates between "condition" and "standard" level tags for non-long term care enforcement, since it is essential to know whether or not identified noncompliance is found at the condition-level, that is, whether it is considered substantial noncompliance. Each hospital condition of participation has its own condition tag. There are also a varying number of "standard" tags within each condition. The number of standard-level tags identified in the SOM Appendix does not correspond to the number of individual "standards" required in the regulations; usually there are more tags than actual standards, because standards may involve multiple items or requirements under specific CoP that lend themselves to separate evaluation.

While we understand that each tag identified in a CMS-2567 may be viewed as a separate deficiency, we also recognize that the division of the regulations for each "condition" and "standard" into individual tags was to facilitate the survey and certification process for surveyors. Moreover, in general a set of documented deficient practices that constitute immediate jeopardy would be cited at least in two tags, since there must be a citation at the condition-level to indicate substantial noncompliance, along with citation of any pertinent standard-level tags, which are subsets of the condition tags. We do not believe it was the intent of the statute to count each of these tags related to the same set of circumstances or practices as separate deficiencies under the Hospital VBP Program.

We have concluded, therefore, that a more reasonable interpretation of the Hospital VBP statute is to view each hospital survey for which the CMS-2567 form cited immediate jeopardy as a deficiency, for Hospital VBP purposes only. Thus, a hospital would have to have been cited on a CMS-2567 for immediate jeopardy on at least two surveys during the performance period in order to be considered as having multiple deficiencies that pose immediate jeopardy. Accordingly, we proposed to define in our regulations the term "cited for deficiencies that pose immediate jeopardy" under the Hospital VBP Program to mean that, during the applicable performance period, the hospital had more than one survey for which it was cited for an immediate jeopardy on the Form CMS-2567, Statement of Deficiencies and Plan of Correction.

As required by the statute, hospitals cited during the performance period for multiple deficiencies that pose immediate jeopardy to the health or safety of patients would be excluded from the Hospital VBP Program for the applicable fiscal year. Because we sometimes adopt different performance periods for different measures for purposes of the same program year, we proposed to exclude hospitals cited for such deficiencies during any of the finalized performance periods for the applicable program year for purposes of that interpretation.

We welcomed public comment on this interpretation of the immediate jeopardy exclusion and on our proposals.

Comment: A majority of commenters expressed their support for the proposal to define the phrase "cited for deficiencies that pose immediate jeopardy" as meaning that, during the applicable performance period a hospital was cited for immediate jeopardy on

at least two surveys using the Form CMS-2567, Statement of Deficiencies and Plan of Correction. One commenter indicated this approach was reasonable and strikes an appropriate balance between the importance of ensuring high quality care and the punitive nature of disqualifying a hospital from value-based purchasing incentives.

Response: We thank those commenters who support our proposal and agree that it allows for an appropriate balance in the Hospital VBP Program between assuring high quality care and not unreasonably excluding a hospital from participation in the Hospital VBP Program.

Comment: A number of individual commenters associated with one hospital, as well as several other commenters, objected to the proposed definition for the term "cited for deficiencies that pose immediate jeopardy." The commenters suggested that there is variation in immediate jeopardy citation practices which raises legitimate concerns about the validity of the citations. One commenter suggested that CMS eliminate use of immediate jeopardy citations in the Hospital VBP Program. Several others suggested the term be defined to include only those hospitals whose Medicare provider agreement is actually terminated as a result of the inability to remove an immediate jeopardy within 23 days. Two commenters suggested that immediate jeopardy citations based on violations of the Life Safety Code be excluded from consideration under the Hospital VBP Program. These commenters believed that variations in Life Safety Code citations are wide and that these types of deficiencies often are not related to patient safety. Another commenter suggested that any immediate jeopardy that is corrected while the surveyors are on-site not be included in the definition, since a deficiency that can be

corrected in that timeframe does not warrant the severity of the punishment related to the Hospital VBP Program. This commenter also suggested revising the definition of "immediate jeopardy" given the linkage to the Hospital VBP Program. The commenter believes that immediate jeopardy citations are limited in scope to single patient occurrences, unlike the Hospital VBP Program performance measures that consider a hospital's overall performance. This commenter indicated that such citations in the case of hospitals previously made them subject to loss of deemed status, loss of Medicare certification and civil monetary penalties, and with this proposal the penalty of exclusion from the Hospital VBP Program would be added. The commenter believes the definition should reflect the serious nature of the penalties.

Response: With respect to the suggestion that we eliminate the use of the immediate jeopardy exclusion in the Hospital VBP Program, we do not have the discretion to do so. Section 1886(o)(1)(C)(ii)(II) of the Act specifies that a hospital is excluded from the Hospital VBP Program if it has been cited by the Secretary during the performance period for deficiencies that pose immediate jeopardy to the health or safety of patients. We believe that the statute is clearly referring to our longstanding definition of "immediate jeopardy" and to citations in connection with Federal surveys, or inspections, of hospitals, most of which are conducted on CMS' behalf by State Survey Agencies as part of the Medicare survey and certification process. We do not believe the statute refers only to hospitals whose provider agreements were terminated as a result of their failure to correct their cited immediate jeopardy deficiencies, since the term "cited" is not equivalent to "terminated." Moreover, any hospital not participating in the

Medicare program as a result of a termination action would not be eligible for the Hospital VBP Program, so it is unlikely that the statute was intended for such cases. Likewise, we see no basis for revising the definition of "immediate jeopardy, " which is defined at 42 CFR 489.3 as "a situation in which a provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident," or not considering certain types of immediate jeopardy citations applicable. The definition and the criteria for all immediate jeopardy citations are the same for all types of certified providers and suppliers, not just subsection (d) hospitals. As specified in Appendix Q, Guidelines for Determining Immediate Jeopardy, (Rev. 1, 05-21-04), of the SOM, there are three components that must be present to support an immediate jeopardy citation: actual or potential serious harm, injury, impairment or death of patients; immediacy of the harm, that is, its likelihood to occur in the very near future; and culpability, that is, the hospital knew or should have known about the situation and taken appropriate action prior to the survey. It is not correct to say that immediate jeopardy citations are limited in scope to single patient occurrences, since often such citations reflect serious systemic problems within a hospital that could put many patients at risk of serious harm. Likewise, the issue of being able to "remove" an immediate jeopardy while the survey team is on site should not be confused with the seriousness of the underlying problem or the extent of systemic corrections needed. An immediate jeopardy may be removed while the survey team is on-site when the hospital takes interim measures that remove the immediacy of the threat of future harm,. However, the substantial noncompliance with the Medicare health and

safety standards in such cases remains and must be corrected through systemic changes. Our survey protocol calls for the immediate jeopardy to be noted on the Form CMS-2567 regardless of whether it was removed while the survey team was on-site or not. We do not believe it would be appropriate to modify either the regulatory definition of immediate jeopardy or our longstanding protocols for citing immediate jeopardy for one type of provider, namely subsection (d) hospitals, now that such citations are linked to another Medicare program.

Comment: Multiple commenters stated that there is wide variation among States and CMS Regional Offices and that they can reach differing opinions on similar facts as to whether there is an immediate jeopardy finding. One commenter asserted that CMS Regional Offices are unlikely to overturn an immediate jeopardy citation that is issued by a State surveyor. Several commenters urged that, given the additional payment impact under VBP of immediate jeopardy citations, CMS should ensure that there is uniform guidance for State surveyors and that the definition of immediate jeopardy is well understood and consistently applied by CMS and State Survey Agencies.

Response: In addition to the regulatory definition of immediate jeopardy, we have longstanding, detailed, uniform guidance in Appendix Q of the SOM for determining an immediate jeopardy situation. We also note that the standard protocol for non-EMTALA surveys requires the surveyor or survey team which suspects an immediate jeopardy while they are on-site conducting a survey to call their State Survey Agency management, per State protocol. In the case of deemed hospitals, the CMS Regional Office must also be consulted before an immediate jeopardy may be declared.

In the case of an EMTALA survey, only the CMS Regional Office may determine whether there was an EMTALA violation and, if so, whether it constitutes immediate jeopardy. This necessity for multiple individuals to agree that an immediate jeopardy citation is warranted helps to mitigate the risk of subjectivity in the determination. In addition, with the advent of the statutory linkage between the Hospital VBP Program and immediate jeopardy citations, we recognized the importance of increasing our efforts to ensure consistency across CMS regions and States in issuing immediate jeopardy citations. We have conducted special training for surveyors and regional office staff on identifying immediate jeopardy situations related to the hospital CoP, and will be doing the same with respect to immediate jeopardy situations related to the EMTALA requirements for hospitals. In addition, now that we have begun collecting data on immediate jeopardy citations, we will use the data to support further education and training as needed. For the first Hospital VBP performance period and part of the second performance period we utilized a manual process to collect hospital immediate jeopardy citation information from each CMS Regional Office. In addition, the Automated Survey Processing Environment (ASPEN), an electronic system that supports our survey and certification activity, has been revised to include information about immediate jeopardy citations in surveys entered into ASPEN after July, 2012, enabling automated collection of this data.

We note as a point of information that over eighty percent of subsection (d) hospitals are “deemed” to be in compliance with the Medicare hospital CoP on the basis of their accreditation under a CMS-approved hospital accreditation program. Although

we have the authority to do so, as a matter of policy we do not take enforcement actions based on the results of an accrediting organization's survey of a deemed facility. Accordingly, there are no Medicare immediate jeopardy citations based on an accrediting organization's survey findings. However, this does not mean that deemed hospitals would never be cited for immediate jeopardy, nor does it mean that they are not subject to Medicare hospital surveys conducted either by State Survey Agencies or Federal surveyors. With respect to the Hospital VBP, therefore, there is no advantage to being deemed versus non-accredited. In accordance with section 1864(c) of the Act, the Secretary may authorize State Survey Agencies to conduct validation surveys of deemed facilities. There are two types of validation surveys: 1) representative sample validation surveys, where CMS selects a sample of deemed providers and suppliers to be surveyed under a standard survey (i.e., a survey of compliance with all applicable CoP or Conditions for Coverage) by the State Survey Agencies as part of our annual assessment of the performance of CMS-approved accreditation programs; and 2) substantial allegation validation surveys, more generally known as complaint surveys. The latter are conducted in response to an allegation which, if found to be true, would indicate that a provider or supplier is not in substantial compliance with one or more of the applicable Conditions. In the case of hospitals, the majority of the Medicare surveys conducted are validation surveys involving deemed hospitals. In FY 2010, for example, there were over 4,200 Medicare complaint surveys and over 400 standard surveys of subsection (d) hospitals, and fewer than 500 of these complaint surveys and roughly 100 of the standard surveys were of non-accredited hospitals. Finally, we also note that accrediting

organizations are required to notify CMS promptly if they identify a situation during a survey of a deemed facility which constitutes an immediate jeopardy. Upon receiving such notification, CMS reviews the information the accrediting organization provides and, if it agrees that the situation as described would constitute an immediate jeopardy, either instructs the State Survey Agency to promptly conduct a substantial allegation validation survey or conducts such a survey with a team of Federal surveyors.

Comment: One commenter interpreted the discussion in the proposed rule of the use of the Form CMS-2567, Statement of Deficiencies and Plan of Correction, as implying that State Agency surveyors could issue immediate jeopardy findings using some other form. The commenter urged CMS to clarify that only immediate jeopardy findings issued by CMS or its Regional Offices on the Form CMS-2567 can serve as the basis for an immediate jeopardy determination that will have payment impact under the Hospital VBP Program.

Response: Nothing in the proposed rule indicated that an official notice of immediate jeopardy could be conveyed to a hospital via any form other than the Form CMS-2567. We believe that the commenter may be confused by the fact that, in some instances, the Form CMS-2567 containing the findings of the Federal survey may be issued or transmitted to a hospital by the State Survey Agency rather than the CMS Regional Office. This could happen in the following cases: when the survey was of CoP compliance in a hospital that does not have Medicare "deemed" status on the basis of its accreditation by a CMS-approved Medicare accreditation program; when the survey was of a hospital whose deemed status was previously removed by the CMS Regional Office,

as a result of substantial noncompliance found on a previous survey; or in the case of a hospital with deemed status where the CMS Regional Office has authorized the State Survey Agency to transmit the specific Form CMS-2567 to the hospital.

We are also taking this opportunity to clarify that we will consider only those Form CMS-2567s which are issued to a hospital based on a Federal survey, both for our general enforcement purposes and for determining immediate jeopardy citations for the Hospital VBP Program. We recognize that it is not uncommon for States to also use the Form CMS-2567 as a template for them to issue reports of surveys conducted under their State licensure authority. Even though the report may appear on a Form CMS-2567, and even when the report may refer to an immediate jeopardy, if it is not a report resulting from a Federal survey to assess compliance with Federal standards, it will not be considered applicable for our general enforcement purposes or for the Hospital VBP Program.

Comment: One commenter asked that CMS clarify what the operative date will be for determining the appropriate performance period to which an immediate jeopardy citation will be applied. The commenter noted that the issuance of the Form CMS 2567 to the hospital may occur a lengthy time after surveyors exited the hospital. Another commenter noted that sometimes the same event can result in multiple immediate jeopardy citations which is a cause for concern. Another commenter recommended that CMS apply the definition in the proposed regulation to the FY 2013 Hospital VBP Program.

Response: It is possible for several Federal surveys to be conducted simultaneously in a hospital. This could happen, for example, if a particular complaint warranted an investigation under both the hospital CoP, 42 CFR Part 482, and the EMTALA requirements found in 42 CFR 489. We recognize that it is more an artifact of our survey process and the ASPEN electronic system which supports Federal surveys that separate Form CMS 2567s are generated when such simultaneous surveys occur. We have therefore adopted as part of our protocol that two Form CMS-2567s with immediate jeopardy citations and with the same survey end date are to be counted as one instance of an immediate jeopardy citation. However, use of the survey end date will enable us to identify those cases where multiple surveys were conducted simultaneously.

The survey end date generated in ASPEN will be the date used for assignment to a performance period. We acknowledge that this date will often be earlier than the date on which the Form CMS-2567 is issued to the hospital. In the case of EMTALA surveys, it will always be earlier, since only the CMS Regional Office may determine whether there has been an EMTALA violation, usually after obtaining a Quality Improvement Organization (QIO) physician review of the clinical aspects of the case when required by the statute. The survey end date is a date that can be tracked in ASPEN in an automated fashion, increasing the accuracy of identification of all immediate jeopardy citations for the applicable performance period.

This final rule concerning the Hospital VBP Program will be effective for FY 2013. Therefore, although the performance period for the FY 2013 Hospital VBP

Program occurred prior to October 1, 2013, the definition of immediate jeopardy citations will be in effect and applied to the FY 2013 Hospital VBP performance period.

Comment: Several commenters indicated that, given their concerns about the variation they perceive in immediate jeopardy citation practices among States and Regional Offices, they believe that they should be able to appeal any immediate jeopardy citation issued to them. One commenter noted that all appeals should be exhausted before a hospital would be excluded from the Hospital VBP Program.

Response: "Immediate jeopardy" is one of several levels of noncompliance that may be cited in a hospital, with the other two being substantial noncompliance (that is, so-called "condition-level" noncompliance) and standard-level deficiencies. In accordance with 42 CFR 498.3(b)(14), the level of noncompliance found by CMS is an initial determination (and therefore appealable) only in the case of a skilled nursing facility or nursing facility, and then only in certain circumstances. The level of citations issued to a hospital is, therefore, not appealable under the current regulation. Among other things, a hospital may appeal deficiency findings that lead to the termination of a provider agreement under 42 CFR 489.53, which is an initial determination defined at 42 CFR 498.3(b)(8). Appeals procedures for providers, including hospitals, and certified suppliers are found in 42 CFR Part 498. We will consider future rulemaking on this issue.

Comment: Several commenters objected to our proposal that, because we sometimes adopt different performance periods for different measures for purposes of the same Hospital VBP Program year we would exclude hospitals cited for immediate

jeopardy during any of the finalized performance periods for the applicable program year. Several commenters noted that the mortality measurements performance period is 3 years long and indicated that it is unreasonable to exclude a hospital from the Hospital VBP Program for 3 years due to two immediate jeopardy citations in one portion of this performance period.

Response: We believe commenters erred in describing a 3-year performance period for the 30-day mortality measures. We finalized above a 21-month performance period for these measures for the FY 2016 VBP Program, but have not proposed to adopt a performance period of 3 years. We interpret the commenters to express concern about the possibility of immediate jeopardy citations during a relatively wide date range resulting in hospitals' being excluded from a Hospital VBP Program year.

Section 1886(o)(1)(C)(i) of the Act defines the term "hospital" for purposes of the Hospital VBP Program as "a subsection (d) hospital (as defined in subsection (d)(1)(B)," subject to certain exclusions outlined in section 1886(o)(1)(C)(ii) of the Act. One of those exclusions, found in subparagraph (II), excludes from the definition of the term hospital any hospitals "for which, during the performance period for such fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients."

We do not believe that we have the statutory authority to include hospitals in the Hospital VBP Program when they have been cited for such deficiencies during any of the finalized performance periods described further above. Subject to our interpretation of the term, "cited for deficiencies that pose immediate jeopardy" described further above,

we believe that we must exclude hospitals so cited during any finalized performance period for a fiscal year regardless of the length of the applicable performance period. While we recognize that, for certain types of measures, the length of time during which immediate jeopardy citations may result in exclusion from the Hospital VBP Program may be longer than for others, we believe that the Hospital VBP statute requires us to exclude those cited hospitals.

After consideration of the public comments we received, we are finalizing our proposed immediate jeopardy definitions and exclusion processes without modification, including our codification of the definitions of "cited for deficiencies that pose immediate jeopardy" and "immediate jeopardy" for purposes of the Hospital VBP Program in 42 CFR 412.160.

D. Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Statutory History

In accordance with section 1886(m)(5) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting (LTCHQR) Program. Under the LTCHQR Program, for rate year 2014 and each subsequent rate year, in the case of a long-term care hospital (LTCH) that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by two percentage points.

Section 1886(m)(5)(D)(iii) of the Act requires the Secretary to publish the selected measures for the LTCHQR Program that will be applicable with respect to the FY 2014 payment determination no later than October 1, 2012.

Under section 1886(m)(5)(D)(i) of the Act, the quality measures for the LTCHQR Program are measures selected by the Secretary that have been endorsed by an entity that holds a contract with the Secretary under section 1890(a) of the Act, unless section 1886(m)(5)(D)(ii) of the Act applies. This contract is currently held by the National Quality Forum (NQF). Section 1886(m)(5)(D)(ii) of the Act provides that an exception may be made in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity that holds a contract with the Secretary under section 1890(a) of the Act. In such a case, section 1886(m)(5)(D)(ii) of the Act authorizes the Secretary to specify a

measure(s) that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The LTCHQR Program was implemented in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

2. LTCH Program Measures for the FY 2014 Payment Determination and Subsequent Fiscal Years Payment Determinations

a. Process for Retention of LTCHQR Program Measures Adopted in Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28092), for the LTCHQR Program, we proposed that once a quality measure is adopted, it is retained for use in subsequent fiscal year payment determinations, unless otherwise stated. For the purpose of streamlining the rulemaking process, we proposed that when we initially adopt a measure for the LTCHQR Program for a payment determination, this measure will be automatically adopted for all subsequent payment determinations or until we propose to remove, suspend, or replace the measure. Quality measures may be considered for removal by CMS if: (1) measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can be no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; (6) a measure that is more strongly associated with

desired patient outcomes for the particular topic is available; or (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. For any such removal, the public will be given a chance to comment through the annual rulemaking process. However, if there is reason to believe continued collection of a measure raises potential safety concerns, we will take immediate action to remove the measure from LTCHQR Program and will not wait for the annual rulemaking cycle. Such measures will be promptly removed and we will promptly notify LTCHs and the public of such a decision through the usual LTCHQR Program communication channels, including listening sessions, memos, email notification, and Web postings and their removal will be formally announced in the next annual rulemaking cycle.

We invited public comment on our proposal that once a quality measure is adopted, it is retained for use in the subsequent fiscal year payment determinations unless otherwise stated.

Comment: Several commenters supported CMS' approach to retaining measures. Other commenters expressed appreciation for CMS' proposal to streamline the process for quality measure retention and to use the same process proposed in the Hospital IQR Program.

Response: We thank the commenters for their support of our proposed approach for retaining adopted measures for use in subsequent fiscal year payment determinations.

Comment: Many commenters objected to CMS' approach to retain quality measures and suggested that CMS re-propose measures each year and invite public comment before measures are finalized for use. Another commenter noted that measures

when implemented may produce unintended consequences and that stakeholders should have the opportunity in the rulemaking process to raise these issues.

Response: Our proposal to retain previously finalized LTCHQR Program measures for subsequent fiscal year determinations aligns with our proposal to retain measures in other Medicare quality reporting programs such as the Hospital IQR Program. We believe this policy will help streamline the rulemaking process and that, in most cases, the comment process during the year we initially propose to adopt a measure is sufficient to identify any potential problem with the measure. However, if we have any indication that the continued use of a measure is causing potential safety concerns, which includes causing unintended consequences, we will take immediate action to remove that measure from the program. To the extent that stakeholders identify other types of unintended consequences (that is, unintended consequences that would not raise patient safety concerns), we also welcome and would consider comments on these issues at any time. We also plan to work with technical experts and solicit public input through venues such as technical expert panel meetings, listening sessions, special open door forums, and our helpdesk for the LTCHQR Program to ensure that each of the adopted measures remains appropriate for continued inclusion in the LTCHQR Program.

After consideration of the public comments we received, we are finalizing our proposal to retain adopted quality measures for subsequent fiscal year payment determinations unless we propose to remove, suspend, or replace the measure.

b. Process for Adopting Changes to LTCHQR Program Measures

As mentioned previously, quality measures selected for the LTCHQR Program must be endorsed by the NQF unless they meet the statutory criteria for exception. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process (http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx). The NQF undertakes review of: (a) new quality measures and national consensus standards for measuring and publicly reporting on performance, (b) regular maintenance processes for endorsed quality measures, (c) measures with time limited endorsement for consideration of full endorsement, and (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review (http://www.qualityforum.org/Measuring_Performance/Ad_Hoc_Reviews/Ad_Hoc_Review.aspx).

The NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to NQF on an annual basis. As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence for review by a NQF Technical Expert panel which, in turn, provides input to the Consensus

Standards Approval Committee which then makes a decision on endorsement status and/or specification changes for the measure, practice, or event.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28092), we proposed that if the NQF updates an endorsed measure that we have adopted for the LTCHQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the Program. Specifically, we would revise the LTCHQR Program Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We proposed posting updates on our LTCH Quality Reporting Web site at: http://www.cms.gov/LTCH-Quality-Reporting/, with the provision of sufficient lead time for LTCHs to implement the changes where changes to the data collection systems would be necessary.

We proposed continuing to use the rulemaking process to adopt changes to measures when the changes substantially change the nature of the measure. We believe

that our proposal adequately balances our need to incorporate NQF updates to NQF-endorsed LTCHQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the measure we originally adopted. We invited public comment on this proposal.

Comment: Commenters noted that standards of quality may change from year to year and believed that it was not clear how CMS will determine what a "substantial" change is, requiring public input, versus an "unsubstantial" change, not requiring public input. One commenter noted that "even minor changes to the definitions and exceptions [of a measure] can result in a substantive change to a quality measure." Several commenters suggested that CMS set out the process for adopting NQF measure updates that arise from the NQF review process and the process for determining what is a "substantive" versus "non-substantive" measure change. Some commenters stated that CMS should solicit public comments to adopt these changes.

Response: The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate non-substantive updates made by the NQF into the measure specifications we have adopted for the LTCHQR Program so that these measures remain up-to-date. We also recognize that some changes the NQF might make to its endorsed measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

Therefore, after consideration of the public comments received, we are finalizing a policy under which we will use a subregulatory process to make non-substantive updates to NQF-endorsed measures used for the LTCHQR Program. With respect to what constitutes a substantive versus a non-substantive change, we expect to make this determination on a measure-by-measure basis. Examples of non-substantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures used in the Hospital IQR and Hospital VBP Programs). We also believe that non-substantive changes might include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the LTCHQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to the LTCH setting. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance and measure review process.

These policies regarding what is considered substantive versus non-substantive changes would apply to all LTCHQR Program measures.

3. CLABSI, CAUTI, and Pressure Ulcer Measures

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756), we adopted three quality measures for the FY 2014 payment determination as listed in the following table:

Previously Finalized LTCHQR Quality Measures for the FY 2014 Payment Determination	
NQF #0138	Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU] Patients
NQF #0139	Central Line Catheter-Associated Blood Stream Infection (CLABSI) Rate for ICU and High-Risk Nursery (HRN) Patients
Application of NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay)

The three measures finalized for FY 2014 payment determination were NQF-endorsed at the time of the FY 2012 IPPS/LTCH PPS final rule, although not for the LTCH setting. We also stated that we expected the NQF would review some of these measures for applicability to the LTCH setting and we anticipated this review might result in modifications to one or more of the measures.

As part of its endorsement maintenance process, under NQF's Patient Safety Measures Project (http://www.qualityforum.org/projects/patient_safety_measures.aspx), the NQF reviewed the CAUTI and CLABSI measures previously adopted and expanded the scope of endorsement to include additional care settings, including LTCHs. The original NQF-endorsed numbers were retained for these two expanded measures, but the

measures were re-titled to reflect the expansion of the scope of endorsement. NQF #0138 (Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days, for Intensive Care Unit [ICU] Patients) is now titled National Health Safety Network (NHSN) Catheter -Associated Urinary Tract Infection (CAUTI) Outcome Measure. NQF #0139 (Central Line Catheter-Associated Blood Stream Infection [CLABSI] Rate for ICU and High- Risk Nursery (HRN) Patients is now titled National Health Safety Network (NHSN) Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure (http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Patient_Safety_Measures.aspx). These expanded measures allow for the calculation of a Standardized Infection Ratio (SIR).[133,134,135,136] For the remainder of this rule, we refer to these measures as the CAUTI measure and CLABSI measure, respectively. We proposed adopting the changes to the NQF-endorsed CAUTI and CLABSI measures that we previously finalized for the FY 2014 payment determination, consistent with our stated intention to update these measures with changes resulting from NQF's review of the measures. Further, we proposed adopting the NQF-endorsed CAUTI measure and CLABSI measure for the FY 2015 payment determination and all subsequent fiscal year

[133]Centers for Disease Control and Prevention. (2012, January). Central Line-Associated Bloodstream Infection (CLABSI) Event. Retrieved from http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf

[134] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure. Retrieved from http://www.qualityforum.org/QPS/0139

[135] Centers for Disease Control and Prevention. (2012, January). Catheter Associated Urinary Tract Infection Event. Retrieved from: http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf

[136] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. Retrieved from http://www.qualityforum.org/QPS/0138

payment determinations. We also proposed incorporating any future changes to the CAUTI measure and CLABSI measure to the extent these changes are consistent with our proposal to update measures.

We proposed retaining an application to the LTCH setting of the measure Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), as finalized in the FY 2012 IPPS/LTCH PPS final rule for the FY 2014 payment determination, for FY 2015 and all subsequent fiscal year payment determinations. We also noted that the Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) measure was undergoing NQF review for expansion in the scope of endorsement to include additional care settings, including LTCHs and, to the extent that the measure is updated in a manner that does not substantially change the nature of the measure, we would incorporate the updates consistent with our previous proposal to update measures.

This measure underwent review for expansion by the NQF Consensus Standards Approval Committee (CSAC) on July 11, 2012 (http://www.qualityforum.org/About_NQF/CSAC/Meetings/2012_CSAC_Meetings.aspx). The CSAC recommended that the NQF expand its endorsement of the measure to the LTCH setting. For the remainder of this final rule, we refer to this measure as the Pressure Ulcer measure. For more information on the history of this measure in the LTCHQR Program, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51753 through 51756).

We invited public comment on our proposal to adopt the revised CAUTI measure (NQF #0138) and CLABSI measure (NQF #0139) beginning with the FY 2014 payment determination. We also invited public comment to retain an application to the LTCH setting of the Pressure Ulcer measure (NQF #0678) (which was finalized last year in the FY 2012 IPPS/LTCH PPS final rule for the FY 2014 payment determination) for the FY 2015 payment determination and subsequent fiscal year payment determinations.

Comment: Many commenters strongly supported CMS' use of the HAI measures CAUTI and CLABSI in the LTCHQR Program for the FY2014 payment determination and subsequent fiscal years' payment determinations. One commenter noted that although it is important to move forward with including these HAI measures, they specifically expressed concerns related to the validation of the data pertaining to these measures.

Response: We appreciate the commenters' support of these measures for use in the LTCHQR Program. We interpret the comment expressing concern related to data validation to be recommending that we validate HAI data. We intend to work with the CDC to develop an efficient, and accurate, data validation approach, and will address this issue in future rulemaking. Furthermore, we recognize that the validation methods currently being used by States that have conducted some level of validation are not standardized or consistent. We will take these additional concerns under consideration as we consider CAUTI and CLABSI data validation.

Comment: One commenter believed that the CAUTI rate is open to observer bias due to a lack of education regarding colonization versus infection. As a result, the

commenter believed that almost all facilities will show progressively improving outcomes in this measure over time as they improve the education of staff on the colonization/infection issue. The commenter believed that this demonstrated improvement will be misleading because, instead of representing an actual decrease in the CAUTI rate, it will reflect a decrease in false positive infection reporting due to colonization. The commenter believed that effects of such a distortion would likely be significant, potentially rendering the first year or two or reporting worthless.

Response: Education is always an important, ongoing component of surveillance. We agree that a better distinction by clinicians between true UTI and asymptomatic bacteriuria may result from CAUTI surveillance. While this result could affect reported CAUTI rates, it would also lead to improved patient outcomes such as reduction of unnecessary antimicrobial usage, reduction in antimicrobial-resistant organisms and decreased adverse reactions to unnecessary medications. Therefore, we do not believe that delaying CAUTI surveillance so that LTCHs might better educate clinicians before implementing the CAUTI measure is the best method to improve patient outcomes.

Comment: One commenter expressed concern about the LTCHQR Program's proposal to use the CAUTI measure. The commenter noted that although the proposed CAUTI measure intended to harmonize measures across the SNF, IRF, and LTCH settings, it did not take into account the significant differences between these healthcare settings. Specifically, the commenter argued that this proposed measure failed to account for higher frequency of urinary catheter use in LTCHs and that this factor had the

potential of severely distorting quality measure reporting data. The commenter believed that, for example, because the measure denominator is derived in part from "the number of urinary catheter days for each location," disproportionately high LTCH denominators may significantly skew interpretations of the data.

Response: Under the LTCHQR Program, CAUTI data will be analyzed solely for LTCHs. LTCHQR Program CAUTI data will not be compared to any data collected from hospitals, IRFs or SNFs. We believe that the use of a CAUTI measure in the Hospital IQR Program and the IRFQR Program harmonizes this measure across care settings and will not skew interpretations of the measure under the LTCHQR Program.

We note that, at this time, we do not require SNF CAUTI surveillance.

Comment: One commenter recommended not finalizing the CAUTI measure or at least excluding Asymptomatic, Bacteremic, Urinary Tract Infection (ABUTI) from the measure. The commenter added that data relating to ABUTI patients is not relevant to LTCH quality and performance improvement because there is no reason for an LTCH to submit blood cultures for an asymptomatic patient.

Response: We appreciate the commenter's recommendation to exclude Asymptomatic Bacteremic Urinary Tract Infection (ABUTI) from the CAUTI measure or not finalize the use of the CAUTI measure. However, we disagree that ABUTI is irrelevant to the LTCH patient population. Bacteremic urinary tract infections do occur among LTCH patients, and these infections may occur in patients without fever or localizing urinary tract symptoms. What is required to meet ABUTI criteria is presence of the same microorganism(s) in blood and urine cultures obtained from the same

patient. These microbiologic findings are indicative of severe infection, and excluding these infections from the LTCH measure would mean omitting what may be important information about LTCH quality. The inclusion of ABUTI in the measure is also part of the NQF-endorsed specifications for the measure.

Comment: Several commenters noted support for the clinical relevance of the CAUTI measure for the LTCH patient population.

Response: We appreciate the commenters' recognition of the clinical importance of the CAUTI measure for the LTCH patient population. We agree with the importance of catheter associated urinary tract infections and role of infection control measures to prevent these infections. According to the CDC, CAUTI is the most common healthcare-associated infection (HAI) and is reported 30 percent more frequently than all other infections reported through NHSN. As an HAI, the CDC estimates that there are 449,334 CAUTIs and 13,000 deaths per year with an estimated associated cost of $340,000,000.[137] Furthermore, as indicated in the HHS National Action Plan to Prevent HAIs (http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html), catheter-associated urinary tract infection is also a leading type of preventable HAI.[138]

Comment: Some commenters expressed concern with the Pressure Ulcer measure's NQF endorsement status. At the time of proposal, commenters noted that the measure was NQF-endorsed for the nursing home patient population, and was undergoing

---

[137] Scott, RD. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. March 2009. Available at: http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf.

[138] Klevens RM, Edwards JR, Richards CL, Horan TC, Gaynes RP, Pollock DA, Cardo DM. Estimating healthcare-associated infection and deaths in U.S. hospitals, 2002. Public Health Reports 2007: 122:160-166. Available at http://www.cdc.gov/ncidod/dhqp/pdf/hicpac/infections_deaths.pdf

NQF review for re-specification and expansion to additional settings. Commenters suggested there be more transparency in the NQF endorsement process, and that CMS provide links to NQF documents and measure specifications. One commenter expressed a preference to not submit pressure ulcer quality measure data until the NQF has completed its review. Some commenters noted that CMS failed to provide information pertaining to this measure's specifications, and that LTCHs would also like the opportunity to review the re-specified measure for appropriateness before determining whether it should be finalized for FY2015 LTCHQR Program

Response: We thank the commenters for their input. On July 11, 2012, the NQF CSAC recommended that the NQF expand its endorsement of the Pressure Ulcer measure to other settings, including the LTCH setting without changes to the specifications. We expect that the measure will be ratified for endorsement by the NQF Board of Directors, as the final step in the NQF endorsement process.

Therefore, we expect the measure, if endorsed for the LTCH setting, will be the same as the measure that we previously finalized. We note, however, that because the NQF has not yet expanded its endorsement of the Pressure Ulcer measure to the LTCH setting, we cannot adopt the NQF-endorsed version of that measure. For that reason, we are retaining the measure that we previously finalized in FY 2012 IPPS/LTCH PPS final rule for the 2014 LTCHQR Program, which is an application of this measure to the LTCH setting.

We do not agree with the commenters' assertion that we failed to provide information pertaining to the measure's specifications. In the FY 2012 IPPS/LTCH PPS

final rule (76 FR 51754 through 51755), we provided the link to the CMS Web site (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html?redirect=/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp) where the Pressure Ulcer measure's specifications, as applicable to the nursing home setting (setting for which the measure was endorsed and in use at the time of the FY 2012 IPPS/LTCH PPS final rule), were publically available. We further noted that for additional information related to this measure, including definitions related to worsening, unstageable and the staging of the pressure ulcers, as well as topics such as the inability to stage pressure ulcers with eschar or slough (unstageable), the public could view the Minimum Data Set 3.0 (MDS 3.0) Resident Assessment Instrument Manual, page 24 of Section M, Skin Conditions, which describes the NPUAP approach.

Further, on January 31, 2012, we posted on CMS LTCHQR Program Web site an initial LTCHQR Program guidance document, which was followed by an updated guidance document on March 8, 2012. These guidance documents included measure specifications for the Pressure Ulcer measure and clearly identified data elements from the LTCH CARE Data Set proposed for use in the LTCH setting. The March 8, 2012 guidance document was incorporated into the draft LTCHQR Program Manual and can be found on the CMS Web site: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html, Appendix E, Titled: Centers for Medicare & Medicaid Services Long-Term Care Hospital Quality Reporting Program Guidance.

Comment: Two commenters expressed concern that LTCHs would be held responsible for pressure ulcers that develop during the time that an LTCH patient receives care in an acute care hospital before being transferred back to the LTCH within three days (also known as an "interrupted [LTCH] stay"). One commenter recommended that the discharge form be modified to exclude pressure ulcers that were acquired during an interrupted stay from the calculation.

Response: LTCH patients that are transferred from an LTCH for three days or less are considered to have had an "interrupted stay," are not discharged from the LTCH, and are still considered to be LTCH patients. With respect to these patients, we believe that LTCHs should be taking quality of care issues into account when they arrange for transfers. However, we also acknowledge that there might be times when, despite efforts made by the LTCH, a patient develops a worsening pressure ulcer during the time spent in the other care setting. We are continuing to evaluate this issue and intend to address it in future rulemaking. We note that the LTCHQR Program is a pay-for-reporting program, which means that LTCHs will satisfy their reporting requirements based on whether or not they report the existence of a worsening pressure ulcer, not based on whether the pressure ulcer actually worsens.

Comment: One commenter expressed concern regarding the presence of a pressure ulcer that cannot be staged and stated that such an ulcer should not be classified as "unstageable simply because it was not examined." This commenter further noted that patients being admitted to an LTCH would be expected to have their wounds assessed within the 48 hour window and that it is highly unlikely that a dressing applied before

admission would be left in place for more than 48 hours on any wound after admission to a hospital. This commenter stated that "it would border on negligent if a dressing was not removed from a known wound on an admission to an LTCH within the 3 days assessment."

The commenter further noted that a device applied over a known pressure ulcer, such as a NPWT pump or cast would never be utilized for a superficial, partial-thickness stage II pressure ulcer. An orthopedic device applied near /over a known pressure ulcer may not be removable to allow observation of a pressure ulcer on admission to an LTCH. However, the patient hospital discharge information would have identified the presence of an ulcer and typically its stage. If a dressing, wound device or cast was not removed, it would highly likely be due to the complexity of the wound, indicating the ulcer is at least full-thickness." Commenters also stated that it was unclear whether pressure ulcers that cannot be examined due to the placement of a medical device, a cast, or a non-removable dressing can be coded as "unstageable" on the LTCH CARE Data Set(s).

Response: We appreciate this feedback related to the assessment and coding of unstageable pressure ulcers in the LTCH setting. The LTCH CARE Data Set includes data elements to allow LTCHs to record, at admission and discharge, the presence of pressure ulcers that are unstageable due to a medical device, a cast or non-removable dressing, or the presence of non-viable tissue such as slough or eschar. The instructions for the coding of pressure ulcers that are unstageable can be found in the draft LTCHQR Program Manual located at the CMS Web site: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html. For

additional information related to this measure, including definitions related to worsening, unstageable and the staging of the pressure ulcers, as well as topics such as the inability to stage pressure ulcers with eschar or slough, we refer readers to the draft LTCHQR Program Manual located at the CMS Web site: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html.

Further, as noted in the FY 2012 IPPS/LTCH PPS final rule, unstageable wounds include deep tissue injuries and pressure ulcers covered by non-removable dressings, or non-viable tissue such as slough or eschar. These are not currently included in this NQF-endorsed measure since unstageable wounds cannot be measured, and therefore the presence of worsening cannot be determined. For example, a pressure ulcer that presents with slough or eschar cannot be staged, and is not considered worsened. Only after, and if, debridement occurs, and the dead tissue is removed, can such a wound be properly staged. If after wound debridement, the wound is staged and subsequently evaluated to have increased in the stage, the wound is considered worsened. However, such a wound may not be considered worsened if the stage remains unchanged after debridement and staging.

After consideration of the public comments we received, we are retaining an application to the LTCH setting of the Pressure Ulcer measure for the FY 2015 payment determination and subsequent fiscal year payment determinations. Further, we are finalizing the adoption of the updated NQF endorsed CAUTI (http://www.qualityforum.org/QPS/0138) and CLABSI

(http://www.qualityforum.org/QPS/0139) measures for the FY 2014 payment determination and subsequent fiscal year payment determinations.

Set out below are the quality measures for the FY 2014, FY 2015, and subsequent fiscal year payment determinations.

Quality Measures for the FY 2014, FY 2015 and Subsequent Fiscal Year Payment Determinations	
NQF #0138	National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
NQF #0139	National Health Safety Network (NHSN) Central line-associated Blood Stream Infection (CLABSI) Outcome Measure
Application of NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay)

We proposed using the same data collection and submission methods finalized for these measures (CAUTI, CLABSI and Pressure Ulcer) in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51752 through 51756). We proposed that data collection for these measures, if they are adopted in the FY 2013 IPPS/LTCH PPS final rule, would remain the same for the FY 2014 payment determination and all subsequent fiscal year payment determinations.

For the proposed CAUTI measure and CLABSI measure, descriptions of the measures are available on the NQF Web site at: http://www.qualityforum.org/QPS/0138 and http://www.qualityforum.org/QPS/0139, respectively. Further, the measure specifications, data collection and reporting requirements for CAUTI and CLABSI are available at http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf and http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf, respectively.

Links to the CDC sites listed above are also provided in the LTCHQR Program Manual, which is available for download on the CMS Web site: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html.

For the Pressure Ulcer measure, the data collection instrument is the Long-Term Care Hospital (LTCH) Continuity Assessment Record & Evaluation (CARE) Data Set available for download at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html. Because there are no mandatory standardized data sets being used in LTCHs, we created a new data set, the LTCH CARE Data Set, for use in LTCHs for data reporting for the Pressure Ulcer measure beginning October 1, 2012. This data set incorporates data items contained in other, standardized and clinically established pressure ulcer data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and CARE tool (Continuity Assessment Records & Evaluation). Beginning on October 1, 2012, we proposed that LTCHs will begin to use a data collection document entitled the "LTCH CARE Data Set" as the vehicle by which to collect and electronically submit the data for the Pressure Ulcer measure for the LTCHQR Program. This data set consists of the following components: (1) Pressure ulcer documentation; (2) selected covariates related to pressure ulcers; (3) patient demographic information; and; (4) a provider attestation section.

Specific details related to the LTCH CARE Data Set(s) are available on our Web site for the LTCHQR Program at http://www.cms.gov/LTCH-Quality-Reporting/. The

Technical Submission Specifications Final Version 1.00.3 for the electronic submission of the data set(s) is also available on the LTCH Quality Reporting Technical Information Web page http://www.cms.gov/LTCH-Quality-Reporting/05_LTCHTechnicalInformation.asp#TopOfPage."

Comment: Some commenters encouraged CMS to refrain from implementing the use of the LTCH CARE Data Set for the FY 2014 and FY 2015 data collection, citing LTCHs' concern that LTCHs have not been properly prepared, and might not be ready to submit the LTCH CARE Data Set, and that CMS will not be ready to receive this data.

Response: We appreciate the commenters' concerns related to the readiness of the LTCH CARE Data Set. However, we believe that the data set will be ready for use on October 1, 2012. Furthermore, we believe that we are able to receive this data beginning on October 1, 2012.

We note that, since September 2011, we have undertaken ongoing activities, with input from stakeholders such as LTCHs, technical experts, and measure developers to support LTCHQR Program implementation. Further, since we issued the FY 2012 IPPS/LTCH PPS final rule, we have undertaken several key implementation activities including: the development of the LTCH CARE Data Set; posting of public notice for its use (September 21, 2011); issuing a guidance document (January 31, 2012); issuing an updated guidance document (March 8, 2012); and the issuing of a draft LTCHQR Program Manual (April 27, 2012) which includes coding instructions, terms and definitions, and measure specifications for the Pressure Ulcer measure.

Further, we posted draft technical submission specifications for the LTCH CARE Data Set (October 28, 2011) and final technical submission specifications (posted on May 31, 2012). The guidance document, the draft LTCHQR Program manual, and data submission specifications as well as updates and announcements related to the LTCHQR Program are located and maintained on the CMS Web site: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html. Further, through our measure development contractor RTI International, a technical expert panel was convened that was comprised of clinical experts in the care of LTCH patients that sought input on the implementation of pressure ulcer items through the LTCH CARE Data Set (March 8, 2012), as well as technical expert panels in January 2011 and July 2011. We also conducted a National Train-the-Trainer LTCH-focused training conference (May 1-2, 2012), held provider-focused special open door forums (December 16, 2010, September 21, 2011, and April 13, 2012) and software developer/vendor-focused open calls (November 16, 2011 and June 28, 2012) to support the implementation of the LTCHQR Program.

We also received OMB approval for the use of the LTCH CARE Data Set for collection of data for the Pressure Ulcer measure on April 24, 2012 in accordance with the Paperwork Reduction Act. The OMB Control Number is 0938-1163. We believe that these actions have prepared LTCHs to implement the LTCHQR Program; including using the LTCH CARE Data Set for data submission.

Comment: We received specific support from MedPAC stating that they were encouraged by our efforts to implement the LTCH CARE Data Set, applauding CMS' efforts to collect data in a uniform manner. MedPAC further stated that the CARE (Continuity Assessment Record and Evaluation) Tool, from which data elements used in the LTCH CARE Data Set are derived, performed reliably in LTCHs, Skilled Nursing Facilities, and Inpatient Rehabilitation Facilities, as did earlier testing efforts using other setting-specific instruments.

Several commenters expressed various concerns about the requirement to submit quality data using the LTCH CARE Data Set for the LTCHQR Program. While many commenters supported the development of a LTCH-specific tool, they disagreed that the LTCHQR Program was the appropriate mechanism for its development. A commenter noted that LTCHs are at the extreme end of the acute care spectrum and should not be included when discussing sub-acute care settings. This commenter believed that it would be more accurate to group LTCHs with general acute care hospitals than to group them in the same space with skilled nursing facilities or nursing homes. Other commenters expressed concerns that an assessment tool specifically for LTCHs would enable a better understanding of the medical complexity of patients treated in LTCHs. One commenter noted that the LTCH CARE Data Set is not NQF-endorsed for use as an LTCH quality measure.

Several commenters noted that requiring LTCHs to submit an assessment tool goes beyond what was required or intended in section 3004 of the Affordable Care Act. Several commenters were concerned that the LTCH CARE Data Set requirements were

established in a subregulatory manner. Another commenter noted that the CARE Tool has only been used in a demonstration program and has not been tested or validated and several noted that it should incorporate input from stakeholders.

Response: We thank MedPAC for its support and recognition of the importance of uniform and standardized data collection methods. We interpret the commenter to mean that although LTCHs are a post-acute setting, they are more similar to acute care hospitals, and that LTCHs should not be included in discussions or comparisons to skilled nursing facilities or nursing homes, but rather be considered more within the acute care spectrum of care than within the post-acute realm. We further interpret this commenter to be suggesting that quality measures used in LTCHs should not be of the same measure construct as those used in the post-acute setting, and should not use the same data elements or data collection submission method, such as a method similar to the MDS 3.0. We note that for the purpose of LTCHQR Program, we acknowledge that LTCHs are a unique setting and while LTCHs share similarities to acute and post-acute settings, we do not intend to undertake comparisons of data for the Pressure Ulcer measure across post-acute or acute settings.

We acknowledge the commenters' concern regarding some of the data elements that are included on the LTCH CARE Data Set. In response to these concerns, we are clarifying that with respect to the pressure ulcer measure, LTCHs will only be required to complete a subset of the data elements from the LTCH CARE Data Set. These elements are: (1) a limited set of administrative items that are necessary in order to identify each LTCH and properly attribute patients to it for purposes of calculating the measure rate,

(2) the data elements necessary to populate the pressure ulcer measure, consistent with application of the NQF-endorsed specifications for that measure to the LTCH setting, and (3) the data elements necessary to enable CMS to validate that the pressure ulcer measure data elements were accurately reported. All other data elements on the LTCH CARE Data Set can be completed on a voluntary basis by LTCHs and will have no impact on the measure calculations for the Pressure Ulcer measure or on our determination of whether the LTCH has met the reporting requirements under the LTCHQR Program. We will post on our Web site a detailed matrix that identifies which data elements will be required, and which will be voluntary, and this matrix will also be incorporated into the final LTCHQR Program Manual which will be posted on CMS LTCHQR Program Website and available for download from http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html.

Comment: Several commenters expressed concern that the LTCH CARE Data Set was being implemented in its entirety for the LTCHQR Program and that items not required for calculation of the Pressure Ulcer measure were being collected unnecessarily. One commenter also noted that the data on the Pressure Ulcer measure could be collected without the LTCH CARE Data Set. One commenter noted that the only data elements needed to collect data on the Pressure Ulcer measure are hospital and patient identifying information, number of pressure ulcers (stage 2 or higher) at admission and discharge. One commenter suggested that CMS refrain from collecting data elements required for covariate risk-adjustment until such risk adjustment is to be used to calculate LTCH performance.

Response: We thank the commenters for their input. As we note above, we are limiting the data elements that an LTCH must complete for purposes of reporting the Pressure Ulcer measure to those described above. We note that the covariate data elements, which enable the measure rate to reflect a risk adjustment, are part of the NQF-endorsed specifications for the measure and are also part of the specifications we have adopted for the application of this measure to the LTCH setting.

Comment: One commenter stated that CMS needs to put into place a number of additional policies before it can implement the LTCHQR Program. These policies include clear administrative requirements; contact information for a quality administrator; a clear and reliable data submission process; a preview period for quality reports prior to their being made public, an appeals and reconsideration process; a quality support infrastructure, a data validation methodology, and standards for the minimum number of cases needed to be reported per measure.

Response: We provide information specific to the data submission requirements, for example, administrative related requirements, in the LTCH CARE Data Submission Specifications Overview Document provided in the downloadable Final LTCH CARE Data Submission Specifications (v1.00.3), on the CMS Web Site http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html, and will be providing additional administrative requirements in mid August, 2012. In addition, we are working to provide final guidance related to program requirements in the LTCHQR Program Manual provided on the CMS Web site:

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html. Specific details related to NHSN HAI reporting and administrative-related requirements for the CAUTI measure and CLABSI measure can be found on the CDC Web site: http://www.cdc.gov/nhsn.

Comment: Several commenters urged CMS to propose use of the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System as the submission mechanism through the regulatory process so that the public can be afforded a proper notice and comment period. One commenter was concerned with whether the QIES ASAP System has been pilot tested or validated and whether the burden of reporting into them has been explored.

Response: The QIES ASAP System is a secure, intranet-based data submission and data storage system that we have adopted for a variety of purposes at CMS, including the storage of data used for Home Health Compare and Nursing Home Compare. The QIES ASAP System permits information to be shared securely, quickly, and conveniently with providers. It has been successfully used by CMS for 15 years. As part of our implementation plan for the LTCHQR Program, we considered various options for data submission and storage.

We specifically selected the QIES ASAP System because it is already a successfully proven system that provides facilities with the ability to submit standardized patient-level data into the QIES National Repository. Examples of current use include Inpatient Rehabilitation Facilities (IRF) submission of the IRF Patient Assessment Instrument (IRF PAI) data; Home Health Agencies submission of the Outcome and

Assessment Information Set (OASIS) data; and nursing facilities and swing beds submission of the Minimum Data Set (MDS) data. Therefore, we selected the QIES ASAP System to support the data submission of LTCHQR quality measures into the QIES national data base.

Selection of the QIES ASAP System for data submission and storage was publically announced on October 2011, in our LTCH CARE Data Set Data Submission Specifications Overview Document, found on the CMS Web site: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html. Since October 2011, we have undertaken numerous efforts to educate stakeholders on the QIES ASAP System. These efforts include hosting LTCH software developer/vendor calls on November 2011 and June 28th, 2012. During these calls we provided details on the QIES ASAP System our data submission method. Similarly, we presented data submission information at the May 1, 2012 LTCH National Train-the-Trainer Conference as well as on our public vendor and software developer calls, and on the LTCH Special Open Door Forums. Since October 2011, through our training and use of email listservs to the LTCHs and their vendor community, we have invited participation on the vendor calls, using these calls to alert both LTCHs and their vendors of the data submission specifications and to request comments and questions related to the LTCH submission methods and specifications. Lastly, we posted a link to the CMS technical issues mail box on the CMS Web site which is: LTCH Tech Issues@cms.hhs.gov.

Comment: Many commenters supported the use of the NHSN for reporting and believe it is capable of handling LTCHQR Program data collection. However, some commenters expressed concern at the ability of NHSN to handle LTCHQR Program data collection. These commenters encouraged CMS to work with CDC to determine NHSN's readiness to handle additional programs.

Response: The CDC has assured us that the NSHN system is adequate and will be able to handle the LTCHQR Program HAI data reporting. We also note that of the 450 LTCHs in the nation, over 300 are already enrolled and reporting into NHSN.

For detailed discussions of the history of the LTCHQR Program, including the statutory authority and further details on the three measures previously finalized for FY 2014 payment determination, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756). We have reproduced a portion of the data collection and submission timeline finalized for FY 2014 payment determination in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756) in the following table.

Timeline for Submission of Data for the LTCHQR Program for the FY 2014 Payment Determination	
Data Collection Timeframe: Calendar Year (CY) 2012	**Final Submission deadline for data related to the LTCH Quality Reporting Program FY 2014 payment determination**
Q4 (October 1-December 31, 2012)	May 15, 2013

We refer readers to section VIII.D.5. of the preamble to this final rule for the timeline for data submission under the LTCHQR Program for the FY 2015 payment determination.

Comment: Many commenters expressed concern that key components of the LTCHQR Program were not yet in place, yet data collection is to begin on October 1. Several commenters urged CMS to delay submission of the LTCH CARE Data Set. Commenters noted that CMS did not include details on the LTCH CARE Data Set in previous rules. These commenters also noted that the data set was not released until April 27, 2012 and the May 1 Provider Training was the first formal opportunity the details of the LTCHQR Program were communicated to the public. One commenter noted that, given the continuing revisions to the LTCH CARE Data Set, the LTCH community will have insufficient time to prepare and train. Another commenter suggested that LTCHs be granted a 90-day deferral for reporting admissions and discharges between October 1 and December 31, 2012 (with submissions via NHSN continuing as finalized).

Response: We thank the commenters for their input and recommendations. As we explain in our response to previous comments, we believe that we have made substantial and ongoing efforts to educate LTCHs on the data submission process and the data elements in advance of the October 1, 2012 data submission start date. Although we have made some changes to the LTCH CARE Data Set since we first made information about it publicly available, we advised stakeholders of the changes and do not consider them to be significant in nature. In addition to the training provided on May 1-2, 2012, we have also engaged in informative and educational communication with LTCHs and stakeholders on reporting mechanisms and submission timeframes through open door forums, and vendor/software developer calls, since September, 2011.

We disagree that we provided insufficient notice to the public regarding the LTCH CARE Data Set. Such information was provided during open door forums, vendor calls, and publically posted on the CMS Web site for LTCHs dating back to October 2011. Further, the Data Set was posted for public comments under the Paperwork Reduction Act in the September 2, 2011 **Federal Register** (76 FR 54776) http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html, file number CMS-10409). From comments received at the live National Train-the-Trainer conference, we are working to integrate additional language, coding clarification, and corrections that attendees provided. We intend to issue these changes in early August 2012.

Comment: Many commenters requested that CMS release the free, downloadable LTCH Assessment Submission Entry & Reporting (LASER) software no later than August 1, 2012 so that LTCHs can have at least two months to implement and practice using the software and CMS' consultant can have time to correct any problems with the system.

Response: LASER software is a free, Java-based application that provides an option for facilities to collect and maintain their LTCH CARE Data Set for subsequent submission to the QIES ASAP System. We will release a demonstration-version of LASER in middle of August to provide LTCHs the opportunity to familiarize themselves with the LASER software and the features of the tool. This demonstration version of the software tool will give LTCHs sufficient time to practice using the software before data

submission begins on October 1, 2012. We will also offer training on the LASER software in August and will release the production version of LASER on the QIES Technical Support Office Web site by end of August.

We interpret the reference to "CMS' consultant" as meaning the CMS contractor who will be responsible for supporting LASER. The LASER software is currently undergoing multi-level and quality assurance testing to identify issues, which we anticipate will reduce the risk of data submission problems.

We do not believe that we should move up the LASER release dates as some commenters suggested. The LASER software is currently undergoing critical and rigorous testing by quality assurance (QA) staff. It is vital that the QA testing of the actual production version of the software tool continue up until the end of August to ensure there are no defects in the final version. In addition, we released the Validation Utility Tool (VUT) to allow LTCHs and their vendors to test their software to ensure it meets our minimum requirements for successful completion and submission of a LTCH CARE Data Set record. For information related to LASER and the LTCH CARE Data Set Data Submission Specifications, please use the CMS Web site: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html.

Comment: Several commenters noted that CMS never finalized the FY 2014 data collection timeline for the Pressure Ulcer measure. The commenters believed that CMS only finalized the data collection period for the CAUTI and CLABSI measures.

Response: We believe that we finalized the FY 2014 data collection period for the Pressure Ulcer measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756). We specified that "we were adopting as final the proposed timeline for data submission for the New or Worsened Pressure Ulcers measure and in accordance with the timetable and schedule set forth in section VII.C.4.b. of the preamble, with data collection to begin October 1, 2012, for the FY 2014 payment determination." In section VII.C.4.b we specified that the HAI measure submission timeframe would be October 1, 2012 through December 31, 2012 events for the FY 2014 payment determination, and that LTCHs would have to submit their data no later than May 15, 2013.

We also included the FY 2014 data submission timetable for the Pressure Ulcer measure in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28094), and we believe that the public has been given ample opportunity to comment on it. Therefore, for FY 2014 payment determination, the data submission timeframe for the three quality measures (CAUTI, CLABSI and the Pressure Ulcer measure) will begin October 1, 2012 and reporting will include quality data from October 1, 2012 through December 31, 2012. LTCHs will have until May 15, 2013 to submit the data.

Comment: One commenter expressed concern about the timeframes for completing and submitting the LTCH CARE Data Set. The commenter also noted that there are several instances of conflicting directions for its completion as outlined in the draft LTCHQR Program Manual and provided specific examples regarding conflicting directions. The commenter noted that the industry was concerned about a potential conflict between the 3-day rule for the CARE tool and other reporting timeframes. The

commenter further noted that the submission time will not impact patient safety and that the data entered into LTCH CARE Data Set and NHSN will not be completely accurate since neither is risk adjusted.

Response: We thank the commenter for providing feedback on the draft LTCHQR Program Manual and for making recommendations to improve the clarity of our guidance for completing the LTCH CARE Data Set pertaining to assessment of patient's "usual status," assessment time frame for admission assessment, and relevant approaches to completing each item. In addition, we have invited the public to submit questions and comments related to the LTCHQR Program and the draft LTCHQR Program Manual to the email address for the LTCHQR Program at LTCHQualityQuestions@cms.hhs.gov.

As a result of this commenter's feedback we agree that we have given conflicting information, specifically regarding conflicting guidance given in Chapter 2 of the draft LTCHQR Program Manual. In light of this and additional comments from the public sent to our LTCH help desk, we have revised relevant language in Chapter 2 of the draft LTCHQR Program Manual to provide further clarification to LTCH providers on the completion of the LTCH CARE Data Set. Specifically, we have clarified language pertaining to assessment of patient's "usual status", assessment time frame for admission assessment, and relevant approaches to completing each item on the LTCH CARE Data Set.

Further, we have clarified language pertaining to other aspects of the draft LTCHQR Program Manual, specifically about the type of staff required to complete the

LTCH CARE Data Set and timing of data submission requirements for the LTCH CARE Data Set for the FY 2014 payment update determination. CMS will be posting this revised manual for download at the CMS Web site: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html. We continue to welcome comments from the public and appreciate the need for clarity and communication with providers to ensure successful implementation of LTCHQR Program. Hence, we are continuing to provide additional clarification and guidance through our Web site, open door forums, and training material postings. Information related to these free resources is provided on the CMS LTCHQR Program Web site.

We disagree that the current time frame and guidance will result in inaccurate and inconsistent data being entered into the database. We further disagree that whether or not data is submitted within these timeframes, it will have no impact on patient safety. In the draft LTCHQR Program Manual, we encourage all providers to follow CDC recommendations related to the submission of HAI related data. Although an absolute end date of May 15th for the submission of HAI data is given, the purpose of that ultimate deadline is to allow LTCH facilities time to submit any corrections or missing data. Further, data collection approach and timeframes were set in line with the NQF-endorsed CAUTI measure, CLABSI measure and Pressure Ulcer measure. In our FY 2012 IPPS/LTCH PPS final rule, we stated that reporting for CAUTI measure and CLABSI measure should be in accordance with the CDC guidelines and reporting should occur as close to the time of the event as possible.

We also disagree with the commenter's suggestion that these measures are not risk adjusted. The HAI measures are risk adjusted and use the SIR rather than a rate. This is the preferred form of risk adjustment, will include stratification at the unit-level for the CAUTI measure and CLABSI measure and reflect the NQF-endorsed CAUTI measure and CLABSI measure specifications. The NQF-endorsed Pressure Ulcer measure includes risk adjustment for factors such as body mass index, presence of diabetes mellitus, presence of peripheral vascular disease/peripheral arterial disease, bowel incontinence, and mobility.

After consideration of the public comments we received, we are finalizing the use of the data collection and submission methods finalized for the CAUTI, CLABSI and Pressure Ulcer measures for the LTCHQR Program.

4. LTCHQR Program Quality Measures for the FY 2016 Payment Determinations and Subsequent Fiscal Years Payment Determinations

a. Considerations in Updating and Expanding Quality Measures under the LTCHQR Program for FY 2016 and Subsequent Payment Update Determinations

We believe that development of a LTCHQR Program that is successful in promoting the delivery of high quality healthcare services in LTCHs is paramount. We seek to adopt measures for the LTCHQR Program that promote better, safer, and more efficient care. Our measure development and selection activities for the LTCHQR Program take into account national priorities, such as those established by the National Priorities Partnership (http://www.nationalprioritiespartnership.org/), HHS Strategic Plan (http://www.hhs.gov/secretary/about/priorities/priorities.html), and the National Strategy

for Quality Improvement in Healthcare (http://www.healthcare.gov/center/reports/quality03212011a.html). To the extent practicable, we have sought to adopt measures that have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

In addition, we consider input from the multi-stakeholder group, the Measures Application Partnership (MAP) (http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx), in selecting measures for the LTCHQR Program. Section 1890A(a)(1) of the Act, as added by section 3014(a) of the Affordable Care Act, requires the entity with a contract under section 1890(a) of the Act, currently the NQF, to convene multistakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures. Under section 1890A(a)(2) of the Act, as added by section 3014(b) of the Affordable Care Act, the Secretary must make available to the public a list of quality and efficiency measures described in section 1890(b)(7)(B) that the Secretary is considering under title XVIII of the Act. Section 1890A(a)(3) of the Act further requires the entity with a contract under section 1890(a) of the Act to transmit the input of the multistakeholder groups to the Secretary not later than February 1 of each year, beginning in 2012. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration the input of the multistakeholder groups in selecting quality and efficiency measures. The MAP is the public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input on measures as required

by section 1890A(a)(3) of the Act. The MAP's input on quality and efficiency measures was transmitted to the Secretary and is available at (http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885). As required by section 1890A(a)(4) of the Act, we considered the MAP's recommendations in selecting quality and efficiency measures for the LTCHQR Program.

Comment: Several commenters noted that CMS should, in its selection of measures, more closely align with the recommendations of MAP. Some commenters noted that the MAP did not recommend any of the measures proposed for the FY 2016 LTCHQR Program, but rather, "supported the direction" of these measures.

Response: While submission of measures to the MAP and consideration of their recommendations are part of our measure selection process, we also consider the input of stakeholders, subject matter and industry experts through the technical expert panels periodically convened by our measure development contractor, as well as national healthcare priorities suggested by groups such as MedPAC, and as set forth in the National Quality Strategy.

Comment: Several commenters encouraged CMS to seek input on measures from stakeholders such as LTCH associations as well as technical expert panels.

Response: Throughout the measure selection process, we have sought input from a variety of stakeholders, including technical experts, stakeholders, and LTCHs. A CMS Listening Session was held on November 15, 2010, Special Open Door Forums were held on December 16, 2010, September 21, 2011 and April 13, 2012; and our measure developer contractor convened LTCHQR technical expert panels on January 31, July 6,

September 27, December 13 2011, and March 8, 2012. We will continue to solicit input from stakeholders throughout the development and expansion of the LTCHQR Program.

Comment: One commenter suggested that CMS consider the MAP recommendations to pursue measures of Experience of Care, Care Planning, Patient/Family/Caregiver Goals, and Avoiding Unnecessary Hospital and ED Admissions.

Response: We will continue to work with the MAP as well as LTCH stakeholders to identify measure concepts and measures that address HHS priorities, align with quality initiatives in other settings, are evidence-based, have a low probability of unintended adverse consequences, and may drive quality improvement.

Comment: Several commenters encouraged CMS to adopt only measures that are NQF-endorsed for the LTCH setting. One commenter noted that the NQF needs to add an LTCH provider to its panel. Several commenters expressed uncertainty as to whether the expansion of existing measures to the LTCH setting would be a good approach to creating LTCH measures, and one commenter encouraged CMS to adopt only measures that have been specified and tested in the LTCH setting.

Response: We have generally adopted NQF-endorsed measures whenever possible. However, where such measures do not exist, we may adopt measures that are not NQF-endorsed under the Secretary's exception authority set out in section 1886(m)(5)(D)(ii) of the Act. We have, where possible, actively worked with the NQF to expand endorsement of measures to LTCH setting, and the NQF has expanded its endorsement of the CAUTI and CLABSI measures to LTCHs. We believe that the NQF

endorsement process is public and transparent and would encourage LTCHs and stakeholders to participate in that process. Furthermore, we are also working to develop measures on readmissions and functional status that are specific to the LTCH setting and will be seeking NQF endorsement for these measures.

b. New LTCHQR Program Quality Measures Beginning with the FY 2016 Payment Determination

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28094), for the FY 2016 payment determination and subsequent fiscal year payment determinations, we proposed to adopt five additional quality measures for the LTCHQR Program in addition to the three previously discussed measures (CAUTI measure, CLABSI measure and Pressure Ulcer measure), see table below. Our proposal to add these five measures is part of our effort to promote overarching health care aims and goals in an effective and meaningful manner. We also seek to minimize the burden of data collection for LTCHs.

We indicated that we would respond to public comments on this proposal in this final rule.

Proposed New Quality Measures for the FY 2016 LTCHQR Program Payment Determination and Subsequent Payment Determinations	
NQF Measure ID	**Measure Title**
Application of NQF #0680	Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)
NQF #0682	Percent of Residents Who Were Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay)
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel
Application of NQF #0302	Ventilator Bundle
Not NQF endorsed	Restraint Rate per 1,000 Patient Days

(1) New Quality Measure #1 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

According to the CDC, as of 2011, there is on average over 200,000 hospitalizations due to influenza every year.[139] The Agency for Healthcare Research and Quality (AHRQ) reports that in 2004, there were more than 37,000 hospitalizations in which influenza was noted during the stay. For over 21,000 of these hospitalizations, influenza was listed as the primary diagnosis. The aggregate hospital costs for these roughly 21,000 hospitalizations were estimated at $146 million.[140]

Although influenza is prevalent among all population groups, the rates of death and serious complications related to influenza are highest among those ages 65 and older and those with medical complications that put them at higher risk. The CDC reports that an average of 36,000 Americans die annually from influenza and its complications, and most of these deaths are among people 65 years of age and over.[141] In 2004, 70,000 deaths were caused by influenza and pneumonia, and more than 85 percent of these were among the elderly.[142] Given that many individuals receiving health care services in LTCHs

---

[139]Centers for Medicare & Medicaid Services (2011, May). Adult immunization: Overview. Retrieved from https://www.cms.gov/adultImmunizations/

[140] Milenkovic M, Russo CA, Elixhauser A. (2006). Hospital stays for influenza, 2004 (Healthcare Cost and Utilization Project statistical brief no.16). Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from http://www.hcup-us.ahrq.gov/reports/statbriefs/sb16.pdf

[141] Centers for Medicare & Medicaid Services (2011, May). Adult Immunization: overview. Retrieved from https://www.cms.gov/Immunizations/

[142] Gorina Y, Kelly T, Lubitz J, et al. (2008, February).Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf

are elderly and/or have several medical conditions, many LTCH patients are within the target population for the influenza vaccination.[143,144] Healthy People 2010 (Objective 14-29) and Healthy People 2020 (Objective IID-12.8) each set a goal of 90 percent of adults vaccinated against influenza in long-term care facilities.[145,146] However, among adults age 65 years and older, only 72.1 percent were vaccinated during the 2006-2007 influenza season and only 69.6 percent of adults age 65 years and older were vaccinated during the 2009-2010 influenza season.[147,148] According to information currently available on the Nursing Home Compare Web site (http://www.medicare.gov/NHCompare), the national average for the percentage of short-stay residents given the influenza vaccine is roughly 82 percent.[149] No comparable information is currently available on patients in the LTCH setting.

In light of the evidence outlined previously, particularly that many individuals receiving care in the LTCH setting are within the target population for influenza vaccination, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28095), we proposed

---

[143] Centers for Disease Control and Prevention. (2008, September). Influenza e-brief: 2008-2009 flu facts for policymakers. Retrieved from http://www.cdc.gov/washington/pdf/flu_newsletter.pdf

[144] Zorowitz, RD. Stroke Rehabilitation Quality Indicators: Raising the Bar in the Inpatient Rehabilitation Facility. Topics in Stroke Rehabilitation 2010; 17 (4):294-304.

[145] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (n.d.). Healthy People 2010 archive. Retrieved from http://www.healthypeople.gov/2010 /

[146] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and infectious diseases. Retrieved from http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23

[147] Centers for Disease Control and Prevention. (2008). State specific influenza vaccination coverage among adults—United States, 2006-2007 influenza season. MMWR, 57(38), 1033-1039. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5738a1.htm

[148] Centers for Disease Control and Prevention (2011, May). Seasonal influenza (flu): final estimates for 2009–10 seasonal influenza and influenza A (H1N1) 2009 monovalent vaccination coverage—United States, August 2009 through May, 2010. Retrieved from http://www.cdc.gov/flu/professionals/vaccination/coverage0910estimates.htm

[149] Centers for Medicare & Medicaid Services (2011). Nursing Home Compare. Available from http://www.medicare.gov/NHCompare/

NQF #0680, Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay), for application in the LTCHQR Program for the FY 2016 payment determination and subsequent fiscal year payment determinations. We noted that at the time of our proposed rule this measure was endorsed for short-stay nursing home residents, but believed this measure was highly relevant for the LTCH setting because, as stated above, many patients receiving care in the LTCH setting are elderly and within the target population for influenza vaccination. The MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs.[150]

Section 1886(m)(5)(D)(ii) of the Act, the exception authority provides that "in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." We reviewed NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures for influenza vaccination in the LTCH setting. We are unaware of any other measures for influenza vaccination in the LTCH setting that have been approved by a voluntary consensus standards body and endorsed by NQF. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28096), we proposed adopting the NQF-endorsed measure the Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) for application in the LTCH setting

[150] National Quality Forum (2012)Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885. pp. 105

for the LTCHQR Program under the Secretary's authority to select non-NQF measures. This proposal was also consistent with the 2008 NQF steering committee recommendation that "in the interest of standardization and minimizing the burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and recommending measures for endorsement"[151] Data on this measure as it applies to nursing home residents are currently collected and reported as part of the Nursing Home Quality Initiative.

We proposed that data for this measure be collected using the same data collection and submission framework that we finalized for the FY 2014 payment determination.[152] We intend to revise the LTCH CARE data set to include new items which assess patient's influenza vaccination status should this proposed measure be adopted. These items will be based on the items from the MDS 3.0 items.[153] Further, the draft LTCHQR Program Manual will be updated with specifications and data elements once this measure is finalized. At the current time, we refer readers to the MDS 3.0 QM User's Manual available on our Web site at:

---

[151] National Quality Forum (2008, December) National Voluntary Consensus Standards for influenza and pneumococcal vaccinations Available from http://www.qualityforum.org/Publications/2008/12/National_Voluntary_Consensus_Standards_for_Influenza_and_Pneumococcal_Immunizations.aspx

[152] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this proposed measure, is currently approved under Paperwork Reduction Act (PRA) by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The OMB Control Number is 0938-1163. The file number for the LTCH PRA package is CMS-10409.

[153] Centers for Medicare & Medicaid Services). MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 pRelease. Retrieved from https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp.

https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf[154] for technical specifications and data elements for this measure as it is currently implemented in the nursing home setting until we provide guidance for LTCHs in the LTCHQR Program Manual.

By building on the existing reporting and submission infrastructure for LTCHs, such as the LTCH CARE Data Set, which will be used for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. We proposed that the data collection would cover the period from October 1 through March 31 of each year, which corresponds with how NQF specifies this measure as well as other endorsed influenza vaccination measures. We refer readers to section VIII.D.6. of this preamble to this final rule for more information on data collection and submission.

We invited public comment on this proposed measure for the FY 2016 payment determination and subsequent FYs payment determinations.

Comment: Several commenters expressed support for the expansion of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short-stay) to the LTCHQR Program. Commenters noted that LTCH patients are often part of the elderly and/or vulnerable population, in which influenza disease is especially prevalent, and that the measure, which was originally developed for the nursing home setting, would be relevant to the LTCH population and

[154] Centers for Medicare and Medicaid Services (2012, March). MDS 3.0 Quality Measures User's Manual. V5.0. pp. 15. Retrieved from: https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.

would ensure appropriate vaccination practice amongst these vulnerable patients. Commenters encouraged CMS to move forward with recommendations to the MAP and development of specifications and testing for use of the measure in LTCHs.

Response: We appreciate the commenters' support for our proposal to include the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short-Stay) in the LTCHQR Program. We agree that influenza is a serious concern amongst the elderly and vulnerable LTCH patients and that appropriate vaccination is important in this population. The MAP supported the direction of this measure for use in the LTCH setting.[155]

In addition, we applied to the NQF for expansion of this measure to the LTCH setting and the expansion was approved by the NQF Consensus Standards Approval Committee (CSAC) on April 9, 2012 and ratified by the NQF Board of Directors on May 2, 2012. Therefore, this measure is now NQF-endorsed for use in the LTCH setting. At the time of NQF endorsement, the title was changed to reflect that the measure now applies to other settings, including the LTCH setting. The title of the measure is now Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short-Stay). An updated description of the measure is available on the NQF Web site at: http://www.qualityforum.org/QPS/0680.

Comment: Several commenters expressed concern that the introduction of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short-stay) to the LTCHQR Program is redundant, given its

[155] National Quality Forum (2012) Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885. pp. 105; Accessed February 03, 2012

inclusion in the Hospital IQR Program. Commenters remarked that approximately 83 percent of LTCH discharges had a preceding stay at an inpatient facility and are likely to have been vaccinated in the inpatient facility. Commenters believed that inclusion of this measure in both quality reporting programs would result in wasted resources and inefficiencies. Commenters also expressed concern that the inclusion of the measure in both quality reporting programs could result in multiple vaccinations of the same patient, leading to patient safety concerns.

Response: We appreciate the comments and acknowledge the commenters' concern for redundancy and over-vaccination. The specifications of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short-stay) are written to ensure that patients are not double counted, resources are not wasted and patients are only given one vaccine per influenza season. Because the numerator statement of the measure includes patients who received the influenza vaccine during the most recent hospital stay (either inside or outside the facility/hospital), LTCHs can report that a patient received the vaccine at another facility prior to arriving at the LTCH and is not pressured to re-vaccinate the patient for purposes of being able to properly report the measure. The measure is designed to act as a safe guard for patients who did not receive a vaccine in another setting. We acknowledge that facilities will need to adhere to the principles of proper care coordination, and documentation to avoid over-immunization, as well as under-immunization. However, the specifications of the measure are designed to encourage facilities to only vaccinate when the patient has not already received the vaccination in another setting.

Comment: A few commenters believed that this measure was not appropriate for patients in the LTCH setting, due to the severity of illness of the patients in the LTCH setting. Commenters recommended further testing to determine the risk of complications from the vaccine and the appropriateness of the measure in this setting.

Response: We appreciate the comment and agree that patients in LTCHs are especially vulnerable. However, because these populations are older and more vulnerable they have higher rates of death and complications due to influenza and are in greater need of protection. CDC reports that pneumonia and influenza were the fifth leading cause of death amongst individuals ≥65 years and that between 1997 and 2007 deaths among people aged ≥65 years accounted for 87.9 percent of deaths related to pneumonia and influenza.

Due to their increased vulnerability, these patients, as the commenters suggest, are also at increased risk for complications from the vaccination. For this reason, the specifications for this measure were developed in accordance with current guidelines issued by the CDC Advisory Committee on Immunization Practices (ACIP) available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6033a3.htm. By taking into account the ACIP guidelines, the measure is designed to balance the risk of complications with the susceptibility to and mortality from influenza in this high risk population.

In addition, our measure development contractor convened a LTCH technical expert panel and introduced the Percentage of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short-stay) (NQF #0680) measure for discussion. Our measure development contractor advised us that the panel identified

appropriate preventative vaccination as an important concept and good practice in LTCHs. Finally, as noted above, this measure is was recently NQF-endorsed for the LTCH setting.

Comment: Several commenters requested clarifications of and changes to the specifications of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short-stay) quality measure. Commenters specifically asked for clarification of the definition of "appropriately given" as mentioned in the title of the measure. Commenters also expressed concern that the measure does not allow providers to utilize clinical judgment and withhold the vaccine from patients with contraindications. Some commenters believed that LTCHs should not be penalized if a patient refuses the vaccine. Finally, several commenters requested that CMS change the name of the measure to reflect that it is to be used in the LTCH setting (in addition to the SNF setting).

Response: We appreciate the comments and the suggestions for further clarification. As we noted above, the title of this measure changed when the NQF expanded its endorsement to other settings, including the LTCH setting.

This measure is designed to encourage providers to assess vaccination status and when medically appropriate, vaccinate the patient. The term “appropriately given” as used in the measure specifications indicates that the vaccination should be given in accordance with the ACIP guidelines and LTCHs are directed to the guidelines in the specifications.

The measure specifications are written to account for cases when the patient refuses the vaccine or when the medical provider documents that the vaccine was not given due to a contraindication. The numerator of the measure includes: those who received the

influenza vaccine during the most recent influenza vaccine season, either in the facility/hospital or outside the facility/hospital; those who were offered but declined the influenza vaccine; or those who were ineligible due to contraindication(s) (for example, previous severe allergic reaction to influenza vaccine, history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination, or bone marrow transplant within the past 6 months).

Comment: Several commenters were concerned about obtaining documentation for patients who received the vaccine outside of the LTCH. One commenter remarked that an LTCH should not be penalized if it cannot obtain records from outside facilities reflecting whether and/or when a patient received the influenza vaccine, as long as it has made a reasonable effort to do so. Another commenter requested that CMS adopt a regulation which requires other types of facilities (such as acute care hospitals and SNFs) to document in the patient's chart whether an influenza vaccine has been administered and the date of the vaccine and that this documentation be contained in the transfer form.

Response: We refer commenters to the description of the NQF-endorsed measure of at the NQF Web site http://www.qualityforum.org/QPS/0680. Further, we refer commenters to the technical specifications for this measure as currently implemented for the nursing home setting and are available in the MDS 3.0 QM User's Manual on our Web site at: https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.[156]

[156] Centers for Medicare and Medicaid Services (2012, March). MDS 3.0 Quality Measures User's Manual. V5.0. pp. 15. Retrieved from: https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.

Further to the extent that the commenters are asking us to issue guidance on proper vaccine documentation for purposes of ensuring that the receiving facility has an accurate immunization history, we agree that care-coordination is essential to avoid over as well as under-immunization. The influenza vaccination measure, however, was not designed to offer guidance to providers on how to vaccinate. The measure is specified to assess if the patient was vaccinated, where the patient was vaccinated (if they were vaccinated), or why the vaccination was not given (if the patient was not vaccinated). Patients who were not vaccinated due to a contraindication and patients who refused the vaccination are both counted as numerator hits and are accounted for separately in the numerator of the measure.

To that end, and in response to the comment that "an LTCH should not be penalized if it cannot obtain records from outside facilities," LTCHs will not be held accountable for their inability to obtain a patient's current vaccination status. In a situation where the vaccination status in unknown, we would expect that the LTCH provider would make a clinical judgment whether or not to vaccinate a patient taking into account the patient's medical history and current health status, as well as the policy of their LTCH surrounding vaccination. The LTCH must only report the decision that is made, that is, whether the vaccination was or was not given. The measure does not require an LTCH to provide a vaccination that was not appropriate due to a contraindication or a patient refusal, or to provide a vaccination to a patient who was already given a vaccination outside of the LTCH. We encourage all LTCHs to vaccinate according to their facilities policies and the best clinical judgment of the medical

providers treating each individual patient and to document the reason for the vaccination decision.

Comment: One commenter suggested that this measure could be better addressed through a change in Medicare CoP. Further, the commenter noted that CMS can require minimum thresholds for organizational compliance with the measure and the measure is better for CoPs rather than as quality measure.

Response: We thank this commenter and will take into consideration this input during our work on the Medicare CoP. However, at this time, we note that in light of the evidence outlined previously and in the FY 2013 IPPS/LTCH PPS proposed rule, particularly that many individuals receiving care in the LTCH setting are elderly and within the target population for influenza vaccination, we continue to believe the measure is highly relevant for the LTCH setting and appropriate to include in the LTCHQR Program. Further, the MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs. [157]

After consideration of the public comments we received, and in light of the recent NQF endorsement approval for the expansion of this measure to the LTCH setting, we are finalizing the Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #680), which is endorsed and specified for the LTCH setting, for the FY 2016 payment determination and subsequent payment determinations.

[157] National Quality Forum (2012)Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885. pp. 105

(2) LTCH Quality Measure #2 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682)

According to the CDC, pneumococcal disease kills more people in the United States each year than all other vaccine-preventable diseases combined.[158] In 2006, all possible pneumonia diagnoses (including viral, bacterial, and unspecified organisms) killed 55,477 people in the United States and were responsible for 1,232,999 hospital discharges.[159]

Older people and those with chronic health conditions are at higher risk for pneumococcal disease. In 2011 there were more than 40,000 cases of invasive pneumococcal disease in the United States, and approximately one-third of these occurred among persons ages 65 years and older.[160] A 2011 MedPAC report found that pneumonia is among the top 20 most common Medicare Severity Long-Term Care Diagnosis-Related Groups (MS-LTC-DRG).[161] In 2005, Medicare paid an average of $6,342 per hospital discharge for pneumonia-related short-stay hospitalizations.[162] Death related to pneumonia

---

[158] Centers for Disease Control and Prevention. (2009, March). Pneumococcal polysaccharide vaccine: What you need to know. Retrieved from http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf.

[159] Centers for Disease Control and Prevention, National Center for Health Statistics. (various years 1988–2006). National Hospital Discharge Survey. Available from http://www.cdc.gov/nchs/nhds/nhds_publications.htm#nhds.

[160] Centers for Disease Control and Prevention. (2011). Pneumococcal diseases. In The Pink Book: epidemiology and prevention of vaccine preventable diseases (pp. 233-248). Retrieved from: http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/pneumo.pdf.

[161] Medicare Payment Advisory Committee (MedPac). (2011, March) Long-term care hospital services. In Report to the Congress: Medicare payment Policy (pp 231-456). Washington, DC. Available from http://www.medpac.gov/documents/Mar11_EntireReport.pdf.

[162] Health Care Financing Review. Statistical supplement no. 293. (2007). Baltimore, MD: Centers for Medicare and Medicaid Services.

also affects the elderly at a higher rate. In 2004, 70,000 deaths were caused by influenza and pneumonia, and more than 85 percent of these were amongst the elderly.[163]

Individuals in the LTCH setting are at especially high risk of contracting pneumonia as a complication of another medical condition, such as stroke, previous or recent surgery, or ventilation--all of which are conditions for which patients may spend some of their recovery time in the LTCH.[164,165, 166]

Healthy People 2010 (Objective 14-29f) and Healthy People 2020 (Objective IID-13.3) each set a goal of 90 percent of adults vaccinated against pneumococcal disease in long-term care facilities.[167,168] However, estimated pneumococcal vaccination coverage remains below 50 percent in recommended high-risk groups.[169] No comparable information is currently available on patients in the LTCH setting.

In light of the previously described data which we believe reflects the significant impact pneumonia has on Medicare beneficiaries in the LTCH setting, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28096), we proposed a quality measure on the

---

[163] Gorina Y, Kelly T, Lubitz J, et al. (2008, February). Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf.

[164] Fagon JY, Chastre J, Hance AJ, Montravers P, Novara A, Gibert C. Nosocomial pneumonia in ventilated patients: a cohort study evaluating attributable mortality and hospital stay. Am J Med 1993;94:281-8.

[165] Gorina Y, Kelly T, Lubitz J, et al. (2008, February). Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf.

[166] Centers for Disease Control and Prevention. (2011, June). Post-procedure pneumonia (PPP) event. Retrieved from http://www.cdc.gov/nhsn/PDFs/pscManual/10pscPPPcurrent.pdf.

[167] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (n.d.). Healthy People 2010 archive. Retrieved from http://www.healthypeople.gov/2010/.

[168] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and infectious diseases. Retrieved from http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23.

[169] Centers for Disease Control and Prevention, National Center for Health Statistics. (various years 1988–2006). National Hospital Discharge Survey.

pneumococcal vaccine. Specifically, we proposed the measure Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682) for application in the LTCHQR Program for the FY 2016 payment determination and subsequent fiscal year payment determinations. We recognized that at the time of our proposed rule, the NQF had endorsed this measure for short stay nursing home residents but we believed this measure was highly relevant to LTCHs as described previously. This measure reports the percentage of short-stay nursing home residents who were assessed and appropriately given the pneumococcal vaccine (PPV) during a 12-month reporting period. We proposed this measure because, as stated previously, patients in LTCHs are at high risk of contracting pneumonia as a complication of another medical condition. The MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs.[170]

As indicated previously, section 1886(m)(5)(D)(ii) of the Act provides the Secretary with authority to adopt non-NQF-endorsed measures. We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for pneumococcal vaccination in the LTCH setting. We are unaware of any other measures for pneumococcal vaccination in the LTCH setting that have been approved by voluntary consensus standards bodies and endorsed by NQF. We proposed adopting an application of the Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682) for application in the LTCHQR Program. This application is also consistent with the 2008 NQF steering committee

[170] National Quality Forum (2012) Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885. pp. 105.

recommendation that "in the interest of standardization and minimizing the burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and recommending measures for endorsement."[171] Data for this measure as it applies to nursing home residents are currently collected and reported as part of the Nursing Home Quality Initiative.

A description of this measure's technical specifications and the data elements that are currently used for the Nursing Home Quality Initiative are available in the MDS 3.0 QM User's Manual available on our Web site at: http://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.[172]

We proposed that submission of data for this measure will be incorporated into the existing data collection and submission framework for LTCHs adopted for the FY 2014 payment determinations.[173] We intended to revise the LTCH CARE data set to include new items which assess patient's pneumococcal vaccination status should this proposed measure be adopted. These items will be based on the items from the Minimum Data Set (MDS) 3.0 items.[174]

---

[171] National Quality Forum (2008, December) National Voluntary Consensus Standards for influenza and pneumococcal vaccinations rretrieved from http://www.qualityforum.org/Publications/2008/12/National_Voluntary_Consensus_Standards_for_Influenza_and_Pneumococcal_Immunizations.aspx.

[172] Centers for Medicare and Medicaid Services (2012, March). MDS 3.0 Quality Measures User's Manual. V5.0. pp. 15. Retrieved from: https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.

[173] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is approved under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 Federal Register (76 FR 54776). The OMB Control Number is 0938-1163. The file number for the LTCH PRA package is CMS-10409.

[174] Centers for Medicare & Medicaid Services). MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp.

By building on the existing LTCH reporting and submission infrastructure, such as the LTCH CARE data set, which will be used by LTCHs for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. We invited public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

Comment: Several commenters expressed support for the expansion of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Pneumococcal Vaccine (short-Stay) to the LTCHQR Program. Commenters remarked that patients in LTCHs often come from elderly and/or vulnerable populations, in which pneumococcal disease is especially prevalent. As such, the measure, which was originally developed for the nursing home setting, would be relevant to the LTCH population and would ensure appropriate vaccination practice among these vulnerable patients. Commenters encouraged CMS to move forward with recommendations to the MAP and development of specifications and testing for use of the measure in LTCHs.

Response: We appreciate the commenters' support for our proposal to include the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Pneumococcal Vaccine (short-stay) in the LTCHQR Program. We agree that pneumococcal disease is a serious concern amongst the elderly and vulnerable patients in LTCHs and that appropriate vaccination is important in this population. As of May 2, 2012, the NQF expanded its endorsement of this measure to the LTCH setting

and changed the title to Percent of Residents or Patients Who Have Been Assessed and Appropriately Given the Pneumococcal Vaccine.

Comment: Several commenters expressed concern that the introduction of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Pneumococcal Vaccine (short-stay) to the LTCHQR Program was redundant, given its inclusion in the Hospital IQR Program. Commenters stated that approximately 83 percent of LTCH discharges had a preceding stay at an inpatient facility and are likely to have been vaccinated in the inpatient facility. Commenters believed that inclusion of this measure in both quality reporting programs would result in wasted resources and inefficiencies. Some commenters were concerned that the inclusion of this measure in both quality reporting programs could result in patients getting repeat vaccinations resulting in patient safety concerns. One commenter requested more information regarding the number of residents receiving more than one vaccination per season due to lack of documentation and if this will be further investigated in the future. One commenter suggested that CMS track patients' pneumococcal vaccination information across settings, so that multiple doses (which can be contraindicated, add an unnecessary cost to patients' care, and present potential health risks) can be avoided. The commenter noted that this is especially important for patients who require two doses of the vaccine.

Response: We appreciate the comments and acknowledge the commenters' concerns regarding redundancy and repeat vaccination. The specifications of the quality measure are designed to ensure that patients are not double counted, resources are not wasted and patients are only given vaccine according to CDC ACIP guidelines for adult

and pediatric pneumococcal vaccination. Since the proposal of this measure for the LTCHQR Program, the CDC has advised CMS that the ACIP guidelines for adult and pediatric pneumococcal vaccination are currently being re-evaluated, and that the measure specifications might change as a result. For that reason, we are not finalizing this measure for the LTCHQR Program at this time. Once we receive further guidance from the CDC, we will consider whether to re-propose this measure and will take the commenters' concerns into account at that time.

Comment: A few commenters believed that this measure was not appropriate for patients in the LTCH setting. Commenters remarked that this measure is only NQF endorsed for the SNF setting and it is not appropriate to expand a measure to a new setting without appropriate testing and NQF endorsement.

Response: We appreciate the comment and agree that patients in LTCHs are not identical to SNF residents. This measure was recently NQF-endorsed for the LTCH setting. Because LTCH patients are often elderly and more vulnerable they have higher rates of death and complications due to pneumococcal disease. CDC reports that pneumonia and influenza were the fifth leading cause of death amongst individuals 65 years of age and older.[175] Patients in the LTCH setting are especially at high risk of contracting pneumonia as a complication of another medical condition, such as stroke, previous or recent surgery, or ventilation– all of which are conditions for which patients may spend

[175] Centers for Medicare and Medicaid Services (2011,May) Adult Immunizations: Overview. Available from https://www.cms.gov/adultimmuunizations/

some of their recovery time in the LTCH.[176,177, 178] CDC reports that pneumonia is the third-most-frequent HAI among post-surgical patients, with a prevalence of 15 percent.[179] The specifications for this measure instruct providers to deliver the pneumococcal vaccine in accordance with CDC ACIP guidelines for adult and pediatric pneumococcal vaccination. We have recently learned from the CDC, however, that these guidelines are currently being re-evaluated and that the results of this evaluation could affect this measure. For this reason, we are not finalizing this measure for the LTCHQR Program at this time.

Comment: Several commenters requested clarifications of and changes to the specifications of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Pneumococcal (short-stay) quality measure. Commenters specifically asked for clarification of the definition of "appropriately given" and wanted information regarding whether the measure focused on assessment and education or on delivery of the vaccine. Commenters expressed that providers should be able to use medical judgment in delivering the vaccine and that facilities should not be penalized for withholding the vaccine from patients with contraindications. Some commenters believed that facilities should not be penalized if a patient refuses the vaccine. Finally, several commenters requested that we change the name of the measure to reflect the applicability to the LTCH setting.

---

[176] Fagon JY, Chastre J, Hance AJ, et al. (1993). Nosocomial pneumonia in ventilated patients: a cohort study evaluating attributable mortality and hospital stay. Am J Med., 94(3), 281-288.
[177] Gorina Y, Kelly T, Lubitz J, et al. (2008, February). Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf
[178] Centers for Disease Control and Prevention. (2011, June). Post-procedure pneumonia (PPP) event. Retrieved from http://www.cdc.gov/nhsn/PDFs/pscManual/10pscPPPcurrent.pdf
[179] Centers for Disease Control and Prevention. (2009, March). Pneumococcal polysaccharide vaccine: What you need to know. Retrieved from http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf

Response: As we noted above, the CDC has advised that the ACIP guidelines for adult and pediatric pneumococcal vaccination are currently being re-evaluated, and that the measure specifications might change as a result. For that reason, we are not finalizing this measure for the LTCHQR Program at this time. Once we receive further guidance from the CDC, we will consider whether to re-propose this measure and will take the commenters' concerns into account at that time.

Comment: One commenter suggested that CMS take responsibility for tracking vaccinations and sharing this information across facilities. Several commenters were concerned about patients who received the vaccine outside of the facility, especially for those who require two doses of the vaccine. Other commenters expressed concerns related to exclusions and requested that patients for whom the vaccination was contraindicated or refused to be excluded. A few commenters remarked that LTCHs should not be penalized if they cannot obtain records from outside facilities or if patient or family cannot remember this information, as long as it has made a reasonable effort to obtain information. One commenter suggested that this measure could be better addressed through a change in Medicare CoP. Further, the commenter noted that CMS can require minimum thresholds for organizational compliance with the measure and the measure is better for CoPs rather than as quality measure.

Response: As we noted above, the CDC has advised that the ACIP guidelines for adult and pediatric pneumococcal vaccination are currently being re-evaluated, and that the measure specifications might change as a result. For that reason, we are not finalizing this measure for the LTCHQR Program at this time. Once we receive further guidance

from the CDC, we will consider whether to repropose this measure and will take the commenters' concerns into account at that time.

Therefore, after consideration of the public comments we received, we are not adopting the proposed measure Percent of Residents or Patients Assessed and Appropriately Given the Pneumococcal Vaccination for the LTCHQR Program at this time.

(3) LTCH Quality Measure #3 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)

For the FY 2016 payment determination and subsequent fiscal years, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28097 through 28098), we proposed to adopt the CDC-developed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) that is currently collected by the CDC via the NHSN: Influenza Vaccination Coverage among Healthcare Personnel (NQF # 0431). This measure reports on the percentage of health care personnel who receive the influenza vaccination.

As previously noted, influenza virus infections are a major source of preventable mortality in the Medicare population. Between 1976 and 2007, influenza virus infections resulted in an average of 23,607 influenza-related deaths with a yearly range of 3,349 to 48,615 deaths, with approximately 90 percent of these deaths occurring among persons aged 65 or older.[180] Health care personnel are at risk for both acquiring influenza from patients and transmitting it to patients, and health care personnel often come to work

[180] Thompson MG, Shay DK, Zhou H, et al. Estimates of deaths associated with seasonal influenza – United States, 1976-2007. MMWR Morb Mortal Wkly Rep. 59(33):1057-1062.

when ill.[181] One early report of health care personnel influenza infections during the 2009 H1N1 influenza pandemic estimated 50 percent of infected health care personnel had contracted the influenza virus from patients or coworkers in the healthcare setting.[182]

The CDC ACIP guidelines recommend that all health care personnel get an influenza vaccine every year to protect themselves and patients.[183] Even though levels of influenza vaccination among health care personnel have slowly increased over the past 10 years, less than 50 percent of health care personnel each year received the influenza vaccination until the 2009-2010 season, when an estimated 62 percent of health care personnel got a seasonal influenza vaccination. In the 2010-2011 season, 63.5 percent of health care personnel reported influenza vaccination. Healthy People 2020 (Objective IID-12.9) set a goal of 90 percent for health care personnel influenza vaccination.[184] It is important to measure influenza vaccination of health care personnel every season to track progress toward this objective and to make sure that health care personnel and their patients are protected from influenza.[185]

Increased influenza vaccination coverage among health care personnel is expected to result in reduced morbidity and mortality related to influenza virus infection among patients, aligning with the National Quality Strategy's aims of better care and healthy

---

[181] Wilde JA, McMillan JA, Serwint J, et al. Effectiveness of influenza vaccine in healthcare professionals: a randomized trial. JAMA. 1999; 281: 908–913.
[182] Harriman K, Rosenberg J, Robinson S, et al. Novel influenza A (H1N1) virus infections among health-care personnel – United States, April-May 2009. MMWR Morb Mortal Wkly Rep. 2009; 58(23): 641-645.
[183] Fiore AE, Uyeki TM, Broder K, et al. Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR Recomm Rep. 2010. 59(08): 1-62.
[184] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and infectious diseases. Retrieved from http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23.
[185] Lindley MC, Zhang J, Euler G. Health care personnel flu vaccination (2011, November). Retrieved from http://www.cdc.gov/flu/pdf/professionals/vaccination/1112-healthcare.pdf

people/communities. Further, the MAP supported the direction of this measure and believes it is an important aspect of care in LTCHs.[186]

In light of the previously described data which we believe reflects the significant impact influenza has on Medicare beneficiaries in the LTCH setting, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28097), we proposed adopting an influenza measure. Specifically, we proposed to adopt the CDC-developed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure for the FY 2016 payment determination and subsequent fiscal year payment determinations.

We also noted that this measure was undergoing NQF review as part of measure maintenance. As a result of this NQF review, the measure is NQF-endorsed and specified for use for all acute care hospital settings (which includes LTCHs). We proposed this measure because, as stated previously, it aligns with national initiatives. This measure has been finalized for reporting in the Hospital IQR Program and the ASCQR Program.

This measure reports on the percentage of health care personnel who receive the influenza vaccination. Health care personnel refers to all paid and unpaid persons working in health care settings, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from health care personnel. This measure is applicable to LTCHs (we refer readers to the CDC/NHSN Manual, Healthcare Personnel Safety Component Protocol Module, Influenza Vaccination and Exposure Management

[186] National Quality Forum (2012)Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885. pp. 105.

Modules, which is available at the CDC Web site at: http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf for measure specifications and additional details).

We proposed that data collection for this measure would be through the CDC/NHSN (http://www.cdc.gov/nhsn/). It is a secure Internet based surveillance system maintained by the CDC, and can be utilized by all types of health care facilities in the United States, including LTCHs. NHSN collects data via a Web-based tool hosted by the CDC and available at: http://www.cdc.nhsn. For FY 2106 and subsequent fiscal year payment determinations, we proposed that the data collection would cover the period from October 1 through March 31 of each year, which corresponds with how NQF specifies this measure as well as other endorsed influenza vaccination measures.

CDC/NHSN is also the proposed data collection and submission framework for reporting on CAUTI and CLABSI measures for the FY 2015 payment determination.[187] Details related to the procedures for using the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at http://www.cdc.gov/nhsn/hps_fluVacc.html. By building on the CDC/NHSN reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under

[187] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment, Final Rule. **Federal Register** (August 18, 2011; 76 FR 51745-51846). Web. http://www.gpo.gov/fdsys/pkg/FR-2011-08-18/pdf/2011-19719.pdf.

the LTCHQR Program. For additional information on data collection and submission, we refer readers to section VIII.D.6. of this preamble to this final rule.

We invited public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

Comment: Many commenters fully supported the inclusion of the proposed measure in the LTCHQR Program, stating that the measure has been tested in multiple settings, and supported its extension to the LTCH setting. A commenter encouraged the development of an infrastructure to allow facilities to submit summarized data on HCP influenza rates to avoid submission of information unrelated to the measure. Another commenter encouraged CMS to develop the specifications and conduct testing for use in LTCHs.

Response: We appreciate the commenters' strong support for the use of this measure. CDC added aggregate reporting of healthcare personnel influenza vaccination coverage to NHSN. The measure is NQF-endorsed for use in acute care hospital settings including LTCHs.

Comment: One commenter expressed concern that this measure is not an indicator of the quality of care provided by LTCHs, and noted that LTCH patients do not expire due to health care-acquired influenza.

Response: We believe that healthcare personnel vaccination is relevant to the issue of patient safety. Healthcare personnel are at risk for both acquiring influenza from patients and exposing patients to influenza, and health care personnel often come to work

when ill.[188] Further, influenza virus infection is common among healthcare personnel. One study suggested that nearly one-quarter of healthcare personnel were infected during influenza season, but few of these personnel recalled having influenza.[189] In the 2010-11 season, 63.5 percent of healthcare personnel reported influenza vaccination. Healthy People 2020 (Objective IID-12.9) set a goal of 90 percent for health care personnel influenza vaccination.[190] It is important to measure influenza vaccination of health care personnel every season to track progress toward this objective and to make sure that healthcare personnel and their patients are protected from influenza.[191]

Comment: One commenter expressed concern that a LTCH should not be penalized if a healthcare worker is offered, but declines, to receive the influenza vaccine and suggested that refusals be counted in the numerator.

Response: We thank the commenter for this comment. We acknowledge that there may be vaccination refusals. In addition to including healthcare personnel who received a vaccine (at the facility or documented elsewhere), personnel who did not receive the vaccine due to contraindications, and personnel with unknown vaccination status, the numerator statement of the measure includes healthcare personnel who "declined influenza immunization." A description of the measure is available on the NQF Web site at: http://www.qualityforum.org/QPS/0431. Measure specifications are

---

[188] Wilde JA, McMillan JA, Serwint J, et al. Effectiveness of influenza vaccine in healthcare professionals: a randomized trial. JAMA 1999; 281: 908–913.

[189] Elder AG, O´Donnell B, McCruden EA, et al. Incidence and recall of influenza in a cohort of Glasgow health-care workers during the 1993-4 epidemic: results of serum testing and questionnaire. BMJ. 1996; 313:1241-1242

[190] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and infectious diseases. Retrieved from http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23

[191] Lindley MC, Zhang J, Euler G. Health care personnel flu vaccination. http://www.cdc.gov/flu/pdf/professionals/vaccination/1112-healthcare.pdf

available for download under Candidate Consensus Standards Review: Immunizations: 0431- Influenza Vaccination Coverage Among Healthcare Personnel on the NQF Web site at: http://www.qualityforum.org/Projects/n-r/Population_Health_Prevention/Population_Health__Prevention_Endorsement_Maintenance_-_Phase_1.aspx#t=2&s=&p=&e=1 and as part of the Final Report of NQF's Population Health – Prevention Endorsement Maintenance Phase 1 on the NQF Web site at: http://www.qualityforum.org/Projects/n-r/Population_Health_Prevention/Population_Health__Prevention_Endorsement_Maintenance_-_Phase_1.aspx#t=1&s=&p=.

Comment: One commenter suggested that, rather than through the LTCHQR Program, this measure could be better addressed through a change in Medicare CoPs. Further, the commenter noted that CMS can require minimum thresholds for organizational compliance with the measure and the measure is better for CoPs rather than as quality measure.

Response: We thank this commenter and will take into consideration this input during our work on the Medicare CoP. However, at this time, we note that in light of the evidence outlined previously and in the FY 2013 IPPS/LTCH PPS proposed rule, particularly that many individuals receiving care in the LTCH setting are elderly and within the target population for influenza vaccination, we continue to believe the measure is highly relevant for the LTCH setting and appropriate to include in the LTCHQR Program. Our use of this measure also aligns with the MAP's support of the direction of this measure and belief that it is an important aspect of care in LTCHs.

Further, as outlined previously and in the FY 2013 IPPS/LTCH PPS proposed rule, this measure has been finalized for reporting in the Hospital IQR Program and the Ambulatory Surgical Centers Quality Reporting Program. Hence, we assert that this measure is an important aspect of patient safety in all care settings including LTCHs as outlined previously and in the FY 2013 IPPS/LTCH PPS proposed rule.

After consideration of the public comments we received, we are finalizing the Influenza Vaccination Coverage among Healthcare Personnel measure as proposed (NQF #0431) for the FY 2016 payment determination and subsequent fiscal years.

(4) LTCH Quality Measure #4 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Ventilator Bundle (Application of NQF #0302)

In 2009, the most frequently occurring diagnosis in the LTCHs was MS-LTC-DRG 207 (Respiratory Diagnosis with Ventilator Support for 96 or more Hours).[192] Ventilator-Associated Pneumonia (VAP) is a costly, often deadly infection. A systematic review of VAP found: (1) between 10 percent and 20 percent of patients receiving greater than 48 hours of ventilation will develop VAP; (2) ill patients who develop VAP are twice as likely to die as compared with similar patients without VAP; (3) patients with VAP have significantly longer lengths of stay; and (4) patients who have VAP incur over $10,000 in additional hospital costs.[193]

In light of the previously described data on VAP which we believe reflects the significant impact VAP has on Medicare beneficiaries, our measure development

---

[192] Medicare Payment Advisory Commission (MedPAC). (2011, March). Long-term care hospital services. In Report to the Congress: Medicare payment policy (pp. 231–256). Washington, DC: Retrieved from http://medpac.gov/documents/Mar11_EntireReport.pdf.

[193] Safdar, N., Dezfulian, C., Collard, H., Saint, S. "Clinical and Economic Consequences of Ventilator Associated Pneumonia". Critical Care Medicine. 2005: 33(10): 2184-93.

contractor introduced the VAP measure for discussion at a technical expert panel it convened on January 31, 2011. The TEP identified VAP as important for the LTCH setting due to the high percentage of patients on ventilators. However, the panel noted concerns about measuring the rate of VAP due to lack of a consistent definition, concerns of inter-rater reliability, subjective interpretation of VAP, and variability in diagnosing VAP.

Our measure development contractor reviewed this concept again and introduced the Ventilator Bundle (NQF #0302) measure developed by Institute of Healthcare Improvement (IHI) for discussion to address some the concerns noted previously at a July 7, 2011 TEP meeting. This comprehensive ventilator care-bundle process measure is designed to facilitate protocols such as weaning, and mitigate ventilator-related infections, such as VAP. The NQF-endorsed ventilator bundle measure consists of four components: (1) head of the bed elevation $\geq 30^{\circ}$; (2) daily sedation interruption and assessment of readiness to wean; (3) peptic ulcer disease (PUD) prophylaxis; and (4) deep vein thrombosis (DVT) prophylaxis. The measure steward, IHI, also recommends a fifth element be added to the ventilator bundle-process measure: daily oral care with Chlorhexidine (http://www.ihi.org/offerings/MembershipsNetworks/MentorHospitalRegistry/Pages/VentilatorBundle.aspx). A meta-analysis of oral decontamination found a statistically significant reduction in VAP with use of antiseptic oral decontamination, which supports such an addition.[194]

[194] Chan, E., Ruest, A., Meade, M., Cook, D. "Oral decontamination for prevention of pneumonia in mechanically ventilated adults: systematic review and meta-analysis". BMJ. 2007; 334: 889.

We recognize that the Ventilator Bundle (NQF #0302) measure is currently endorsed for ICU patients in the acute care hospital setting; however, we believe this measure is highly relevant for the LTCH setting because ventilator patients are a large segment of the LTCH patient population and a process measure to reduce VAP is important and relevant for the LTCH setting. In addition, the MAP supports the direction of this measure, and stated that it is an important aspect of care in LTCHs.[195] Further, we proposed this measure because it supports the National Quality Strategy by supporting better and safer care that prevents infection among patients at risk for VAP. For the above-described reasons, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28099), we proposed to adopt the Ventilator Bundle measure (NQF #0302) for application in the LTCH setting.

As indicated previously, section 1886(m)(5)(D)(ii) of the Act provides the Secretary with authority to adopt non-NQF-endorsed measures. We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for the ventilator bundle in the LTCH setting. We are unaware of any other measures for the ventilator bundle in the LTCH setting that have been approved by voluntary consensus standards bodies and endorsed by NQF. Therefore, under the authority of section 1886(m)(5)(D)(ii) of the Act, we proposed adopting the Ventilator Bundle (NQF #0302) measure for application in the FY 2016 LTCHQR Program payment determination and subsequent fiscal year payment determinations.

[195] National Quality Forum (2012)Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885. pp. 105.

We further noted that this measure is undergoing endorsement maintenance review at the NQF under the Patient Safety Measures-Complications Project. (http://www.qualityforum.org/Projects/n-r/Patient_Safety_Measures_Complications/Patient_Safety_Measures_Complications.aspx#t=2&s=&p=).

We proposed that data collection and submission of this measure will be through the LTCH CARE Data Set. We intend to revise the LTCH CARE Data Set to include new items to evaluate LTCHs' compliance with each element of the ventilator bundle measure. These items will be based on the data elements of the ventilator bundle in use within hospitals implementing the ventilator bundle process measure (NQF #0302). A description of this measure, as it applies to the acute care setting, is available on the NQF Web site at: http://www.qualityforum.org/QPS/0302.

By building on the existing LTCH reporting and submission infrastructure, such as the LTCH CARE Data Set, which will be used by LTCHs for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program.

We invited public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

Comment: Many commenters supported use of the Ventilator Bundle, and appreciated CMS' recognition of ventilator-associated pneumonia as a costly and deadly infection that is highly prevalent in LTCHs.

Response: We agree with the commenters that ventilator-associated pneumonia is both a deadly and costly infection that is highly relevant to the LTCH setting. We appreciate the commenters' support of this measure.

Comment: Many commenters expressed concern over the lack of NQF endorsement of the measure in the LTCH setting and it not being fully supported by MAP. One commenter recommended the measure be further researched in the LTCH setting. Commenters also expressed concern regarding the measure being under maintenance review under NQFs infections disease project, which has not begun yet.

Response: While we realize that the MAP did not fully support this measure, it supported the direction of the measure and stated that it is an important aspect of care in LTCHs. We also agree with the value of the NQF endorsement process. We proposed an application of the Ventilator Bundle measure (NQF #0302) with the understanding that the measure was being submitted to NQF for maintenance review and update. Our expectation was that the measure would be re-endorsed to include a fifth element (oral cleansing with Chlorhexidine solution), added medical exceptions for each of the five components of the bundle, and expansion to settings beyond the ICU. While the public comments included many concerns related to this proposal, it was our expectation that many of these concerns would be allayed by the update and expansion of the measure.

Subsequent to the proposed rule, we learned that the measure steward, the Institute for Healthcare Improvement (IHI), made a decision to withdraw the Ventilator Bundle measure from consideration for NQF re-endorsement.

After consideration of the public comments we received, and in light of the IHI's withdrawal of this measure from the NQF re-endorsement process, we have decided to not finalize the Ventilator Bundle measure for the LTCHQR Program at this time. We plan to propose an updated version of this measure during future rulemaking.

Comment: Some commenters were concerned about the measure requiring peptic ulcer disease prophylaxis, specifically that this requirement may put patients at risk of clostridium difficile infections.

Response: We appreciate and are aware of the concerns posed these commenters; however there is also evidence that such prophylaxis is beneficial to ventilated patients. A prospective cohort study found patients on mechanical ventilation more than 48 hours had 15.6 times the odds of developing clinically important gastrointestinal bleeding. A multiple regression analysis demonstrated such ventilation to be an independent risk factor. The same study further demonstrated that clinically important gastrointestinal bleeding is associated with an increase in mortality[196]. The Institute for Health Improvement, the steward of this measure, also notes that peptic ulcer disease is a risk factor that increases the mortality and morbidity of ventilator patients and should be maintained in the bundle. They have further specified that if a patient has a medical contraindication to any element of the bundle, as evidenced in the medical record, the patient is considered compliant for that element.[197] However, for the reasons we noted above, we are not adopting this measure in this final rule.

---

[196]Cook, D., Griffith, L., Walter, S., Guyatt, G., Meade, M., Heyland, D., Kirby, A., Tryba, A. "The attributable mortality and length of intensive care unit stay of clinically important gastrointestinal bleeding in critically ill patients". Critical Care. 5. 6 (2001): 368-375.

[197] http://www.ihi.org/knowledge/Pages/Changes/ImplementtheVentilatorBundle.aspx

Comment: One commenter noted that daily sedation vacations and assessment or readiness to wean would not be applicable to LTCH patients because they are usually not orally intubated and often may not be sedated. Another commenter noted that there is no standard definition of "wean." Additional commenters noted this measure is intended for short-term ventilator patients.

Response: While we appreciate this comment, we disagree that this measure is solely intended for the short-term ventilator patient that is orally intubated. We believe that this measure is intended for patients dependent on ventilators, regardless of airway tube placement and length of ventilator use. Our interpretation of the intention of this measure is to support processes that mitigate complications commonly associated with ventilator use, and that it is not solely for "ventilator weaning." However, for the reasons we noted above, we are not adopting this measure in this final rule.

Comment: One commenter requested that each element of the ventilator bundle be modified to allow for the treating physician to determine if it is warranted and in the patient's best interest. Specifically, the commenter requested that an element of the bundle should only be applicable if it is not medically contraindicated. Another commenter noted that failure to accommodate for such contraindications means the measure is not patient-centered.

Response: We thank the commenters for the measure revision recommendations. For the reasons we noted above, we are not adopting this measure in this final rule. We will take the commenter's concerns into account if we consider proposing to adopt an updated version of this measure in future rulemaking.

Comment: Some commenters noted that the CDC has "decertified the traditional VAP measure used within NHSN and is currently monitoring the development and use of ventilator-associated events" and requested that we delay implementation of this measure until CDC releases an updated definition of pertaining to ventilator-associated pneumonia.

Response: We are aware of the work the CDC is doing relative to the VAP measure and ventilator associated events, and we are encouraged by its efforts. For the reasons we noted above, we are not adopting this measure in this final rule. We will take the commenters' concern into account if we consider proposing to adopt an updated version of this measure in future rulemaking.

Comment: Several commenters believed CMS has not "clearly communicated the methods by which the data will be measured and interpreted" for the ventilator bundle measure. Further, another commenter noted that data collection for this measure "would be significant."

Response: We appreciate the concerns expressed by the commenters and will take them into account if we consider proposing to adopt this measure in future rulemaking.

Comment: One commenter noted that CMS failed to identify whether the measure is an outcome measure or a process measure. Another commenter encouraged use of an outcome-based measure.

Response: We noted in the proposed rule that the ventilator bundle is comprehensive process measure designed to mitigate ventilator-related infections, such as

VAP. As we also noted, an outcome-based measure based on ventilator-associated pneumonia was not supported by technical experts due to the difficulty in defining and diagnosing the condition.

Comment: One commenter noted that while CMS convened a technical expert panel to opine on a ventilator associated pneumonia measure, no additional technical expert panels was held to discuss the ventilator bundle.

Response: Both a ventilator associated pneumonia measure and ventilator bundle were discussed at a technical expert panel held on July 11, 2011. The panel was supportive of the ventilator bundle measure compared to the ventilator-associated pneumonia measure.

After consideration of the public comments we received, as noted above, we are not adopting this measure in this final rule.

(5) LTCH Quality Measure #5 for the FY 2016 Payment Determination and Subsequent Fiscal Year Payment Determinations: Restraint Rate per 1,000 Patient Days

Restraints are used to control behavior for people who exhibit disruptive, aggressive, or dangerous behavior in health care settings.[198,199,200,201] The negative outcomes of restraints may include strangulation, loss of muscle tone, decreased bone density (with greater susceptibility for fractures), pressure sores, increased infections, decreased mobility, depression, agitation, loss of dignity, social isolation, incontinence,

---

[198]Sullivan-Marx E, Strumpf N, Evans L, et al. Initiation of physical restraint in nursing home residents following restraint reduction efforts. Res Nurs Health. 1999;22:369-79.

[199] Capezuti E, Evans L, Strumpf N, et al. Physical restraint use and falls in nursing home residents. J Am Geriatr Soc. 1996;44:627-33.

[200] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139-70.

[201] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30-37

constipation, functional decline, abnormal changes in body chemistry and muscular function, and in some cases, patient death.[202,203,204,205,206,207,208,209, 210,211] The use of physical restraints also often constitutes a disproportionate infringement on an individuals' autonomy.[212,213]

Research suggests that other clinical interventions are more effective than restraints in preventing injuries from falls. Interventions involving physiologic care, psychosocial care and environmental manipulation, have been shown to be more effective than restraints, generally without increasing staff time or overall cost of treatment.[214,215,216,217,218,219]

---

[202] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139-70.
[203] Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. J Am Geriatr Soc. 1997;45:773-5.
[204] Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. J Gerontol Nurs.2001;27(4):56-61.
[205]. Evans L, Strumpf N, Allen-Taylor S, et al. A clinical trial to reduce restraints in nursing homes. J Am Geriatr Soc. 1997;45(6):675-81.
[206] Capezuti E, Maislin G, Strumpf N, et al. Side rail use and bed-related fall outcomes among nursing home residents. J Am Geriatr Soc. 2002;50(1):90-6.
[207] Parker K, Miles S. Deaths caused by bed rails. J Am Geriatr Soc. 1997;45:797-802.
[208] Feinsod FM, Moore M, Levenson S. Eliminating full-length bed rails from long term care facilities. Nurs Home Med. 1997;5:257-63.
[209] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30-37.
[210] Mohoney JE. Immobility and falls. Clin Geriatr Med. 1998. 14 (4): 699-726.
[211] Inouye SK, Wagner DR, Acompara D, et al A predictive index for functional decline in hospitalized elderly medical patients. J Gen Intern Med. 1993; 8(12):645-652.
[212] Gastmans C, Milison K. Use of physical restraint in nursing homes: clinical-ethical considerations. J Med Ethics. 2006;32:148-52.
[213] McBrian B. Exercising restraint: clinical, legal and ethical considerations for the patient with Alzheimers's disease. Accide emeg nurs. 2997 Apr 15 (2):94-100.
[214] Capezuti E, Evans L, Strumpf N, et al. Physical restraint use and falls in nursing home residents. J Am Geriatr Soc. 1996;44:627-33.
[215] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139-70.
[216] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30-37.
[217] Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. J Am Geriatr Soc. 1997;45:773-5.
[218] Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. J Gerontol Nurs.2001;27(4):56-61.

The principle of freedom from physical or pharmacological restraint is generally understood and accepted by professional and academic organizations. Groups such as the National Citizens' Coalition for Nursing Home Reform (NCCNHR), the Alzheimer's Association, and the American Physical Therapy Association, as well as numerous nursing homes and academic medical research institutions are involved in limiting the use of restraints. The Untie the Elderly campaign has been working since 1989 to raise public awareness of restraint abuse,[220] and the Advancing Excellence in America's Nursing Homes has recently embedded reduction of the use of restraints in nursing homes as part of an overall goal to increase resident mobility to help nursing home staff address mobility issues including the use of restraints, walking, range of motion, transfer, and prevention of falls.[221]

CMS and other Federal agencies have issued several regulations regarding restraint use in healthcare settings. In the 2006 Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights final rule (71 FR 71378 through 71428), we stated that the use of restraints or seclusion "may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others" (71 FR 71382).[222] Additionally, in 2010, the Food and Drug Administration's Hospital Bed Safety workgroup released clinical guidance for limiting the use of bed rails, reflecting concern about the

---

[219] Evans L, Strumpf N, Allen-Taylor S, et al. A clinical trial to reduce restraints in nursing homes. J Am Geriatr S c. 1997;45(6):675-81.
[220] Untie the Elderly Web site; accessed January 21, 2010, at http://ute.kendaloutreach.org/Default.aspx
[221] Advancing Excellence in America's Nursing Homes Web site; accessed March 24, 2012, at http://www.nhqualitycampaign.org/files/NewGoals_030612.pdf and Physical Restraints Tracking Tool v1.1 (December, 2011) accessible through http://www.nhqualitycampaign.org/files/campaign_updates.htm#cms.
[222] CMS Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights final rule. 2006. Available from https://www.cms.gov/CFCsAndCoPs/downloads/finalpatientrightsrule.pdf.

safety of restraints.[223] To better align with our guidelines, The Joint Commission updated its standards to establish guidelines limiting the use of restraints and seclusion, and clarifying the documentation and usage protocols for hospitals in 2009.[224]

Recognizing the importance of a restraint rate measure, our measure development contractor convened a technical expert panel to review restraint measures for potential use in the LTCHQR Program. The TEP reviewed several NQF-endorsed measures for restraint use, including Restraint Prevalence (vest and limb only) (NQF #0203) endorsed for short-term acute care hospitals, HBIPS-2 Hours of Physical Restraint Use (NQF #0640) endorsed for inpatient psychiatric facilities, HBIPS-3 Hours of Seclusion Use (NQF #0641) endorsed for inpatient psychiatric facilities, and Percent of Residents who were Physically Restrained (Long-Stay) (NQF # 0687) endorsed for residents who have been in the nursing home for over 100 days. We note the measures are NQF-endorsed, although not for the LTCH setting. We submitted NQF #0687 mentioned above to the MAP for consideration. While the MAP supported the direction of this measure, it also advised the measure needed to tested in and specified for the LTCH setting. Subsequently, we also determined that all four of the above-referenced NQF measures were limited in their potential to produce a meaningful measurement in the LTCH setting since these measures have look back and monitoring periods that are problematic for the LTCH setting.

---

[223] FDA Hospital Bed Safety Workgroup; accessed January 25, 2010. Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/MedicalToolsandSupplies/HospitalBeds/default.htm.

[224] The Joint Commission. Restraint/Seclusion for hospitals that use the joint commission for deemed status purposes. 2009. Available from http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=260&ProgramId=1.

Upon further investigation, we identified the "Restraint Rate per 1,000 Patient Days" measure which was developed by the National Association of Long Term Hospitals (NALTH) and is a non-core measure for The Joint Commission ORYX Initiative. This measure is not NQF-endorsed but it is currently specified for and is in use by some LTCHs that submit data for this measure to the NALTH Health Information System. Thus, this measure is a feasible and practical measure for LTCH setting. Therefore we believe it addresses the concerns raised by MAP with respect to NQF #0687 which is the need for specification and use in the LTCH setting.

After review of the previously referenced NQF-endorsed restraint measures, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28100), we proposed the Restraint Rate per 1,000 Patient Days measure for the FY 2016 LTCHQR Program payment determination and subsequent fiscal year payment determinations under the authority in section 1886(m)(5)(D)(ii) of the Act. We proposed to use the exception authority because there are no NQF endorsed measures on restraints for the LTCH setting. Further, as explained previously, we have given due consideration to the existing NQF measures on restraints (although not endorsed for the LTCH setting) and we believe they are not appropriate for the LTCHQR Program. We proposed this measure because we believe it is a relevant, scientifically sound, valid, and an important measure which is also feasible for data collection in the LTCH setting compared to the existing NQF-endorsed restraint measures previously discussed. For this measure, the measure specifications will be made available on the LTCHQR Program Web site at http://www.cms.gov/LTCH-Quality-Reporting/.

We proposed that the data collection and submission of this measure will be through the LTCH CARE Data Set. This is the same data collection and submission framework which we would use to support LTCHs for reporting on the Percent of Residents with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) measure.[225]

By building on existing data reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program.

We invited public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal year payment determinations.

Comment: Several commenters expressed support for inclusion of Restraint Rate per 1,000 Patient Days measure in the LTCHQR Program.

Response: We appreciate the commenters' support of this measure.

Comment: Several commenters stated that this measure is not appropriate for the LTCH setting because restraint use is often necessary and medically appropriate in this setting. Commenters added that this measure has not been tested in the LTCH setting and that support for this measure relies heavily on data obtained regarding restraint use in other settings. Commenters remarked that restraints are needed to prevent harm to the patient caused by removing necessary tubes and lines and that patients in LTCHs more

[225] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is currently approved under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The OMB Control Number is 0938-1163. The file number for the LTCH PRA package is CMS-10409.

frequently receive more invasive and lifesaving treatments when compared to SNFs and other healthcare settings on which the data supporting this measure is based.

Response: We appreciate the commenters' concerns that restraint use is often medically appropriate in the LTCH setting and that a measure of restraint use would thus not be appropriate in the LTCH setting. We agree that there are occasions in which restraint use is appropriate, and do not intend that a quality measure evaluating restraint use eliminate all uses of restraint. However, there are many potential negative outcomes of restraints (strangulation, loss of muscle tone, decreased bone density, pressure sores, increased infections, decreased mobility, depression, agitation, loss of dignity, social isolation, incontinence, constipation, functional decline, abnormal changes in body chemistry and muscular function, patient death, and the loss of autonomy[226,227,228,229,230,231,232,233,234,235,236, 237,238]) and research suggests that other clinical

---

[226] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139-70.
[227] Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. J Am Geriatr Soc. 1997;45:773-5.
[228] Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. J Gerontol Nurs.2001;27(4):56-61
[229]. Evans L, Strumpf N, Allen-Taylor S, et al. A clinical trial to reduce restraints in nursing homes. J Am Geriatr Soc. 1997;45(6):675-81
[230] Capezuti E, Maislin G, Strumpf N, et al. Side rail use and bed-related fall outcomes among nursing home residents. J Am Geriatr Soc. 2002;50(1):90-6.
[231] Parker K, Miles S. Deaths caused by bed rails. J Am Geriatr Soc. 1997;45:797-802.
[232] Feinsod FM, Moore M, Levenson S. Eliminating full-length bed rails from long term care facilities. Nurs Home Med. 1997;5:257-63.
[233] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30-37
[234] Parker K, Miles SH. Deaths caused by bedrails. J Am Geriatr Soc 1997; 45 (7): 797-802.
[235] Mohoney JE. Immobility and falls. Clin Geriatr Med. 1998. 14 (4): 699-726
[236] Feinsod FM, Moore M, Levenson S. Eliminating full-length bed rails from long term care facilities. Nurs Home Med. 1997;5:257-63. Minnick AF, MIon LC< Johnson ME< Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting int eh US. J Nurs Scholarsh. 2007; 39(1): 30-37. Parker K, Miles SH. Deaths caused by bedrails. J Am Geriatr Soc 1997; 45 (7): 797-802. Mohoney JE. Immobility and falls. Clin Geriatr Med. 1998. 14 (4): 699-726 Inouye SK, Wagner DR, Acompara D, et al A predictive index for functional decline in hospitalized elderly medical patients. J Gen Intern Med. 1993; 8(12):645-652

interventions such as psychosocial care and environmental manipulation[239,240,241,242,243], are more effective than restraints in preventing injuries from falls, including physiologic care. Therefore, we cannot ignore the patient safety risks introduced by the use of restraints and the need to reduce their use. Our goal is to implement a measure which encourages providers to think more carefully when using restraints and only use restraints when absolutely necessary.

Comment: A few commenters expressed concerns regarding the definition and specifications of this measure. One commenter was specifically concerned that this measure does not exclude patients who were restrained for acute anxiety or delirium and does not clearly define whether restrains would be mechanical, chemical or both. Another commenter suggested that this measure would compare the number of incidents of restraint per 1,000 days and should instead record the amount of time spent in restraint as incidents can vary widely.

---

[237] Gastmans C, Milison K. Use of physical restraint in nursing homes: clinical-ethical considerations. J Med Ethics. 2006;32:148-52.
[238] McBrian B. Exercising restraint: clinical, legal and ethical considerations for the patient with Alzheimers's disease. Accide emeg nurs. 2997 Apr 15 (2):94-100.
[239] Capezuti E, Evans L, Strumpf N, et al. Physical restraint use and falls in nursing home residents. J Am Geriatr Soc. 1996;44:627-33.
[240] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139-70.
[241] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting int eh US. J Nurs Scholarsh. 2007; 39(1): 30-37
[242] Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. J Am Geriatr Soc. 1997;45:773-5.
[243] Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. J Gerontol Nurs.2001;27(4):56-61

Response: We appreciate the comment and the concern for ensuring that the measure allows for the proper use of restraints. The specifications of the Restraint Rate per 1,000 Patient Days measure clarify that the numerator includes "physical restraints according to the CMS and NQF definition – 'a physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.'" The measure excludes "Restraints that are only associated with medical, dental, diagnostic or surgical procedures and are based on the standard practice for the procedure."

In developing the specifications for a quality measure that measures restraints, we do appreciate that some restraints are necessary and that it is not possible to avoid using restraints at all times. As we explain below, we are not finalizing our proposal to adopt this measure for the LTCHQR Program at this time. We intend to implement a quality measure which reflects the commenters' concerns and encourages reduced use of restraints and frequent re-evaluation of necessity.

Comment: Several commenters expressed concern that this measure is not NQF-endorsed and encouraged CMS to use measures which have been vetted through the NQF process. Commenters encouraged CMS to harmonize across settings and consider using the Hours of Physical Restraint Use measure proposed for inclusion in the IPFQR Program.

Response: We appreciate the comments and understand the commenters' concerns that this measure is not NQF-endorsed. A technical expert panel hosted by our

development contractor on January 31, 2011 and September 27, 2011 recommended the use of the Restraint Rate per 1,000 Patient Days in the LTCH setting. However, we also value the guidance of NQF and appreciate the importance of measures that help us achieve our goal of harmonizing measures across settings.

After consideration of the public comments we received, we are not adopting the Restraint Rate per 1,000 Patient Days in the LTCHQR Program. We intend to further consider this and other measures of restraint use, including the HBIPS-2 Hours of Physical Restraint Use (NQF #0640). We intend to propose a patient restraint measure for the LTCHQR Program in future rulemaking.

Set out below are the quality measures for the FY 2016 payment determination and subsequent payment determinations.

New Quality Measures for the FY 2016 LTCHQR Program Payment Determination and Subsequent Payment Determinations	
NQF Measure ID	**Measure Title**
NQF #0138	National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure**
NQF #0139	National Health Safety Network (NHSN) Central line-associated Blood Stream Infection (CLABSI) Outcome Measure**
Application of NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay)**
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)*
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel*

** Adopted for the FY 2014 payment determination and subsequent payment determinations.

* Adopted for the FY 2016 payment determination and subsequent payment determinations.

5. Timeline for Data Submission Under the LTCHQR Program for the FY 2015 Payment Determination

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28100), for the FY 2015 payment determination, we proposed requiring data submission on LTCH discharges

occurring from January 1, 2013 through December 31, 2013 (CY 2013). We proposed that LTCHs would follow the deadlines presented in the table below to complete submission of data for each quarter for each proposed measure for the FY 2015 payment determination. For each quarter outlined in the table below during which LTCHs are required to collect data, we proposed a final submission deadline occurring approximately 135 days after the end of each quarter by which all data collected during that quarter must be submitted. We believe that this is a reasonable amount of time to allow providers to submit data and make any necessary corrections given that this is a new quality reporting program.

We invited public comment on a proposed submission timeline for the FY 2015 payment determination.

We did not receive any public comments. We are finalizing the FY 2015 timeline for data submission, as proposed.

Set out below is the timeline for submission of LTCHQR Program quality data for the FY 2015 payment determination.

Timeline for Submission of LTCHQR Program Quality Data for the FY 2015 Payment Determination	
Data Collection Timeframe: CY 2013	**Final submission deadline for data related to the LTCH Quality Reporting Program FY 2015 payment determination**
Q1 (January-March 2013)	August 15, 2013
Q2 (April-June 2013)	November 15, 2013
Q3 (July-September 2013)	February 15, 2014
Q4 (October-December 2013)	May 15, 2014

6. Timeline for Data Submission Under the LTCHQR Program for the FY 2016 Payment Determination

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101), for the FY 2016 payment determination, we proposed to require data submission on LTCH discharges occurring from January 1, 2014 through December 31, 2014 (CY 2014). We proposed this timeframe because we believe this will provide sufficient time for LTCHs and CMS to put processes and procedures in place to meet the additional quality reporting requirements. We proposed that LTCHs would follow the deadlines presented in the table below to complete submission of data for each quarter. For each quarter outlined in the table below during which LTCHs are required to collect data, we proposed a final deadline occurring approximately 45 days after the end of each quarter by which all data collected during that quarter must be submitted. We believe that this is a reasonable amount of time to allow LTCHs to submit data and make any necessary corrections. We also proposed that similar calendar year collection and submission deadlines would apply to future years payment determinations.

We invited public comment on a proposed submission timeline for the FY 2016 payment determination.

Comment: One commenter objected to the reduction of the submission timeframe from 135 days to 45 days after each quarter.

Response: During the early phase of LTCHQR Program, recognizing that LTCHQR Program is a new reporting requirement for LTCHs, we are allowing 135 days after each quarter for submission of data for the FY 2014 and FY 2015 payment update

determinations. For the FY 2016 payment determination, we will allow 45 days and believe this is sufficient time for LTCHs to submit data because they will have had an opportunity to become familiar with the data submission requirements.

After consideration of the public comments we received, we are finalizing the timeline for FY 2016, as proposed. Set out below is the timeline for submission of LTCHQR Program quality data for the FY 2016 payment determination.

Timeline for Submission of LTCHQR Program Quality Data for the FY 2016 Payment Determination and Subsequent Fiscal Year Payment Determinations	
Data Collection Timeframe: CY 2014	**Final Submission Deadlines for the LTCHQR Program FY 2016 Payment Determination**
Q1 (January-March 2014)	May 15, 2014
Q2 (April-June 2014)	August 15, 2014
Q3 (July-September 2014)	November 15, 2014
Q4 (October-December 2014)	February 15, 2015

7. Public Display of Data Quality Measures

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs under section 1886(m)(5)(C) of the Act available to the public. In addition, section 1886(m)(5)(E) of the Act requires that such procedures shall ensure that a LTCH has the opportunity to review the data that is to be made public with respect to its facility, prior to such data being made public. In addition, the statute requires that the Secretary shall report quality measures that relate to services furnished in LTCHs on our Internet Web site. Therefore, the Secretary will publicly report quality measure data that is reported under the LTCHQR Program. We did not propose procedures or timelines for public reporting of LTCHQR Program data in the proposed rule.

Comment: One commenter urged CMS to publicly report the LTCHQR Program data on Hospital Compare. This commenter further noted that the lack of established procedures or timelines for public reporting of these data is inappropriate and does not reflect the commitment to accountability and transparency CMS has shown in other quality reporting programs. Another commenter noted that a preview period of quality reports prior to their being made public must be present.

Response: We agree with these commenters. We appreciate the need for accountability and transparency for the LTCHQR Program similar to our other quality reporting programs. To this end, we are continuing to undertake efforts to establish procedures and a timeline for the public reporting of data for the LTCHQR Program and we will communicate this information as soon as it is available. Further, similar to our other quality reporting programs, we will provide for a preview period of quality reports under the LTCHQR Program prior to making quality data public.

E. Quality Reporting Requirements under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

1. Background

Section 109(b) of the Medicare Improvements and Extension Act of 2006, under Division B, Title I of the Tax Relief and Health Care Act of 2006, Pub. L. 109-432 (MIEA-TRHCA) amended section 1833(i) of the Act by redesignating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system "in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7)." Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit "data required to be submitted on measures selected under this paragraph with respect to a year" to the Secretary in accordance with this paragraph will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year.

Subparagraph (B) of paragraph (7) states "[e]xcept as the Secretary may otherwise provide," the provisions of subparagraphs (B) through (E) of paragraph (17) of section 1833(t) of the Act, which contain requirements for quality reporting for hospital outpatient services, "shall apply with respect to services of [ASCs] under this paragraph

in a similar manner to the manner in which they apply under such paragraph" and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC, respectively. Pertinent to this proposed rule are subparagraphs (B) and (E) of section 1833(t)(17) of the Act. Subparagraph (B) of section 1833(t)(17) of the Act requires subsection (d) hospitals to "submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph." Subparagraph (E) of section 1833(t)(17) of the Act requires the Secretary to "establish procedures for making data submitted under this paragraph available to the public." Further, these procedures shall ensure that hospitals have the opportunity to review the data before these data are made public. Additionally, the Secretary must "report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals" on CMS' Internet Web site.

Thus, subsections (i)(7)(B) and (t)(17)(B) of section 1833 of the Act, read together, require that ASCs submit quality data in a form and manner, and at a time, that the Secretary specifies. Pertinent to this final rule, subsections (i)(7)(B) and (t)(17)(B) of section 1833 of the Act, read together, require the Secretary to establish procedures for making data submitted available to the public and to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and cost of care that relate to services furnished in ASCs on CMS' Internet Web site. Subsection (i)(7)(B) of section

1833 of the Act also specifies that these provisions apply except as the Secretary may otherwise provide.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to implement the ASC Quality Reporting (ASCQR) Program beginning with the CY 2014 payment determination (76 FR 74492 through 74517). We adopted claims-based measures for the CY 2014 payment determination for services furnished between October 1, 2012 and December 31, 2012. For the CY 2015 payment determination, we adopted the same claims-based measures as adopted for the CY 2014 payment determination and two structural measures. We did not specify the data collection period for the claims-based measures for the CY 2015 payment determination, but specified that reporting for the structural measures would be between July 1, 2013 and August 15, 2013, for services furnished between January 1, 2012 and December 31, 2012, using an online measure submission Web page available at: http://www.QualityNet.org. For the CY 2016 payment determination, we adopted the same claims-based and structural measures as adopted for the CY 2015 payment determination and one process of care measure. We did not specify the data collection period for the claims-based or structural measures, but specified that data collection for the process of care measure would be via the National Healthcare Safety Network beginning on October 1, 2014, and continuing through March 31, 2015.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration and appeals processes in the

FY 2013 IPPS/LTCH PPS proposed rule rather than in the CY 2013 OPPS/ASC proposed rule because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to be finalized earlier and before data collection for the CY 2014 payment determination, which is to begin with services furnished on October 1, 2012.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105), we issued proposals for administrative requirements, data completeness requirements, extraordinary circumstance waiver or extension requests, and a reconsideration process. As discussed below, we did not propose to validate claims-based and structural measures. Further, we intend to address appeals of reconsideration decisions in a future rulemaking. To be eligible to receive the full annual increase, we proposed that ASCs must comply with the requirements specified below for the respective payment determination year.

We invited public comment on these proposals.

2. Requirements for Reporting under the ASCQR Program

a. Administrative Requirements

(1) Requirements Regarding QualityNet Account and Administrator for the CYs 2014 and 2015 Payment Determinations

A QualityNet account is required to submit quality measure data to the QualityNet Web site and, in accordance with CMS policy, a QualityNet administrator is necessary to set-up a user account for the purpose of submitting this information to the QualityNet Web site. The main purpose of a QualityNet administrator is to serve as a point of contact for security purposes for quality reporting programs. We believe from our experience that a QualityNet administrator typically fulfills a variety of tasks related to

quality reporting, such as creating, approving, editing, and terminating QualityNet user accounts within an organization, and monitoring QualityNet usage to maintain proper security and confidentiality measures. Thus, we highly recommend that ASCs have and maintain a QualityNet administrator. However, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28102), we did not propose that ASCs be required to do so for the CY 2014 payment determination because ASCs are not required to submit data to the quality data warehouse for the CY 2014 payment determination (76 FR 74504) and we do not want to unduly burden ASCs by requiring ASCs to have a QualityNet administrator. We note that a QualityNet account is not necessary to access information that is posted to the QualityNet Web site, such as specifications manuals and educational materials.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74509), for the CY 2015 payment determination, we require ASCs to submit structural measure data to the QualityNet Web page. To enter these data into our data system, we proposed that ASCs will need to identify and register a QualityNet administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. Because submission of structural measure data is not required until the July 1, 2013 to August 15, 2013 time period, we proposed that ASCs would be required to have a QualityNet administrator at the time facilities submit structural measure data in 2013 for the CY 2015 payment determination, which is no later than August 15, 2013. ASCs may have a QualityNet administrator prior to this date, but we did not propose that ASCs be required to do so.

We note that there are necessary mailing and processing procedures for having a QualityNet administrator assigned by CMS separate from completion of the forms by the ASC that can require significant time to complete and we strongly caution ASCs to not wait until the deadline to apply; instead, we recommend allowing a minimum of 2 weeks, while strongly suggesting allowing additional time prior to the deadline to submit required documentation in case of unforeseen issues. Because ASCs will need a QualityNet administrator only to have the ability to set up a user account for the purpose of submitting structural measure data once a year, we proposed that ASCs would not be required to maintain a QualityNet administrator after the entry of the structural measure data in 2013 for the CY 2015 payment determination. Although we highly recommend that ASCs have and maintain a QualityNet administrator, we believe that requiring an ASC to maintain a QualityNet administrator throughout the year would increase the burden on ASCs.

We invited public comment on these proposals.

Comment: Some commenters supported not requiring ASCs to maintain a QualityNet administrator until 2013, but recommended that the inactivity deactivation window be extended to one year because many ASCs will need to access their accounts solely on an annual basis.

Response: We appreciate the commenters' support. We understand the commenters' concerns that the QualityNet accounts may be deactivated because ASCs would not be submitting data frequently. As a commenter noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), QualityNet accounts are

automatically deactivated after a 120-day period of inactivity in accordance with CMS security policy. Both the length of this timeframe and the requirement to maintain a QualityNet administrator when a facility is submitting data to a CMS system are dictated by our security policy. If an account is deactivated due to inactivity, it can be reactivated by contacting the QualityNet Help Desk; contact information for the QualityNet Help Desk is located on the QualityNet Web site.

After consideration of the public comments we received, we are finalizing our proposals without modification that ASCs will need to identify and register a QualityNet administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site and that ASCs would be required to have a QualityNet administrator at the time facilities submit structural measure data in 2013 for the CY 2015 payment determination, which is no later than August 15, 2013.

(2) Requirements Regarding Participation Status for the CY 2014 Payment Determination and Subsequent Payment Determination Years

We finalized in the CY 2012 OPPS/ASC final rule with comment period a policy to consider an ASC as participating in the ASCQR Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the Program on their CY 2012 claims relating to the finalized measures (76 FR 74516).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28103), we proposed that once an ASC submits any quality measure data, it would be considered as participating in the ASCQR Program. Further, we proposed that, once an ASC submits any quality measure data and is considered to be participating in the ASCQR Program, an ASC

would continue to be considered participating in the Program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the Program by indicating on a participation form that it is withdrawing, as discussed below. For example, if an ASC includes any QDCs on its claims for the CY 2014 payment determination, it would be considered participating in the ASCQR Program for the CY 2014 payment determination and for every subsequent payment determination unless the ASC withdraws. Likewise, if an ASC did not submit any QDCs for the CY 2014 payment determination, but submitted quality measure data for the CY 2015 payment determination, the ASC would be considered participating in the ASCQR Program starting with the CY 2015 payment determination and continuing for subsequent payment determinations unless the ASC withdraws from the Program.

We considered whether to propose that an ASC be required to complete and submit a notice of participation form for the CY 2015 payment determination or subsequent payment determination years to indicate that the ASC is participating in the ASCQR Program as we require for hospitals, but decided against this proposal because we were concerned about the burden on ASCs. We believe these proposals will reduce burden on ASCs while accomplishing the purpose of notifying CMS of an ASC's participation in the ASCQR Program.

We proposed that any and all quality measure data submitted by the ASC while participating in the ASCQR Program could be made publicly available. This policy would allow us to provide information on the quality of care provided to Medicare beneficiaries which promotes transparency.

We proposed that, once an ASC submits quality measure data indicating its participation in the ASCQR Program, an ASC must complete and submit an online participation form indicating withdrawal to withdraw from the Program. This form would be located on the QualityNet Web site starting in July 2013. We proposed that an ASC would indicate on the form the initial payment determination year to which the withdrawal applies. We proposed a different process for ASCs to withdraw from participation than the process we proposed for an ASC to participate in the ASCQR Program because of the payment implications of withdrawal. We proposed that, in withdrawing from the Program, the ASC would incur a 2.0 percentage point reduction in its annual payment update for that payment determination year and any subsequent payment determination year(s) in which it is withdrawn.

We will not make quality measure data publicly available for that payment determination year and any subsequent payment determination year(s) for which the ASC is withdrawn from the Program.

We proposed that an ASC would continue to be deemed withdrawn unless the ASC starts submitting quality measure data again. Once an ASC starts submitting quality measure data, the ASC would be considered participating unless the ASC withdraws, as discussed above. Again, we believe that these proposals would reduce the burden on ASCs of having to notify CMS as to when they are participating.

We proposed that an ASC can withdraw from the Program at any time up to August 31, 2013 for the CY 2014 payment determination; we anticipate that this will be the latest date possible to allow an ASC to withdraw before payment determinations

affecting CY 2014 payment are made. We proposed that an ASC can withdraw from the Program at any time up to August 31, 2014, for the CY 2015 payment determination. We will propose withdrawal dates for later payment determinations in future rulemakings.

We proposed that these administrative requirements would apply to all ASCs designated as open in the CASPER system before January 1, 2012, for the CY 2014 payment determination. Because ASCs are not required to include QDCs on claims until October 2012 for the CY 2014 payment determination, an ASC designated as open in the CASPER system before January 1, 2012, would be operating for at least 10 months before having to report any data. We believe this would be a sufficient amount of time for ASCs to be established to report quality data for the CY 2014 payment determination.

For the CY 2015 payment determination, we proposed that these administrative requirements would apply to all ASCs designated as open in the CASPER system for at least 4 months prior to January 1, 2013. We believe that this date and length of operations experience would provide new ASCs sufficient time before having to meet quality data reporting requirements after the ASCQR Program's initial implementation year.

We invited public comment on these proposals.

Comment: Commenters supported the CMS proposal that ASCs would indicate their participation in the ASCQR Program solely by beginning to submit QDCs to CMS because they believe this is the least burdensome means for ASCs to indicate their participation status.

Response: We appreciate the commenters' support. We believe this is the least burdensome means for ASCs to indicate their participation status.

Comment: Commenters supported the CMS proposal to have an active mechanism for ASCs to withdraw from the ASCQR Program. Commenters also agreed quality measure data should not be publicly available for a payment determination year and any subsequent payment determination year(s) for which an ASC is withdrawn from the Program. One commenter stated that this active mechanism will help distinguish those ASCs who are aware of the requirements, but choose not to participate, from those that are participating unsuccessfully or who are not aware of the Program, and could allow for more targeted educational efforts.

Response: We appreciate the commenters' support.

Comment: Commenters agreed that CMS had the right to make any data collected under the ASCQR Program publicly available, but made suggestions regarding various facets of public reporting including the ability of facilities to preview data, delaying public reporting, the ability of facilities to resolve accuracy concerns, limiting the information reported for the first years of the Program to whether the ASC successfully participated in the ASCQR Program, and including explanatory narrative for individual measures.

Response: We thank the commenters for their views and suggestions. Regarding public reporting, we only proposed that any and all quality measure data submitted by the ASC while participating in the ASCQR Program could be made publicly available; commenters agreed with this proposal. We did not make any other proposals regarding

public reporting. We will consider these additional comments addressing public reporting of ASCQR Program data in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposals without modification regarding participation in and withdrawing from the ASCQR Program as discussed above.

b. Requirements Regarding Form, Manner, and Timing for Claims-Based Measures for CYs 2014 and 2015 Payment Determinations

(1) Background

In the CY 2012 OPPS/ASC final rule with comment period, we adopted claims based measures for the CYs 2014 and 2015 payment determinations (76 FR 74504 through 74509). We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, an ASC must submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims (76 FR 74515 through 74516). Further, we finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. We did not finalize a date by which claims would be processed to be considered for CY 2014 payment determinations.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), we proposed that claims for services furnished between October 1, 2012 and December 31, 2012 would have to be paid by the administrative contractor by April 30, 2013 to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date

would allow ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

We did not finalize a data collection and processing period for the CY 2015 payment determination, but stated that we intended to do so in the CY 2013 OPPS/ASC proposed rule.

We invited public comments on these proposals.

Comment: Some commenters agreed with the CMS proposal that claims for services furnished between October 1, 2012 and December 31, 2012 that are paid by April 30, 2013 be included in the data used for the CY 2014 payment determination stating that they believed that this April 30, 2013 date would allow for sufficient time for claims processing. However, other commenters believed the proposed period for the collection of claims data may be too abbreviated to capture all pertinent data. Because ASCs have up to 1 year to submit claims for services rendered, some commenters suggested that the period for the collection of claims data be as close to 1 year from the date the service was provided to be included in a payment determination. Some of the commenters that suggested that a longer time period for claims be included, suggested that claims for services furnished between January 1, 2013 and December 31, 2013 be processed by June 30, 2014 for the CY 2015 payment determination.

Response: We appreciate the commenters' support of our proposals that claims for services furnished between October 1, 2012 and December 31, 2012 that are paid by April 30, 2013 be included in the data used for the CY 2014 payment determination. We

agree that sufficient time should be allowed for claims processing to obtain complete data. We have conducted an internal analysis of claims submission by ASCs and have found that over 90 percent of ASC claims are submitted and paid in our proposed timeframe. Therefore, we believe that our proposed April 30 paid date provides sufficient time for claims to be submitted. In addition, while we appreciate that a longer timeframe, for example to June 30, may be desirable, we believe that April 30 is the latest date that would still allow us to acquire and analyze the claims data, make payment determinations, and importantly, allow sufficient time for the administrative contractors to program their systems.

We did not make any proposals regarding a data collection and processing period for the CY 2015 payment determination, but have done so in the CY 2013 OPPS/ASC proposed rule.

Comment: One commenter expressed concern with the lag between the quality data reporting period and the payment reductions in the ASCQR Program, noting that CMS finalized its proposal to reduce ASC payments in 2014 based on data submitted in 2012. This commenter believed that CMS should align the penalty reporting period with the penalty year.

Response: We understand the commenter's concern with the lag between when data are reported and when payment is affected, and we will strive to reduce this lag without significant adverse effects on data completeness and quality. We interpret the commenter's desire to align the penalty reporting period with the penalty year to mean that, for example, claims for services furnished in CY 2014 would be used to affect

CY 2014 payment. This could only be accomplished if we applied any reduction retroactively and recouped funds for any such reduction. We do not believe this a feasible approach because it could cause undue financial hardship on an ASC to have to refund monies and it would be administratively burdensome for us.

After consideration of the public comments we received, we are finalizing our proposal, without modification, that claims for services furnished between October 1, 2012, and December 31, 2012 be paid by the administrative contractor by April 30, 2013, to be included in the data used for the CY 2014 payment determination.

(2) Minimum Threshold for Claims-Based Measures Using QDCs

In the CY 2012 OPPS/ASC final rule with comment period, we finalized that data completeness for claims-based measures would be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claim. In other words, the numerator will be the total number of claims meeting measure specifications that have QDCs and the denominator will be the total number of claims meeting measure specifications. We stated our intent to propose how we would assess data completeness for claims-based measures in this proposed rule (76 FR 74516). For the initial reporting years, we believe that a lower threshold for data completeness should be established for data collection because ASCs are not familiar with how to report quality data under the ASCQR Program, and because many ASCs are relatively small and they may need more time to set up their reporting systems.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), for the CYs 2014 and 2015 payment determinations, we proposed that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe 50 percent is a reasonable minimum threshold based upon the considerations discussed above for the initial implementation years of the ASCQR Program. We intend to propose to increase this percentage for subsequent payment determination years as ASCs become more familiar with reporting requirements for the ASCQR Program.

As stated in CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), ASCs will add the appropriate QDCs on their Medicare Part B claim forms, the Form CMS-1500s submitted for payment, to submit the applicable quality data. A listing of the codes with long and short descriptors is available in transmittal 2425, Change Request 7754 released March 16, 2012 which can be found on our Web site at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2425CP-.pdf. Details on how to use these codes for submitting numerators and denominator information has been available since April 2012 in the ASCQR Program Specifications Manual and the QualityNet Web site at https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228772323772.

We invited public comment on these proposals.

Comment: Several commenters strongly supported the proposed 50 percent minimum threshold for data completeness of claims-based measures for the CYs 2014

and 2015 payment determinations. Some commenters recommended that claims where Medicare is the secondary payer should be excluded from calculations of data completeness for the CY 2014 payment determination because private payers will not be fully informed of the G-codes until the January 2013 tape release.

Response: We appreciate the commenters' support. We understand that, although CMS issued the G-codes for the ASCQR Program with the April 2012 HCPCS release, private payers will not have the files for use until January 1, 2013. When we finalized our policy for calculating data completeness for the CY 2014 payment determination in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we did not specify whether claims where Medicare is the secondary payer would be included for data completeness. However, in the CY 2013 OPPS/ASC proposed rule, we stated that we were proposing to use the same method for determining data completeness that was finalized for the CY 2014 payment determination for the CY 2015 payment determination and subsequent payment determination years and specified that, in calculating data completeness, claims where Medicare is the primary or secondary payer would be included. However, because private payers will not have the QDCs in their required HCPCS data files until January 1, 2013, claims with QDCs received prior to January 1, 2013, can be rejected for having invalid codes. As it is not possible for ASCs to submit differing codes on primary versus secondary payer claims for at least some payers, we are specifying that only claims where Medicare is the primary payer – not the secondary payer – will be used in the calculation of data completeness for the CY 2014 payment determination. We intend to finalize what claims would be included in

calculating data completeness for the CY 2015 payment determination in the CY 2013 OPPS/ASC final rule with comment period.

Comment: One commenter claimed that statistics from the PQRS Program, which uses G-codes on claims for quality measure reporting, show that claims-based reporting is much less accurate than registry-based reporting. This commenter recommended that ASCs not be subject to payment reductions for CY 2014, the first year when payment can be reduced under the ASCQR Program.

Response: We thank the commenter for this information. However, we do not know of any analysis for claims-based and registry-based data collected under the PQRS to support the claim that statistics from the PQRS Program show that claims-based reporting is less accurate than registry-based reporting. We are aware of a recently released competitive Request for Proposal (RFP) entitled "Physician Quality Reporting System and Electronic Prescribing Incentive Program Data Assessment, Accuracy and Improper Payments Identification Support" where we seek, among other purposes, to validate and verify the accuracy of Group Practice Reporting Option claims and registry data submitted by or on behalf of eligible professionals. This RFP is currently available and results from any connected work have not yet been initiated.

We do not agree that all ASCs should not be subject to payment reductions for the first year of the Program. We delayed the start of required data collection for the CY 2014 payment determination until October 1, 2012 (76 FR 74516) as suggested by public comments. We have provided time for ASCs to practice using QDCs. QDCs for ASCQR Program reporting may be used beginning with April 2012 services. Based upon

an internal analysis, ASCs are successfully submitting these codes on their Medicare claims. Therefore, we did not proposed and are not delaying the implementation of the payment reduction under the ASCQR Program.

Comment: Many commenters expressed their views on and made suggestions for ASCQR Program measures and measure specifications.

Response: We thank the commenters for taking the time to express these views and suggestions. However, we did not make any proposals regarding measures or measure specifications. We will consider these comments when we make proposals regarding ASCQR Program measures or measure specifications.

After consideration of the public comments we received, we are finalizing our proposal that the minimum threshold for successful reporting for the CYs 2014 and 2015 payment determinations be that at least 50 percent of claims meeting measure specifications contain QDCs. As discussed above, only claims where Medicare is the primary payer will be used in the calculation of data completeness for the CY 2014 payment determination.

c. ASCQR Program Validation of Claims-Based and Structural Measures

We received comments on the CY 2012 OPPS/ASC proposed rule requesting that rules for data validation be adopted as soon as possible (76 FR 74515). We noted that structural measures historically have not been validated through independent medical record review in our quality reporting programs for hospitals due to the lack of relevant information in medical record documentation for specific data elements of the measures, such as use of a safe surgery checklist. Likewise, we have not historically validated

claims-based measures for hospitals. Thus, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), consistent with other CMS quality reporting programs, we did not propose to validate claims-based measures (beyond the usual claims validation activities conducted by our administrative contractors) and structural measures for the ASCQR Program.

Comment: Several commenters urged CMS to reconsider the need for data validation to ensure standardization and accuracy. Some of these commenters believed that such a data validation process should involve independent review of medical records. One commenter stated that, although it may be acceptable at this time to not perform validity testing on the data, it recommended that prior to using ASC measures for accountability purposes (for example, public reporting, pay for performance), CMS develop and deploy a plan for such testing. The commenter believed that scientific acceptability of the measure is, in part, based on the quality of the data that is used. Having taken such a validation step would be informative in both refining the measure and arriving upon a set of ASC measures.

Response: We appreciate and share the commenters' concern about standardization and the desire for accuracy. We agree that, before using data collected for a quality data reporting program for such activities as public reporting, it is preferable to be able to assess the accuracy of the data reported (we note that the ASCQR Program is a pay for reporting program and not pay for performance program). However, this preference is counterbalanced by the feasibility of being able to do so. Structural measures historically have not been validated through independent medical record review

in our quality reporting programs for hospitals (the Hospital IQR and Hospital OQR Programs). We have not validated structural measures due to the lack of relevant information in medical record documentation for specific data elements of the measures, such as use of a safe surgery checklist. Because we do not believe at this time that there is a method for us to effectively validate structural measure data, we are not requiring a data validation process for our current structural measures under the ASCQR Program.

In regard to the current ASCQR Program claims-based measures, the number of events expected to be reported is small because most of the measures are for adverse or rare events. In this situation, any random selection of cases would require a burdensome sample size. Further, we expect the accuracy for reported adverse events to be high. Because we do not believe at this time that any results that could be obtained justify the burden associated with a data validation process which would necessitate an independent validation effort, we also are not requiring a data validation process for our current claims-based measures.

As we gain more experience with the ASCQR Program, we will reassess whether a data validation process for claims-based and structural measures is needed.

3. Extraordinary Circumstances Extension or Waiver for the CY 2014 Payment Determination and Subsequent Payment Determination Years

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times.

Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104 through 28105), we proposed procedures for extraordinary circumstance extension or waiver requests for the submission of information, including but not limited to, QDCs submitted on claims, required under the ASCQR Program.

In the event of extraordinary circumstances, such as a natural disaster, that is not within the control of the ASC, we proposed to adopt a process for an extension or waiver for submitting information for meeting program requirements that is similar to the one adopted for the Hospital OQR Program because this process has been effective for hospitals, and we believe such a process also would be effective for ASCs. We proposed that an ASC would complete a request form that would be made available on the QualityNet Web site and submit the request to CMS. We proposed that the following information must be noted on the form:

- ASC CMS Certification Number (CCN) and related National Provider Identifier(s) [NPI(s)];
- ASC Name;
- Contact information for a person at the ASC with whom CMS can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- ASC's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and

● A date when the ASC would be able to submit required ASCQR Program information, and a reasonable basis for the proposed date.

We proposed that the request form would be signed by a person who has authority to sign on behalf of the ASC and a request form would be required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, we proposed that CMS would—

(a) Provide a written acknowledgement using the contact information provided in the request, notifying the ASC contact that the ASC's request has been received;

(b) Provide a formal response to the ASC contact using the contact information provided in the request notifying the ASC of our decision; and

(c) Complete its review of any request and communicate its response within 90 days following CMS's receipt of such a request.

We proposed that we would also have discretion to grant waivers or extensions to ASCs that have not been formally requested by them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. We proposed that, if we make the determination to grant a waiver or extension to ASCs in a region or locale, we would communicate this decision to ASCs and vendors through routine communication channels, including, but not limited to, e-mails and notices on the QualityNet Web site.

We invited public comment on this proposed process for granting extraordinary circumstances extensions or waivers for the submission of information for the ASCQR Program.

Comment: Many commenters supported having a process for ASCs to apply for an extension or waiver of the submission of information under the ASCQR Program in the event of extraordinary circumstances. Some of these commenters recommended that the period of time an ASC can apply be extended, for example, to 90 days after such an event, rather than 45 days as proposed.

Response: We appreciate the commenters' support. Regarding the timeframe to request an extension or waiver, we have found that 45 days is sufficient time for hospitals to make such a request under the Hospital OQR Program. We believe that 45 days also would be sufficient time for ASCs to make such requests. We believe that more than 45 days to complete and submit a form will only serve to delay the process. We also proposed and are finalizing a policy that we would have discretion to grant waivers or extensions to ASCs that have not been formally requested by them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale.

Comment: Some commenters noted unforeseen issues related to information technology failures that could prevent ASCs from participating in the ASCQR Program. Examples of such included clearinghouses stripping the QDCs from claims before the claims go to the MAC for processing and problems with billing software not allowing the reporting of a code with a zero dollar charge.

Response: We are aware of situations where clearinghouses are removing QDCs from claims as well as of non-Medicare payers rejecting claims with QDCs as having invalid codes. We note that we issue an update tape containing all valid HCPCS codes

and that clearinghouses should abide by the complete listing of HCPCS codes and should not remove these HCPCS codes from claims. However, we would consider inappropriate removal or rejection of QDCs by clearinghouses as well as private payers an extraordinary circumstance if the ASC was able to sufficiently document refusal by a clearinghouse or private payer to follow our HCPCS usage standards that could result in the ASC suffering substantial risk of having a payment reduction under the ASCQR Program. This documentation must include substantive efforts made by the ASC to inform the clearinghouse or private payer of the need to follow our HCPCS usage standards. We also are aware of the need for the placement of a nominal value in the payment field for some billing software and we have issued guidance on this issue. This guidance is currently available in the Question and Answer Tool on the QualityNet Web site located at http://www.Qualitynet.org under the question with Answer ID 158904 entitled "What are the G-codes for the ASC measures, and where and how do I use them?"

After consideration of the public comments we received, we are finalizing our proposals without modification regarding a process for an extension or waiver of the submission of information required under the ASCQR Program.

4. ASCQR Program Reconsideration Procedures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

We have established similar processes by which participating hospitals can submit requests for reconsideration of quality reporting program payment determinations for the Hospital IQR Program and the Hospital OQR Program. We believe these reconsideration

processes have been effective in the hospital quality reporting programs and such a process would be effective for ASC quality reporting. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28105), we proposed to implement a reconsideration process for the ASCQR Program modeled after the reconsideration processes we implemented for the Hospital IQR and Hospital OQR Programs.

We proposed that an ASC seeking reconsideration would be required to submit to CMS a Reconsideration Request form that would be made available on the QualityNet Web site. We proposed that the request form would be signed by a person who has authority to sign on behalf of the ASC and that this form must be submitted by March 17 of the affected payment year (for example, for the CY 2014 payment determination, the request must be submitted by March 17, 2014).

We proposed to use a deadline of March 17 to provide sufficient time for an ASC to see the effects of a payment reduction on its January claims. Administrative contractors have 30 days to process (pay or deny) clean claims. Administrative contractors have 45 days to process claims other than clean ones (that is, claims that require the contractor to query for more information, look at medical documentation, among others) (Claims Processing Manual, Chapter 1, Section 80; sections 1869(a)(2), 1816(c)(2) and 1842(c)(2) of the Act). We proposed March 17 because this date is 45 days after an ASC would have had the opportunity to provide one full month of services (that is, March 17 is 45 days after January 31).

This Reconsideration Request form would contain the following information:

- ASC CCN and related NPI(s);

- ASC Name;
- CMS-identified reason for not meeting the affected payment year's ASCQR Program requirements as provided in any CMS notification to the ASC;
- ASC basis for requesting reconsideration. We proposed that the ASC must identify the ASC's specific reason(s) for believing it met the affected payment year's ASCQR Program requirements and should receive the full ASC annual payment update;
- Contact information for a person at the ASC with whom CMS can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include physical address, not just a post office box); and,
- A copy of all materials that the ASC submitted to comply with the affected payment year's ASCQR Program requirements. With regard to information submitted on claims, we proposed that ASCs would not be required to submit copies of all submitted claims, but instead would focus on the specific claims at issue. Thus, ASCs would submit relevant information, which could include copies of the actual claims at issue.

Following receipt of a request for reconsideration, we proposed that we would:

- Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the ASC contact notifying the ASC that the ASC's request has been received; and
- Provide a formal response to the ASC contact, using the contact information provided in the reconsideration request, notifying the ASC of the outcome of the reconsideration process.

We stated that we intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration.

We stated that we intend to issue proposals regarding appeals of ASCQR Program reconsideration decisions in a future rulemaking.

We invited public comment on our proposed reconsideration procedures.

Comment: Several commenters supported the CMS proposal to have a reconsideration process. Some of these commenters recommended longer timeframes for an ASC to submit a request than the proposed March 17th deadline, including April 15th and a minimum of 90 days.

Response: We appreciate the commenters' support. We also appreciate suggestions by some commenters to extend the time to submit a reconsideration request. However, we believe the March 17 deadline to submit a reconsideration request provides ASCs with sufficient time to assess the effects of a payment reduction on their January claims. We also note that the March 17 deadline is later than the February 2 deadline that the Hospital OQR Program allows and the Hospital OQR Program also involves a calendar year payment determination.

Comment: Some commenters believed that the need for appeals could be mitigated if CMS incorporates a reporting feedback program that periodically updates ASCs on their reporting status.

Response: We thank these commenters for expressing this view. An automated reporting system with feedback reports as is supplied for the Hospital IQR and OQR

Programs will be available for the ASCQR Program. We plan to begin a reporting feedback program during 2013. We intend to provide feedback on the October 1, 2012, to December 31, 2012 claims-based measures, via a report that will be supplied via an ASC's QualityNet account. ASCs will be able to access these automated reports via their QualityNet accounts beginning in 2013. Information regarding feedback reports will be available on the QualityNet Web site (http://www.QualityNet.org).

After consideration of the public comments we received, we are finalizing our proposals regarding ASCQR Program reconsideration procedures for the CY 2014 payment determination and subsequent payment determination years.

Comment: Commenters expressed views and suggestions regarding additional topics including mechanisms to increase ASC awareness of the ASCQR Program and alternate reporting mechanisms.

Response: We thank these commenters for their suggestions for improving the ASCQR Program. Although we did not make proposals on these topics, we will consider these views for future rulemaking and program development. We have been making efforts to supply information to ASCs regarding the ASCQR Program including information posted on the QualityNet Web site (http://www.QualityNet.org), an educational mailing to ASCs, and an online question and answer tool (http://cms-ocsq.custhelp.com) which is also accessible via the QualityNet Web site.

F. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

1. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for rate year (RY) 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during such rate year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable rate year.

We note that section 1886(s)(4)(A)(i) of the Act uses the term "rate year." Beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD-9-CM codes, which are effective on October 1 of each year. The change allows for annual payment updates and the ICD-9-CM coding update to occur on the same schedule and appear in the same **Federal Register** document, thus making updating rules more administratively efficient. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the 12-month period of October 1 through September 30 is referred to as a fiscal year (76 FR 26435). For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435). For purposes of the

discussion below, the term “rate year” and “fiscal year” both refer to the period beginning October 1 and ending September 30. To avoid any confusion that may be caused by using the term “rate year” with respect to the inpatient psychiatric hospitals and psychiatric units quality reporting program, we will use the term “fiscal year” rather than “rate year” throughout this proposed rule, even when we are referring to statutory provisions that refer to “rate year.”

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than such payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, measures selected for the quality reporting program must have been endorsed by the entity with a contract under

section 1890(a) of the Act. The NQF currently holds this contract. The NQF is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We generally prefer to adopt NQF-endorsed measures in our reporting programs with some exceptions as provided by law.

For purposes of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Finally, pursuant to section 1886(s)(4)(D)(iii) of the Act, the Secretary shall publish the measures applicable to the FY 2014 IPFQR Program no later than October 1, 2012.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the quality reporting program. Such procedures must ensure that a facility has the opportunity to review its data prior to such data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on a CMS Web site.

2. Application of the Payment Update Reduction for Failure to Report for FY 2014 Payment Determination and Subsequent Years

Beginning in FY 2014, section 1886(s)(4)(A)(i) of the Act requires the application of a 2.0 percentage point reduction to the applicable annual update to a Federal standard rate for those psychiatric hospitals and psychiatric units that fail to comply with the quality reporting requirements implemented in accordance with section 1886(s)(4)(C) of the Act, as detailed below. The application of the reduction may result in an annual update for a fiscal year that is less than 0.0 percent and in payment rates for a fiscal year being less than the payment rates for the preceding fiscal year. Pursuant to section 1886(s)(4)(B) of the Act, any such reduction is not cumulative and it will apply only to the fiscal year involved. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28106), we proposed to add new regulatory text at 42 CFR 412.424 to codify these requirements.

We invited public comment on the proposed application of the payment reduction to the annual update of the standard Federal rate for failure to report data on measures selected for FY 2014 and subsequent years. We did not receive any public comments on this issue.

We are finalizing the policy for the application of the payment reduction to the annual update of the standard Federal rate for failure to report quality data for FY 2014 and subsequent years as proposed.

3. Covered Entities

The quality reporting requirements in this final rule cover those psychiatric hospitals and psychiatric units that are reimbursed under Medicare's IPF PPS

(42 CFR 412.404(b)). For more information on the application of and exceptions to the IPF PPS reimbursement, we refer readers to the section IV. of the November 15, 2004 IPF PPS final rule (69 FR 66926). In this final rule, we are using the term "inpatient psychiatric facility" (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology we have used in the past in our IPF PPS regulations (42 CFR 412.402).

Comment: A few commenters requested that CMS clarify the applicability of the IPFQR Program. One commenter recommended that CMS indicate the applicable patient population and facilities for the IPFQR Program. One commenter asked for clarification on the applicability of the IPFQR Program to acute care hospitals containing psychiatric units that are paid under the IPF PPS. A few commenters requested clarification on whether the program applies to an inpatient psychiatric unit within a children's hospital, where both have the same CCN number, and whether the payment reduction applies to that unit's patients or to the entire hospital.

Response: As we note in the above section, the IPFQR Program applies to all IPFs paid under the IPF PPS. The IPF PPS is applicable to freestanding psychiatric hospitals, including government-operated psychiatric hospitals, and distinct part psychiatric units of acute care hospitals and critical access hospitals (CAHs). The IPFQR Program does not apply to inpatient psychiatric units within a children's hospital because children's hospitals are paid under a different payment system. More specifically, the IPF PPS applies to inpatient hospital services furnished by Medicare participating entities

in the United States[244] that are classified as psychiatric hospitals or psychiatric units as specified in § 412.22, § 412.23(a), §§ 482.60 through 82.62, § 412.25, and § 412.27. However, hospitals paid under the provisions specified in § 412.22(c) are not paid under the IPF PPS.[245] If a person is an inpatient of an IPF, then all services (both physical and psychiatric) must be provided by the IPF and are bundled into the IPF payment.[246]

Comment: One commenter suggested that CMS partner with the American Hospital Association (AHA) to educate IPFs about IPFQR Program applicability and to consider delaying the implementation of the IPFQR Program until outreach and education has been conducted.

Response: We thank the commenter for their suggestions and will consider collaborating with the AHA and other entities in future outreach and education efforts. We note that we conducted two Listening Sessions on June 2, 2011 and June 8, 2011 for outreach and educational purposes. The transcript is available on the CMS Web site at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHighlights.html.

We believe these public listening sessions have provided stakeholders adequate information to implement the IPFQR Program within their respective entities/organizations. We considered the burden associated with quality data reporting,

---

[244] As specified in § 400.200, the United States means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

[245] These include Department of Veterans Affairs hospitals, hospitals that are reimbursed under State cost control systems approved under 42 CFR Part 403, hospitals that are reimbursed in accordance with demonstration projects specified in section 402(a) of Pub. L. 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Pub. L. 92-603 (42 U.S.C 1395b-1(note)), and nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

[246] Section 412.404 states that the IPF must furnish all the necessary covered services to a Medicare beneficiary who is an inpatient of the IPF, either directly or under arrangement.

the comments received in this rule and during these public listening sessions, and the statutory mandate to begin this program effective with the FY 2014 payment determination. Based on the general overall support in this rule and the public listening sessions, we believe that the public benefit of reporting of quality data outweighs the burden associated with quality data reporting. We are implementing the IPFQR Program in accordance with the proposed schedule.

4. Quality Measures

a. Considerations in Selecting Quality Measures

For purposes of the IPFQR Program, section 1886(s)(4)(D)(i) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. The statutory requirements under section 1886(s)(4)(D)(ii) of the Act provide an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In implementing the IPFQR Program, our overarching objective is to support the HHS National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care services (http://www.ahrq.gov/workingforquality/nqs/#aims). Implementation of the IPFQR Program will help achieve the three-part aim by creating transparency around the quality

of care provided at IPFs to support patient decision-making and quality improvement. Over time, the IPFQR Program will help align the goals for quality measurement and improvement at IPFs with those of other providers in the health care system.

We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. We have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. We applied the following considerations for the development and selection of measures:

- Given the availability of well-validated measures and the need to balance breadth with minimizing burden, the measures should address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy (NQS): clinical care; person- and caregiver-centered experience and outcomes; safety; efficiency and cost reduction; care coordination; and community/population health.

- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of care measures, including measures of care transitions and changes in patient functional status, with an emphasis on measurement as close to the patient-centered outcome of interest as possible.

- The measure sets should evolve so that they include a focused set of measures appropriate to IPFs that reflects the level of care and the most important areas of service and measures for IPFs as well as measures addressing a core set of measure concepts that align quality improvement objectives across all provider and supplier types and settings.

- Measures should address gaps in quality of inpatient psychiatric care.

- As part of our burden reduction efforts, we continuously seek to weigh the relevance and utility of the measures compared to the burden on hospitals in submitting data under the IPFQR Program. As appropriate, we will align our measures with other Medicare and Medicaid quality programs and may consider how we can incorporate data reporting by means of electronic reporting mechanisms, so that the collection of performance information is part of care delivery.

- To the extent practicable, measures used by CMS should be nationally endorsed by a multistakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature. We consider suggestions and input from technical expert panels (TEPs), convened by CMS contractors, which evaluate IPFQR quality measures for importance, scientific soundness, usability, and feasibility.

We also take into account national priorities and HHS Strategic Plans and Initiatives:

- HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act, which pursues three aims (better care, healthy people, and affordable care) that establish a framework with six identifiable priorities (http://www.hhs.gov/secretary/about/priorities.html and http://www.ahrq.gov/workingforquality/ngs):

- Ensuring that each person and family is engaged as partners in their care.

●● Promoting effective communication and coordination of care.

●● Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.

●● Working with communities to promote wide use of best practices to enable healthy living.

●● Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

●● Making care safer by reducing harm caused in the delivery of care.

● We consider recommendations of the MAP for the inclusion of clinical quality measures (http://www.qualityforum.org.map/). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs.

● HHS is the United States Government's principal department for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. The goals of the HHS Strategic Plan for FYs 2010 through 2015 are: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce

(http://www.hhs.gov/secretary/about/priorities.html). HHS will update this strategic plan every 4 years and measure its progress in addressing specific national problems, needs, or mission-related challenges.

HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries, and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce Healthcare-Associated Infections in clinical settings and the Partnership for Patients exemplify these programs.

- CMS Strategic Plan – CMS strives: (1) to ensure measures for different Medicare and Medicaid quality programs are aligned with priority quality goals, measure specifications are aligned across settings, and outcome measures are used whenever possible; and (2) to move towards the collection of quality measures from electronic health records (EHRs) as appropriate.

We invited public comments on the considerations used for the development and selection of quality measures for the IPFQR Program.

Comment: Two commenters believed that measures adopted for the IPFQR Program should be evidence-based, nationally endorsed, mirror the NQS, and measure high cost, high volume, and problem prone areas. Additionally, the commenters stated that the methodology for adding and removing measures should mirror that of the Hospital IQR Program. Also, the commenters recommended that CMS not add new measures in the near future while IPFs are acquiring more experience with the IPFQR Program.

Response: We thank the commenters for the input on the IPFQR Program quality measures. As indicated in the proposed rule and moving forward in future rulemakings, we intend to consider widely accepted measure criteria established in medical literature, adopt measures that are endorsed by multi-stakeholders, address the priorities of the NQS, and address high cost, high volume and problem prone areas. Our goal is to align the administrative requirements of the IPFQR Program with other quality reporting programs such as the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing the considerations which we will use for the development and selection of the quality measures for the IPFQR Program in the future.

b. Quality Measures Beginning with FY 2014 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28107), we proposed to adopt six quality measures for FY 2014 and subsequent fiscal years. In selecting the proposed quality measures discussed below, we strived to achieve several objectives. First, we believe the measures we proposed relate to the general aims of better care, better health, and lower cost and address the six domains of quality measurement as fully as possible. Second, we believe the measures are tailored to the needs of improved quality in IPFs; thus, the measures selected are those most relevant to IPFs. Third, we believe the measures promote alignment of quality improvement objectives across provider settings. Finally, we believe the measures are minimally burdensome to IPFs.

We recognize that any quality reporting program will impose certain data collection and reporting requirements on participating facilities. However, we believe that the proposed measures minimize the collection and reporting burden on IPFs because, under Medicare's IPF CoPs (42 CFR 482.61), IPFs must maintain documentary evidence of detailed treatment approaches and aftercare considerations. Further, under 42 CFR 482.21, IPFs are required to develop, implement, and maintain an effective, ongoing, hospital-wide data-driven quality assessment and performance improvement (QAPI) program as well as documentary evidence of such program for purposes of demonstrating their operation to CMS. More importantly, §482.21 requires that IPFs measure, analyze, and track certain quality indicators, including adverse patient events, and other aspects of performance that enable the hospital to assess processes of care, hospital services, and operations as part of their QAPI Program. Because the proposed IPFQR Program measures cover processes that IPFs are currently recording as Medicare CoPs, we do not believe that reporting on the proposed measures under the IPFQR Program would impose a significant additional burden on IPFs. We note that over one-quarter of IPFs[247] are also already reporting data needed to calculate the proposed measures to The Joint Commission (TJC) for purposes of TJC accreditation. Thus, the IPFQR Program will impose little additional burden for those IPFs.

After considering the recommendations and feedback from content area experts and multiple stakeholders, we proposed, for the FY 2014 payment determination and subsequent years, six NQF-endorsed, Hospital-Based Inpatient Psychiatric Services

[247] Out of the 1,741 existing IPFs, 450 are currently reporting the proposed measures to TJC. This equates to approximately 26 percent of IPFs that already report the measures on a regular basis.

(HBIPS) measures, which have been developed by and are maintained by TJC for purposes of assessing the quality of inpatient psychiatric services. These measures are: (1) HBIPS-2: Hours of Physical Restraint Use (NQF #0640); (2) HBIPS-3: Hours of Seclusion Use (NQF #0641); (3) HBIPS-4: Patients Discharged on Multiple Antipsychotic Medications (NQF #0552); (4) HBIPS-5: Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (NQF #0560); (5) HBIPS-6: Post Discharge Continuing Care Plan Created (NQF #0557); and (6) HBIPS-7: Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge (NQF #0558).[248]

These six proposed process measures are NQF-endorsed and were recommended by the MAP[249] for inclusion in the IPFQR Program. The six proposed measures align with three of the six priorities of the National Quality Strategy: patient safety, promoting effective prevention and treatment practices (clinical quality of care), and promoting effective communication and coordination of care. Technical specifications for these measures can currently be found on the Web site of TJC, the measure steward, at: http://www.manual.jointcommission.org/releases/TJC2012B/HospitalBasedInpatientPsychiatricServices.html.

As noted earlier, these six HBIPS measures are currently in use by an estimated 450 TJC-accredited IPFs, thereby posing minimal collection burden for these facilities. We note that an estimated 1,100 facilities, which do not routinely report to TJC, will

---

[248] TJC has developed seven Hospital-Based Inpatient Psychiatric Services (HBIPS) measures. Only six of these seven measures were proposed for the FY 2014 payment determination; HBIPS-1 was not proposed.
[249] Measure Application Partnership, *Pre-Rulemaking Final Report: Input on Measures under Consideration by HHS for 2012 Rulemaking*, pages 95-96,. Available at: http://www.qualityforum.org/map/.

incur some data collection burden. In addition, summary analyses of current measure results provided to CMS by TJC demonstrate variation in performance among the facilities currently reporting results for these measures, suggesting continued opportunity for quality improvement.

Section 1886(s)(4)(D)(i) of the Act requires that quality measures selected for the IPFQR Program be endorsed by the entity with a contract under section 1890(a) of the Act. As discussed earlier, the current holder of this contract is NQF. The proposed measures are currently NQF-endorsed for reporting overall performance rates and rates for four age groups (children, adolescents, adults, and older adults). We proposed to require reporting of data for all four age groups for which the measures are currently endorsed. More details regarding this proposal are included in section VIII.F.7. of the preamble of this final rule. In addition to aligning with previous collection and reporting of these measures by TJC, our proposal reflects the feedback provided by the subject-matter TEP convened by the CMS measure development contractor for this program and focus groups of hospitals and vendors involved in providing inpatient psychiatric services.

We proposed to collect aggregate data rather than patient-level data for FY 2014 and subsequent years in recognition of the considerable burden to IPFs not accustomed to reporting patient-level data. Hospitals are free to use our paper abstraction tool and utilize commonly available software, like spreadsheets, to enter and compute measure rates. We intend to provide a template using a commonly available spreadsheet format used by many hospitals which will be available on the QualityNet Web site

(http://www.qualitynet.org/). Further, IPFs are free to procure services from TJC vendors to assist them with data collection. However, we note that we do not require the use of TJC vendors. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of the preamble of this final rule. The six proposed measures for FY 2014 and subsequent years are described in more detail below.

Comment: Many commenters strongly supported the six proposed measures for the IPFQR Program. The commenters believed that these measures are appropriate and will make these data available on behavioral health public and will provide opportunities for national benchmarking and maximizing performance improvement.

Response: We appreciate the encouragement and support of the measures. We are committed to promoting and improving the quality of care for Medicare beneficiaries with mental illnesses.

(1) HBIPS-2 (Hours of Physical Restraint Use)

The use of physical restraints increases a patient's risk of physical injury as well as psychological harm.[250,251] This intervention is intended for use only if a patient is in imminent danger to him/herself or others and if less restrictive interventions have failed. It is not intended to address staff shortages or to be used as a form of discipline or coercion. The President's New Freedom Commission on Mental Health[252] explicitly recommends the reduction of restraint use to improve quality of care. A measure

[250] Evans, D., Wood, J., & Lambert, L. (2003). Patient injury and physical restraint devises: a systematic review. Journal of Advanced Nursing, 41: 274-282.
[251] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report*. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003.
[252] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report*. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003.

designed to reduce the use of restraints will also help achieve the National Quality Strategy's goal to improve patient safety and reduce the risk of harm from care.

In addition to initiatives to reduce the use of restraints, the subject-matter TEP convened by our measure development contractor identified patient safety as an important measure concept and recommended the use of the measure HBIPS-2 (Hours of Physical Restraint Use) in a national IPF quality reporting program. HBIPS-2 is a process measure that is reported as the total number of hours of physical restraint (HBIPS-2) use for all patients admitted to an inpatient psychiatric facility. We believe that fewer reported hours of physical restraint use suggest higher quality of care because reduced restraint time lowers patient risk for physical injury and psychological harm.

The numerator is defined as the total number of hours that all psychiatric inpatients were maintained in physical restraint. The denominator is defined as the number of psychiatric inpatient hours overall. Total leave days are excluded from the denominator.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS-2 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting data on the measure for purposes of TJC accreditation. HBIPS-2 received support from the MAP and is aligned with the National Quality Strategy priority for providing safer care.

We invited public comments on the inclusion of the proposed quality measure HBIPS-2, Hours of Physical Restraint Use, in the IPFQR Program beginning with the FY 2014 payment determination. We discuss our proposals for collection requirements and submission timeframes in section VIII.F.7. of the preamble of this final rule.

Comment: Several commenters supported the inclusion of this proposed measure.

Response: We thank the commenters for the support of this measure.

Comment: One commenter recommended that HBIPS-2 be revised to reduce provider burden and data variability.

Response: We thank the commenter for the feedback on the measure. The NQF submission materials for HBIPS-2 submitted by TJC included data from a sample of pilot hospitals that demonstrated that the data elements for the measure can be collected in a standardized and reliable manner. As we have mentioned, data on this measure are currently reported by approximately 450 TJC-accredited IPFs. During focus groups with representatives of these facilities, convened by our measure development contractor, respondents reported that burden of reporting data on the HBIPS-2 measure was not unreasonable as it is already reported by a subset of IPFs, and is consistent with the level of burden associated with other quality measures. We recognize that some reporting burden may occur; however, we believe that the significance and importance of the measurement of hours of physical restraints use in IPFs outweighs the burden of reporting.

Comment: One commenter recommended risk adjusting or stratifying the measure by diagnosis category and admission characteristics (for example, voluntary

versus involuntary) to increase its usefulness and interpretability. The commenter further recommended excluding the day of admission when assessing the number of hours of restraint to control for variation related to diagnosis category and admission characteristics.

Response: We appreciate the commenter's feedback. This measure is consistent with current treatment guidelines, endorsed by NQF, and currently reported, as specified, to TJC. We note that in making its endorsement decision, NQF carefully considered the measurement period that includes the day of admission and the need to risk adjust or stratify performance on HBIPS-2. TJC is currently monitoring reported performance to further assess the use of physical restraints.

Comment: One commenter recommended modifying the measure to assess the amount of time spent in restraint in minutes rather than in hours.

Response: We appreciate the commenter's feedback. During focus groups sessions with both TJC-accredited IPFs and nonaccredited IPFs, our measure development contractor found that the current practice of reporting HBIPS-2 in hours is useful and understandable to them. We believe that reporting HBIPS-3 in minutes would require additional user testing before it could be implemented.

After consideration of the public comments we received, we are finalizing the HBIPS-2, Hours of Physical Restraint Use measure for the FY 2014 payment determination and subsequent years.

(2) HBIPS-3 (Hours of Seclusion Use)

The use of seclusion increases a patient's risk of physical injury as well as psychological harm.[253,254] This intervention is intended for use only if a patient is in imminent danger to him/herself or others and if less restrictive interventions have failed. It is not intended to address staff shortages or to be used as a form of discipline or coercion. The President's New Freedom Commission on Mental Health explicitly recommends the reduction of seclusion use to improve quality of care.[255] Measures designed to reduce the use of seclusion will also help achieve the National Quality Strategy's goal to improve patient safety and reduce the risk of harm from care.

[253] Holmes, D., Kennedy, S.L., & Perron, A. (2004). The mentally ill and social exclusion: a critical examination of the use of seclusion from the patient's perspective. Issues in Mental Health Nursing, 25: 559-578.
[254] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report*. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003.
[255] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report*. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003.

The subject-matter TEP convened by our measure development contractor identified patient safety as an important measure concept and recommended the use of HBIPS-3 (Hours of Seclusion Use) in a national IPF quality reporting program. HBIPS-3 is a process measure that is reported as the total number of hours of seclusion use for all patients admitted to an IPF. We believe that fewer reported hours of seclusion use suggest higher quality of care because reducing seclusion time lowers patient risk for physical injury and psychological harm.

The numerator is defined as the total number of hours all psychiatric inpatients were held in seclusion. The denominator is defined as the number of psychiatric inpatient hours overall. Total leave days are excluded from the denominator.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS-3 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting the measure for purposes of TJC accreditation. HBIPS-3 received support from the MAP and is aligned with the National Quality Strategy priority for providing safer care.

We invited public comment on the inclusion of the proposed quality measure HBIPS-3, Hours of Seclusion Use, in the IPFQR Program beginning with the FY 2014 payment determination. We discuss our proposals for collection requirements and submission timeframes in section VIII.F.7. of the preamble of this final rule.

Comment: Several commenters supported the inclusion of this proposed measure.

Response: We thank the commenters for the support of this measure.

Comment: One commenter suggested that HBIPS-3 should be revised to reduce provider burden and data variability.

Response: We thank the commenters for their feedback on the measure.

The NQF submission materials for HBIPS-3 submitted by TJC included data from a sample of pilot hospitals that demonstrated that the data elements for the measure can be collected in a standardized and reliable manner. As we have mentioned, this measure is currently reported by approximately 450 TJC-accredited IPFs. During focus groups with representatives of these facilities, convened by our measure development contractor, respondents reported that burden of reporting HBIPS-3 was not unreasonable as it is already reported by a subset of IPFs, and is consistent with that associated with other quality measures. We recognize there may be some reporting burden. However, we believe that the significance and importance of the measurement of hours of seclusion use in IPFs outweighs the burden of reporting.

Comment: One commenter recommended risk adjusting or stratifying the measure by diagnosis category and admission characteristics (for example, voluntary versus involuntary) to increase its usefulness and interpretability. The commenter further recommended excluding the day of admission when assessing the number of hours of seclusion to control for variation related to diagnosis category and admission characteristics.

Response: We appreciate the commmenter's feedback. This measure is consistent with current treatment guidelines, endorsed by NQF, and reported, as

specified, to TJC. We note that in making its endorsement decision, NQF carefully considered the measurement period that includes the day of admission and the need to risk adjust or stratify performance on HBIPS-3. TJC is currently monitoring reported performance to further assess the use of seclusion.

Comment: One commenter recommended modifying the measure to assess the amount of time spent in seclusion in minutes rather than in hours.

Response: We appreciate the commenter's recommendations. During focus group sessions with TJC-accredited IPFs and non-accredited IPFs, our measure development contractor found that the current practice of reporting HBIPS-2 in hours is useful and understandable to them. We believe that reporting HBIPS-3 in minutes would require additional user testing before it could be implemented.

After consideration of the public comments we received, we are finalizing the HBIPS-3 (Hours of Seclusion Use) measure for the FY 2014 payment determination and subsequent years

(3) HBIPS-4 (Patients Discharged on Multiple Antipsychotic Medications)

An estimated 30 percent to 50 percent of patients in IPFs are treated with two or more antipsychotic medications, which can lead to serious side effects. Among patients without a history of treatment failure on a single antipsychotic, there is insufficient evidence to conclude that patients experience better outcomes if they are prescribed multiple antipsychotics compared to a single antipsychotic. Given the risk of side effects, stakeholders such as the National Association of State Mental Health Program Directors

have called for the reduction of unnecessary use of multiple antipsychotics.[256] The American Psychiatric Association recommends the use of multiple antipsychotics only if a patient has had failed attempts on single antipsychotics. In efforts to promote effective treatment practices, a National Quality Strategy priority, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28109), we proposed to include the process measure HBIPS-4, Patients Discharged on Multiple Antipsychotic Medications, in the FY 2014 IPFQR Program. The MAP and the subject-matter TEP convened by our measure development contractor support the inclusion of this measure in the IPFQR Program.

TJC designed HBIPS-4 as part of a paired set with HBIPS-5 (described below), meaning they were developed to be used together. HBIPS-4 is reported as the rate of patients discharged on multiple antipsychotics among patients discharged on at least one antipsychotic medication. We believe that lower rates are indicative of higher quality of care because reducing the use of multiple antipsychotics reduces the potential risks of harmful side effects to patients. However, there is no expectation that zero percent is the desired outcome because it is recognized that in some circumstances, use of multiple antipsychotics may be appropriate.

The numerator is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications. The denominator is defined as all psychiatric inpatient discharges in which the patient was discharged on one or more antipsychotic medications. The measure excludes patients who died, patients with an

[256] National Association of State Mental Health Program Directors. Technical report on polypharmacy. Alexandria, VA: 2001. Retrieved from http://www.nasmhpd.org/general_files/publications/med_directors_pubs/Polypharmacy.PDF.

unplanned departure resulting in discharge due to elopement, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

Taken together, HBIPS-4 and HBIPS-5 are intended to help reduce unnecessary use of multiple antipsychotics and to promote better clinical outcomes and reduced side effects for patients.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS-4 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs already are collecting and reporting the measure for purposes of TJC accreditation. HBIPS-4 received support from the MAP and is aligned with the National Quality Strategy priority for promoting effective prevention and treatment practices.

We invited public comment on the inclusion of the proposed quality measure HBIPS-4, Patients Discharged on Multiple Antipsychotic Medications, in the IPFQR Program beginning with the FY 2014 payment determination. We discuss our proposals for collection requirements and submission timeframes in section VIII.F.7. of the preamble of this final rule.

Comment: Several commenters supported the inclusion of this proposed measure.

Response: We appreciate the commenters' support of the measure.

Comment: One commenter objected to the paired measures HBIPS-4 and HBIPS-5, as they are currently specified, citing the potential for misinterpretation since a

low performance rate on HBIPS-4 indicates higher quality care while a high performance rate on HBIPS-5 indicates higher quality care. The commenter suggested combining HBIPS-4 and HBIPS-5 into a single measure.

Response: We appreciate the commenter's input on HBIPS-4 and HBIPS-5. Currently, these two measures are endorsed by NQF as paired measures; the measure specifications are consistent with medical guidelines and are currently reported, as specified, to TJC. Consistent with our experience with other reporting programs, we understand that some consumers may misinterpret low rates on HBIPS-4 as poor performance. In order to minimize confusion and misunderstanding, we intend to test displays with target audiences and incorporate feedback into the display before public reporting.

Comment: Two commenters believed that the denominator for HBIPS-4 is defined as "psychiatric inpatients discharged on one or more routinely scheduled antipsychotic medications" as opposed to "all psychiatric inpatient discharges."

Response: We inadvertently did not correctly describe the denominator in the proposed rule. We clarify that the denominator is all psychiatric inpatient discharges "in which a patient was discharged on one or more antipsychotic medications." We will ensure that the language is accurate in future documents.

After consideration of the public comments we received, we are finalizing the HBIPS-4 (Patients Discharged on Multiple Antipsychotic Medications) measure for the FY 2014 payment determination and subsequent years. We note that the denominator is

defined as all psychiatric inpatient discharges in which a patient was discharged on one or more antipsychotic medications.

(4) HBIPS-5 (Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification)

In efforts to promote effective treatment practices, a National Quality Strategy priority, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28109), we proposed to include the process measure HBIPS-5, Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification, in the FY 2014 IPFQR Program. The MAP and the subject-matter TEP convened by our measure development contractor support the inclusion of this measure in the IPFQR Program.

TJC designed HBIPS-5 as part of a paired set with HBIPS-4, meaning they were developed to be used together. HBIPS-5 is collected on those patients discharged on multiple antipsychotics and is reported as the rate of patients discharged on multiple antipsychotics with appropriate justification. This measure was designed in recognition that there is a subsample of patients for whom multiple antipsychotic use may be appropriate. TJC has identified the following justifications as appropriate reasons for discharging a patient on multiple antipsychotics: (1) the medical record contains documentation of a history of a minimum of three failed trials of monotherapy; (2) the medical record contains documentation of a recommended plan to taper to monotherapy or documentation of a plan to decrease the dosage of one or more antipsychotic medications while increasing the dosage of another antipsychotic medication to a level that manages the patient's symptoms with one antipsychotic medication (that is,

cross-taper); and (3) the medical record contains documentation of augmentation of Clozapine. Higher rates on HBIPS-5 indicate higher quality of care because documenting the reasons for assigning two or more antipsychotics suggests that careful consideration of the benefits of this course of treatment were weighed against the potential patient side effects.

The numerator statement is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications with appropriate justification. The denominator is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications. The measure excludes patients who died, patients with an unplanned departure resulting in discharge due to elopement, patients with an unplanned departure resulting in discharge due to failing to return from leave, and patients with a length of stay less than or equal to 3 days.

Taken together, we believe that HBIPS-4 and HBIPS-5 will help reduce unnecessary use of multiple antipsychotics and will lead to better clinical outcomes and reduced side effects for patients.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS-5 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS-5 received support from the MAP

and is aligned with the National Quality Strategy priority for promoting effective prevention and treatment practices.

We invited public comment on the inclusion of the proposed quality measure HBIPS-5, Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification, in the IPFQR Program beginning with the FY 2014 payment determination. We discuss our proposals for collection requirements and submission timeframes in section VIII.F.7. of the preamble of this final rule.

Comment: Several commenters supported the inclusion of this proposed measure.

Response: We appreciate the commenters' support of the measure.

After consideration of the public comments we received, we are finalizing the HBIPS-5 (Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification) measure for the FY 2014 payment determination and subsequent years.

(5) HBIPS-6 (Post-Discharge Continuing Care Plan Created)

When patients are discharged from the hospital, they may benefit from communication of information regarding the care they received or recommendations for their continued care. For a seamless transition from one treatment setting to another, providers that receive patients from inpatient settings need to know information regarding the patient's treatment during hospitalization, recommendations for post-discharge care, and any medications the patient was discharged on. A discharge plan facilitates this transition of information from one setting to another and has been shown to have positive effects on readmissions.

The promotion of effective care coordination is a National Quality Strategy priority. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28110), we proposed process measure HBIPS-6, Post-Discharge Continuing Care Plan Created, to promote care coordination for patients in inpatient psychiatric settings. TJC designed HBIPS-6 as part of a paired set with HBIPS-7; they were developed to be used together. HBIPS-6 measures whether a post-discharge continuing care plan is created. However, the creation of a care plan does not necessarily mean the plan is communicated to the patient's next provider. Therefore, HBIPS-7 measures whether a post-discharge continuing care plan is created and transmitted to the next level of care provider. Together, these two measures can assist facilities in determining where breakdowns in care processes occur. Quality care under HBIPS-6 is indicated by patients who are discharged with a continuing care plan that includes the reason for the hospitalization, the principal discharge diagnosis, discharge medications, and the next level of care recommendations. HBIPS-6 is collected on all patients admitted to IPFs. We believe that higher rates on this measure suggest better quality of care because greater numbers of post-discharge plans indicate greater opportunities for improved patient-provider and provider-provider communication, thus leading to improved patient care and health.

The numerator is defined as psychiatric inpatients for whom the post-discharge continuing care plan is created and contains all of the following: reason for hospitalization, principal discharge diagnosis, discharge medications, and next level of care recommendations. The denominator is defined as all psychiatric inpatient discharges. Populations excluded from the denominator include patients who died,

patients with an unplanned departure resulting in discharge due to elopement, patients or their guardians who refused aftercare, patients or guardians who refused to sign authorization to release information, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS-6 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. It is appropriate to facility-level assessment of quality of care provided by IPFs. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS-6 received support from the MAP and is aligned with the National Quality Strategy priority for promoting better care coordination.

We invited public comment on the inclusion of the proposed quality measure HBIPS-6, Post-Discharge Continuing Care Plan Created, in the IPFQR Program beginning with the FY 2014 payment determination. We discuss our proposals for collection requirements and submission timeframes in section VIII.F.7. of the preamble of this final rule.

Comment: Several commenters supported the inclusion of this proposed measure.

Response: We appreciate the commenters' support for the measure.

Comment: One commenter stated that for this measure, patient lab results and pending tests should be included in care plans.

Response: We thank the commenters for the input for this measure. We agree that, when appropriate, this information should be provided in care plans. However, for purposes of this measure, these are not required data elements.

Comment: One commenter objected to HBIPS-6 because the commenter believed that it is simply a "check-box" measure that does not advance quality of care.

Response: We disagree with the commenter's characterization of this measure. We believe that assessing the creation of a continuing care plan that includes important post-discharge information is an important step in improving care coordination and quality of care. Furthermore, the measure specifications are consistent with clinical guidelines and have been endorsed by NQF.

Comment: Two commenters recommended expanding the exclusion for the measure to cover other possible reasons for a lack of post-discharge care, such as out of jurisdiction, no psychiatric care required, and admission for observation with pre-arranged discharge back to sending provider or to another facility, such as a jail.

Response: We appreciate the helpful feedback from the commenters. This measure is endorsed by NQF, and the measure specifications are consistent with medical guidelines; it is currently reported as specified. We regularly review measure specifications and consider whether they continue to be consistent with best medical practices. We will consider these suggestions during the measure maintenance process.

After consideration of the public comments we received, we are finalizing the HBIPS-6 (Post-Discharge Continuing Care Plan Created) measure for the FY 2014 payment determination and subsequent years.

(6) HBIPS-7 (Post-Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider upon Discharge)

The promotion of effective care coordination is a National Quality Strategy priority. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28110), we proposed process measure HBIPS-7, Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider upon Discharge, to promote care coordination for patients in inpatient psychiatric settings. TJC designed HBIPS-7 as part of a paired set with HBIPS-6; they were developed to be used together. While the creation of a discharge care plan (as measured in HBIPS-6) is an important part of providing coordinated care, simply creating the plan does not ensure that the necessary information is transferred to the patient's next provider. HBIPS-7 measures both aspects of coordinated care--the creation of a discharge plan and the transmittal of that plan to the next provider. Together, these two measures can assist facilities in determining where breakdowns in care processes occur. As specified by TJC, the discharge plan should be transmitted by the fifth post-discharge day. This measure is collected on all patients admitted to IPFs. We believe that higher rates on this measure suggest better quality care because the greater the number of post-discharge plans created and transmitted, the greater opportunities for improved patient-provider and provider-provider communication and understanding of what is necessary to improve patient health.

The numerator is defined as psychiatric inpatients for whom the post-discharge continuing care plan was transmitted to the next level of care. The denominator statement is defined as all psychiatric inpatient discharges. Populations excluded from

the denominator include patients who died, patients with an unplanned departure resulting in discharge due to elopement, patients who refused (or whose guardians refused) aftercare, patients who refused to sign (or whose guardians refused to sign) authorization to release information, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS-7 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS-7 received support from the MAP and is aligned with the National Quality Strategy priority for promoting better care coordination.

We invited public comment on the inclusion of the proposed quality measure HBIPS-7, Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider upon Discharge, in the IPFQR Program beginning with the FY 2014 payment determination. We discuss our proposals for collection requirements and submission timeframes in section VIII.F.7. of the preamble of this final rule.

Comment: Several commenters supported the inclusion of this proposed measure.

Response: We appreciate the commenters' support for the measure.

Comment: One commenter recommended changing the timeframe for transmittal of the discharge plan from "by the fifth post-discharge day" to "within one post-discharge

day." One commenter suggested an exclusion be added to the specifications for instances where the next level of care is unavailable; for instance, effective follow-up care may not be obtainable for uninsured homeless patients. Two commenters recommended expanding the exclusion for the measure to cover other reasons for a lack of post-discharge care such as out of jurisdiction, no psychiatric care required, and admission for observation with pre-arranged discharge back to sending provider or to another facility, such as a jail.

Response: We appreciate the suggestions for this measure. We believe that the timeframe and exclusions currently included in the NQF-endorsed measure are valid as specified.

After consideration of the public comments we received, we are finalizing the HBIPS-7 (Post-Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider upon Discharge) measure for the FY 2014 payment determination and subsequent years.

In summary, we are finalizing six quality measures to be reported in aggregate form for FY 2014 and subsequent years. These six measures are shown in the table below. Measures adopted for the IPFQR Program will remain in the quality program for all subsequent years unless specifically stated otherwise (for example, through removal or replacement). We discuss the adopted collection requirements and submission timeframes for these measures in section VIII.F.7. of the preamble of this final rule.

Quality Measures Beginning with the FY 2014 IPFQR Program			
National Quality Strategy Priority	**NQF #**	**Measure ID**	**Measure Description**
Patient Safety	0640	HBIPS-2	Hours of Physical Restraint Use
	0641	HBIPS-3	Hours of Seclusion Use
Clinical Quality of Care	0552	HBIPS-4	Patients Discharged on Multiple Antipsychotic Medications
	0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification
Care Coordination	0557	HBIPS-6	Post-Discharge Continuing Care Plan Created
	0558	HBIPS-7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge

c. Maintenance of Technical Specifications for Quality Measures

We will provide a user manual that will contain links to measure specifications, data abstraction information, data submission information, a data submission mechanism known as the Web-based Measure Tool, and other information necessary for IPFs to participate in the IPFQR Program. This manual will be posted on the QualityNet Web site at: https://www.QualityNet.org. We will maintain the technical specifications for the quality measures by updating this manual periodically and including detailed instructions for hospitals to use when collecting and submitting data on the required measures. These updates will be accompanied by notifications to IPFQR Program participants, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for

NQF-endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28111), we stated that, through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We stated in the proposed rule that we believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28111), we proposed that if the NQF updates an endorsed measure that we have adopted for the IPFQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the

updates can be found. We also would post the updates on the CMS QualityNet Web site at https://www.QualityNet.org. We would provide sufficient lead time for IPFs to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate NQF updates to NQF–endorsed IPFQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invited public comment on this proposal.

We did not receive any public comments on our proposal to use a subregulatory process to incorporate updates that do not substantially change the nature of the measure. However, we proposed the same approach for incorporating measure updates across the various quality reporting programs in the FY 2013 IPPS/LTCH PPS proposed rule, and we did receive public comments on that approach for other systems. We are making changes here in response to those public comments in order to adopt consistent policy for the IPFQR program.

Comment: Many commenters supported the proposed subregulatory process to update the measure specifications of adopted NQF-endorsed measures in the Specifications Manual for nonsubstantive changes that arise from the NQF maintenance review, as well as the continuation of the rulemaking process for substantive changes that arise from NQF review. Several commenters objected to these proposals, and expressed

concern that there is no clear definition of nonsubstantive updates. These commenters believed that changes such as conversion of measures to ICD-10 codes and eMeasures format, and exclusions to the patient population should be considered substantive changes that would warrant rulemaking. Some commenters stated that all changes to measures that are not NQF-endorsed measures should be subject to the rulemaking process.

Response: We thank those commenters that supported our proposal to update NQF-endorsed measures using a subregulatory process. The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates made by the NQF into the measure specifications we have adopted for the IPFQR Program so that these measures remain up-to-date. We also recognize that some changes the NQF might make to its endorsed measures are substantive in nature and might not be appropriate for adoption using a subregulatory process. Therefore, we are finalizing a policy under which we will use a subregulatory process to make nonsubstantive updates to NQF-endorsed measures used for the IPFQR Program. With respect to what constitutes substantive versus nonsubstantive changes, we expect to make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure. We believe that nonsubstantive changes may include updates to NQF endorsed measures based upon changes to guidelines upon which the measures are based.

We will continue to use notice-and-comment rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the IPFQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus nonsubstantive would apply to all measures in the IPFQR program. We note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. We will revise the Specifications Manual so that it clearly identifies updates and provide links to where additional information on the updates can be found.

5. Possible New Quality Measures for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the inpatient psychiatric setting. Therefore, through future rulemaking, we intend to propose new measures that will help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services, through the widespread dissemination and use of performance information. Additionally, we are considering initiating a call for future measures to solicit input to assess the following

measure domains: clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. This approach will enhance better psychiatric care while bringing the IPFQR Program in line with other established quality reporting and performance improvement programs such as the Hospital IQR Program, the Hospital OQR Program, and the ESRD QIP.

We welcomed public comment on considerations of additional measure topics for the IPFQR Program in future rulemaking.

Comment: One commenter asserted that measures with regard to the monitoring of patients on antipsychotic medications for metabolic syndrome, primary care follow-up, treatment adherence post-acute care, and coordination of care between psychiatric care and alcohol/substance abuse treatment are needed. The commenter also suggested that CMS include measures assessing patients' experience with care, such as the National Association of State Mental Health Program Directors' Inpatient Consumer Survey, in the IPFQR Program. Another commenter recommended risk-adjustment models be considered in the measures for the IPFQR Program to address patient characteristic differences. A commenter suggested including the HBIPS-1: Admission Screening for Violence Risk, Substance Use, Psychological Trauma History and Patient Strengths Completed, which was developed by TJC in conjunction with the other six HBIPS measures.

Response: We thank the commenters for the valuable input and will take it into consideration for future measure development and selection.

6. Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making the data submitted under the IPFQR Program available to the public. Such procedures shall ensure that an IPF has the opportunity to review the data that is to be made public with respect to the psychiatric hospital or unit prior to such data being made public. The data collected will be displayed on the CMS Web site. Under these requirements, for each payment determination year, we proposed to publicly display the submitted data on the CMS Web site beginning in the first quarter of the calendar year following the respective payment determination year. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28112), we proposed that, before the data are publicly displayed, IPFs will have the opportunity to preview their data between September 20 and October 19 of the respective payment determination year.

We believe the proposed timeframe allows sufficient time for both IPFs and CMS to correct any potential mistakes and fulfill the preview requirement in section 1886(s)(4)(E) of the Act.

We welcomed public comment on the proposed preview and public display procedures for FY 2014 and subsequent years.

Comment: Some commenters suggested that a footnote should be used in cases where a hospital has a small sample size (n) and that rates should not be reported. One commenter recommended that CMS establish a minimum number of cases.

Response: We thank the commenters for the suggestions for the footnote and the minimum number of cases and will take them into consideration when we gain experience from this coming year's data.

After consideration of the public comments we received, we are finalizing the public display requirements for preview and public display procedures for the FY 2014 payment determination and subsequent years as proposed. Set out below are the preview and public display timeframes for FY 2014 through FY 2016.

Public Display For FY 2014, FY 2015, AND FY 2016		
Payment Determination Year (Fiscal Year)	**30-day Preview Period**	**Public Display (Calendar Year)**
FY 2014	September 20, 2013 – October 19, 2013	2014
FY 2015	September 20, 2014 – October 19, 2014	2015
FY 2016	September 20, 2015 – October 19, 2015	2016

7. Form, Manner, and Timing of Quality Data Submission for the FY 2014 Payment Determination and Subsequent Years

a. Background

Section 1886(s)(4)(C) of the Act requires that, for the FY 2014 payment determination and each subsequent year, each IPF submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(s)(4)(A) of the Act, for any IPF that fails to submit quality data in accordance with section 1886(s)(4)(C) of the Act, the Secretary will reduce any annual update to a standard Federal rate for discharges occurring during such fiscal year by 2.0 percentage points.

The complete data submission requirements, submission deadlines, and data submission mechanism known as the Web-Based Measure Tool will be posted on the QualityNet Web site at: http://www.qualitynet.org/. The Web-Based Measure Tool is an Internet database for IPFs to submit their aggregate data. We proposed that IPFs submit data in accordance with the specifications for the appropriate proposed reporting periods to the Web-Based Measures Tool found in the IPF section on the QualityNet Web site (http://www.qualitynet.org/).

b. Procedural Requirements for the FY 2014 Payment Determination and Subsequent Years

In order to participate in the IPFQR Program for the FY 2014 payment determination and subsequent years, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28112), we proposed that IPFs must comply with the procedural requirements outlined below. We have aligned these procedural requirements with the Hospital IQR Program to avoid imposing additional burden on providers and to increase efficiencies by virtue of allowing providers to use similar submission requirements across programs. We proposed that facilities must do the following:

- Register with QualityNet before the IPF begins reporting, regardless of the method used for submitting the data.

- Identify a QualityNet Administrator who follows the registration process located on the QualityNet Web site (http://www.qualitynet.org/).

- Complete a Notice of Participation (NOP). IPFs that wish to participate in the IPFQR Program must complete an online NOP. Submission of an NOP is an indication

that the IPF agrees to participate in the IPFQR Program and public reporting of their measure rates. The timeframe for completing the NOP is between January 1 and August 15 before each respective payment determination year. Accordingly, for the FY 2014 payment determination year, we proposed that the timeframe for completing the NOP would be between January 1, 2013 and August 15, 2013.

- Any IPF that receives a new CMS Certification Number (CCN) on or after the beginning of the respective payment determination year and wishes to participate in the IPFQR Program but has not otherwise submitted a NOP using the new CCN must submit a completed NOP no later than 180 days from the date identified as the open date (that is, the Medicare acceptance date) on the approved CMS Quality Improvement Evaluation System to participate in the IPFQR Program.

- Withdrawals from the IPFQR Program will be accepted no later than August 15 before the beginning of each respective payment determination year. We believe the August 15 deadline will give us sufficient time to update payment determinations for each respective year. Accordingly, we proposed that the withdrawal period for the FY 2014 payment determination year be between January 1, 2013 and August 15, 2013. If in a given payment determination year, an IPF withdraws from the program, it will receive a reduction of 2.0 percentage points to that year's applicable percentage increase. Once an IPF has submitted a NOP, it is considered to be an active IPFQR Program participant until such time as the IPF submits a withdrawal form to CMS.

- We will determine if an IPF has complied with our data submission requirements by validating each IPF's CCN and their aggregated data submission on the QualityNet Web site.

- IPFs must submit the aggregated numerator and denominator data for all age groups, for all measures, to avoid the 2.0 percentage point reduction.

As previously noted, we believe that this proposed aggregated data collection mode using a Web page will reduce burden to IPFs. We anticipate that IPFs already reporting de-identified patient-level data to TJC would be able to easily aggregate and report these data on a secure Web page to CMS.

We welcomed public comment on the proposed procedural requirements for the FY 2014 payment determination and subsequent years.

Comment: One commenter supported the proposal regarding the registration process.

Response: We appreciate the commenter' support.

After consideration of the public comment we received, we are finalizing the procedural requirements for the FY 2014 payment determination and subsequent years as proposed.

c. Reporting and Submission Requirements for the FY 2014 Payment Determination

IPFs choosing to participate in the IPFQR Program must meet the specific data collection and submission requirements as described on the QualityNet Web site (http://www.qualitynet.org/) and TJC's Specifications Manual for Joint Commission National Quality Measures (Specifications Manual) at: http://www.manual.jointcommission.org/releases/TJC2012B/HospitalBasedInpatientPsychiatricS

ervices.html. We note that the Specifications Manual is updated at least twice a year (and may be updated more often as necessary), and IPFs are responsible for using the requirements in the most recent manual. The most current version can be found on the Web site at: https://manual.jointcommission.org/bin/view/Manual/WebHome. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28113), we proposed that IPFs submit aggregate data on the measures on an annual basis, beginning in FY 2014. As noted earlier, IPFs must submit the data to the Web-Based Measures Tool found in the Inpatient Psychiatric Facility section on the QualityNet Web site. However, the data input forms on the QualityNet Web site for such submission will require aggregate data for each separate quarter. Therefore, IPFs will need to track and maintain quarterly records for their data.

For the FY 2014 payment determination, we proposed that IPFs report on the proposed measures for services provided between Q4 of CY 2012 and Q1 of CY 2013. These two quarters' data constitute the expected data available to CMS when we assess reporting compliance. The 6-month timeframe will allow us to establish a full calendar year of reporting by FY 2016 as discussed below. We proposed that IPFs submit their aggregated data between July 1, 2013 and August 15, 2013. The following table summarizes this information.

We welcomed public comment on the proposed reporting and data submission requirements for the FY 2014 payment determination.

Comment: Some commenters requested that CMS allow data file submission from vendors to the QualityNet Web site because it will be in alignment with existing data submission of the Hospital IQR and OQR Programs.

Response: We thank the commenters for their input. We intend to align the data submission practice with the Hospital IQR and Hospital OQR Programs. Based on these comments, we have decided that IPFs may choose to delegate to a vendor the submission of the following two requirements only: (1) aggregate measure data; and (2) population and sample size data. IPFs may choose to submit their own data to CMS and forego any costs associated with paying vendors to submit data on their behalf. If an IPF decides to use a vendor, it is important to note that the IPF, not the vendor, is responsible for all data submitted to CMS and for meeting all the procedural requirements established in this rule.

Comment: A few commenters expressed concern that the start of the program, which is on October 1, 2012, may prove to be unattainable for some facilities, therefore they recommended we delay and implement incremental phases beginning with FY 2014. A few commenters considered April 1, 2013 as a reasonable date to implement the IPFQR Program and several commenters suggested that CMS consider allowing IPFs to only attest or agree to participate instead of reporting data for FY 2014, the first payment year.

Response: We thank the commenters for their input. We recognize that some facilities, especially those facilities that are not currently reporting quality measures, may face challenges. However, we are not requiring facilities to begin submitting data until July 1, 2013 through August 15, 2013. The lag time between October 1, 2012 and the beginning of the data submission period is approximately 9 months which we think provides IPFs sufficient time to be prepared.

Comment: One commenter considered the CMS data collection proposal as duplicative because some IPFs are already submitting the data to TJC. The commenter urged CMS to grant "deemed" status to those IPFs that are already submitting the data to TJC.

Response: We thank the commenter for the input. However, the purpose of the IPFQR Program is to ensure facility-wide quality reporting and ultimately improve quality of care for Medicare beneficiaries receiving behavioral services in the IPF settings. The granting of "deemed" status to some IPFs will make our data collection incomplete and does not meet our intended objectives to obtain all quality measure data from each IPF, apply the appropriate payment, and display the measure rates on the CMS Web site.

Comment: One commenter urged CMS to work with TJC to establish a process for automatic data exchange between CMS and TJC in order to reduce the reporting burden for accredited IPFs. Another commenter recommended using the same process for data submission used by TJC to avoid burden to IPFs.

Response: We thank the commenters for their input. We strive to work closely with TJC to attain maximum alignment in current reporting practices, reporting requirements, and reporting format. We will consider establishing a process for automatic data exchange between CMS and TJC for future efforts through the rulemaking process. We also recognize that approximately 1,500 IPFs are not reporting any IPF quality data to TJC. The vast majority of these IPFs are not hospital-based, and use a different process for accreditation than the TJC.

Comment: One commenter supported the CMS proposal requiring IPFs to submit aggregate versus patient-level data. A few commenters supported the proposed electronic submission of data and expressed concern that the burden of collection occurs at the patient-level of reporting.

Response: We appreciate the commenters' support and input. We recognize there will be some challenges when a new program is initiated. We believe that requiring IPFs to submit aggregate versus patient-level data will prove less burdensome and will allow more time for IPFs to become familiar with our reporting processes, especially for those IPFs that are not currently reporting the measures.

Furthermore, the selected measures minimize the collection and reporting burden on IPFs because, under Medicare's IPF CoPs (42 CFR 482.61), IPFs must maintain documentary evidence of detailed treatment approaches and aftercare considerations. In addition, under 42 CFR 482.21, IPFs are required to develop, implement, and maintain an effective, ongoing, hospital-wide data-driven quality assessment and performance improvement (QAPI) program as well as documentary evidence of such program for purposes of demonstrating their operation to CMS.

Comment: A few commenters requested clarification on whether the IPFQR Program requires data validation.

Response: We are requiring IPFs to submit aggregated data. We did not propose any data validation approach and, therefore, are not requiring one. However, we encourage the IPFs to use a validation method and conduct their own analysis. In future

years, should we modify the program to require patient-level data, we will consider proposals for an appropriate validation method via rulemaking.

Comment: One commenter objected to the collection of aggregate data because it does not allow for validation of data accuracy. The commenter was concerned that consumers could potentially be making healthcare decisions about the quality of care at IPFs based on unvalidated and inaccurate data.

Response: We thank the commenter for the input. We considered both the reduced burden of collecting aggregate data for IPFs, and the challenges in validating aggregate data. We recognize that we cannot feasibly validate aggregate data using a random sample of medical records for all proposed measures because we cannot sample from a list of records submitted by the IPF. We intend to assess accuracy of aggregate reported data to other sources, including TJC. At this time, we believe that the reduced burden of collecting aggregate data outweighs the need to validate patient-level records. We seek to maximize quality reporting among all facilities, including the facilities not currently reporting to TJC. We believe that IPFs will submit accurate data, and base this belief in part on the requirement that IPFs participating in the IPFQR Program acknowledge the accuracy and completeness of their data. This acknowledgement will provides us with some assurance that the submitted data are validated and accurate. We believe that not establishing a validation process at this time will enable IPFs to learn these measures during the initial reporting year. This approach is consistent with our approach to validation requirements in the Hospital OQR and ASCQR Programs during the initial years of these programs. Initially, we want to encourage IPFs to begin

reporting quality data and using the quality measure information for quality improvement purposes.

Comment: One commenter inquired about the possibility of requiring patient-level data in future years and, if so, whether CMS would offer an on-line tool for patient-level data.

Response: In the future, we may consider modifying the IPFQR Program to require patient-level data; if we do pursue such a change, we would do so through rulemaking. We intend to host National Provider Calls to conduct outreach and education sessions and will consider providing educational materials during the sessions. Please check the QualityNet Web site (http://qualitynet.org//) periodically for updates.

Comment: One commenter expressed its inability to comment on the data submission for FY 2014 because the forms have not been posted on QualityNet.

Response: We regret the commenter could not comment on our data submission method. However, although the forms are not yet available, we believe we provided sufficient description of the data submission process in the proposed rule to enable meaningful comment.

After consideration of the public comments we received, we are finalizing the reporting and submission requirements for the FY 2014 payment determination as proposed. IPFs must ensure that all the reporting and submission requirements are followed by their vendors (if data are submitted by vendors on their behalf) because IPFs remain responsible for all submitted data regardless if data are submitted by a vendor or

by the entity/organization themselves. Set out below are the final quality reporting periods and submission timeframes for FY 2014.

Quality Reporting Periods and Submission Timeframes for FY 2014		
Payment Determination (Fiscal Year)	**Reporting Period for Services Provided (Calendar Year)**	**Data Submission Timeframe**
FY 2014	Q4 2012 (October 1, 2012 – December 31, 2012) Q1 2013 (January 1, 2013 - March 31, 2013)	July 1, 2013 – August 15, 2013

d. Reporting and Submission Requirements for the FY 2015 and FY 2016 Payment Determinations

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28113), we proposed that IPFs report on measures for services provided in Q2, Q3, and Q4 of CY 2013 for the FY 2015 payment determination and in Q1, Q2, Q3, and Q4 of CY 2014 for the FY 2016 payment determination. For FY 2014 and FY 2015, we proposed that IPFs report data on the proposed measures for inpatient psychiatric services provided for 6 and 9 months, respectively, to move towards data reporting of services provided within a full calendar year (12 months) by FY 2016.

The reporting of data within the timeframes outlined previously will allow us to align the IPFQR Program with other quality reporting programs that base their data reporting on a calendar year.

We welcomed public comment on the proposed reporting and data submission requirements for the FY 2015 and FY 2016 payment determinations.

Comment: One commenter agreed with the CMS proposed reporting period for FY 2015. Although the commenter agreed with the proposed reporting period for FY 2016, the commenter urged CMS to delay finalizing the proposed reporting requirements for FY 2016 until the FY 2014 rulemaking cycle in order to be more flexible if the data collection efforts do not go as planned.

Response: We thank the commenter for the input. We recognize that as the IPFQR Program evolves, lessons learned from each payment year will be valuable to

improve our reporting processes. We will consider these lessons in future proposals through rulemaking.

After consideration of the public comments we received, we are finalizing the reporting and submission requirements for the FY 2015 and FY 2016 payment determinations as proposed. Set out below are the final quality reporting periods and submission timeframes for FY 2015 and FY 2016.

Quality Reporting Periods and Submission Timeframes for FY 2015 and FY 2016 Payment Determinations		
Payment Determination (Fiscal Year)	**Reporting Period for Services Provided (Calendar Year)**	**Data Submission Timeframe**
FY 2015	Q2 2013 (April 1, 2013 – June 30, 2013) Q3 2013 (July 1, 2013 – September 30, 2013) Q4 2013 (October 1, 2013 – December 31, 2013)	July 1, 2014 – August 15, 2014
FY 2016	Q1 2014 (January 1, 2014 – March 31, 2014) Q2 2014 (April 1, 2014 – June 30, 2014) Q3 2014 (July 1, 2014 – September 30, 2014) Q4 2014 (October 1, 2014 - December 31, 2014)	July 1, 2015 – August 15, 2015

e. Population, Sampling, and Minimum Case Threshold for FY 2014 and Subsequent Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28114), we proposed that participating IPFs must meet specific population, sample size, and minimum reporting case threshold requirements as specified in TJC's Specifications Manual. The

Specifications Manual is updated at least twice a year (and may be updated more often as necessary), and IPFs must follow the requirements in the most recent manual. The most current version can be found on the Web site at: https://manual.jointcommission.org/bin/view/Manual/WebHome.

We proposed that the target population for the proposed measures include all patients, not solely Medicare beneficiaries, to improve quality of care. We believe it is important to require IPFs to submit measures on all patients because quality improvement is of industry-wide importance and should not be focused exclusively on a certain subset of patients. In addition, we need this scope of data in order to be able to assess the quality of care being provided to Medicare beneficiaries. We proposed that IPFs use the applicable sample size requirements found in the Specifications Manual. We noted that the Specifications Manual gives IPFs the option of sampling their data quarterly or monthly. We erroneously noted that the Specifications Manual does not require sampling procedures for measures HBIPS-2 and HBIPS-3. As noted below, the correct language should have been that "the Specifications Manual does not allow sampling procedures for measures HBIPS-2 and HBIPS-3." Therefore, IPFs are required to submit data on all cases for these two measures.

The Specifications Manual uses the term "minimum required stratum sample size" to refer to the required sample size for a given initial patient population stratum.[257] To comply with our proposed reporting requirements, if the initial patient population

[257] For example, for initial population stratum size of 211-877, the most current version of the Specifications Manual requires a minimum stratum sample size of 20 percent of the initial population stratum size. If the initial population size is 44-220, the minimum required stratum sample size is 44.

stratum size is below a certain number of cases,[258] for measures HBIPS-4, HBIPS-5, HBIPS-6, and HBIPS-7, IPFs must submit all applicable measure data rather than sample data. More details on sampling procedures are located in the Specifications Manual available at the Web site: https://manual.jointcommission.org/bin/view/Manual/WebHome.

IPFs that have no data to report for a given measure must enter zero for the population and sample counts. For example, an IPF that has no hours of physical restraint use (HBIPS-2) to report for a given quarter is still required to submit a zero for its quarterly aggregate population for HBIPS-2 in order to meet the reporting requirement. We believe it is important for IPFs to submit data on all measures even when the population size for a given measure is zero or small because it provides us with the opportunity to identify, assess, and evaluate the baseline for the number of cases for each measure in future years. This will also assist us in determining the minimum case threshold for future years in the rule. In cases where the measure rates are calculated based on low caseloads, when the submitted data are publicly displayed on the QualityNet Web site, we proposed to clearly note that the affected measure rates were calculated based on low caseloads that may affect the result.

We invited public comment on the proposed population, sampling, and case thresholds and welcomed any comments on methods and approaches for future years.

Comment: One commenter applauded the CMS sampling proposal and recognized that requiring data on all patients, not just Medicare patients, is important for the program.

Response: We appreciate the commenter's support.

[258] In the most current version of the Specifications Manual this number is 44.

Comment: One commenter recommended that CMS continue to maintain consistency with TJC's requirements on the population, sampling, case threshold, and other technical aspects to ensure future ability to perform benchmarking and quality improvement assessment across the TJC program and IPFQR Program.

Response: We thank the commenter for the input. We seek to align efforts as much as possible, but must also recognize that the IPFQR Program is a separate and distinct program from TJC's program. The IPFQR Program's population of patients includes only inpatient psychiatric facility patients. We expect that IPFs will submit data on Medicare and non-Medicare patients treated under the IPFs CCN, not acute care hospital CCNs. For Medicare fee-for-service patients, the IPF should require their Medicare claims processing department or contractor to correctly identify patients treated and billed under the IPF PPS. We also clarify that the IPFs will identify their applicable non-Medicare patient population by accessing their claims for inpatient psychiatric services submitted to non-Medicare payers, such as Blue Cross Blue Shield. By maintaining consistency in reporting, these efforts will serve to stabilize the data and set benchmarks for future years.

Comment: One commenter noted that the Specifications Manual indicates that it does not "allow" sampling procedures for HBIPS-2 and HBIPS-3 rather than "require" sampling procedures, which is the term CMS used, and which implies that a hospital may choose to require their vendor to implement sampling procedures.

Response: We thank the commenter for pointing out this issue. We have addressed the issue in the introductory discussion above to correctly reflect the Specifications Manual.

After consideration of the public comments we received, we are finalizing the population, sampling, and minimum case threshold for FY 2014 and subsequent years as proposed.

f. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2014 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28114), we proposed to require IPFs to acknowledge their data accuracy and completeness once annually using a QualityNet Web site Web page. To affirm that the data provided to meet the FY 2014 IPFQR Program data submission requirement is accurate and complete to the best of a facility's knowledge, an IPF would be required to submit the Data Accuracy and Completeness Acknowledgment (DACA) form. We would provide a link to this form once IPFs have completed entry of all aggregated measure data. Data submission would not be complete until the IPF submits the DACA form. We proposed that the deadline for submission of both measure data and the DACA form would be no later than August 15 prior to the applicable IPFQR Program payment determination year.

For the FY 2014 payment determination, for which participating IPFs are required to report data for discharges occurring between Q4 of CY 2012 and Q1 of CY 2013, we proposed to make the submission deadline for the DACA no later than August 15, 2013. We proposed that the DACA submission deadlines for FY 2015 and FY 2016 would be

August 15 of CY 2014 and CY 2015, respectively. We proposed August 15 as the DACA submission deadline for several reasons. First, requiring IPFs to acknowledge their data's accuracy and completeness by August 15 of the year before the respective payment determination year provides us with sufficient time to ensure compliance with the program by October 1, the start of the fiscal year, and, therefore, with sufficient time to calculate and apply the annual payment update. Second, we believe that it is reasonable to make the deadline for the DACA the same as the data submission deadline in order to reduce the reporting burden to IPFs. Lastly, using August 15 as the DACA deadline allows us to align our data acknowledgment deadline with other quality reporting programs, such as the Hospital IQR Program.

We invited public comment on our proposed DACA requirements.

Comment: One commenter recommended aligning the DACA deadlines among the Hospital IQR, Hospital OQR, and IPFQR Programs to make it easier for hospitals and IPFs to keep track when completing these tasks.

Response: We thank the commenter for the input regarding the DACA deadline. We strive to align our quality reporting programs across settings to make quality reporting as efficient as possible for the stakeholders. As noted in our proposed rule, we have made every effort to align the IPFQR Program with the Hospital IQR and Hospital OQR Programs. Any differences in the DACA deadlines among the programs result from the inherent differences in the nature of the programs, the kind of measures used, and the timing of the statutorily mandated implementation. In the future, we will continue to work to align DACA deadlines to the extent possible.

After consideration of the public comments we received, we are finalizing the DACA requirements for the FY 2014 payment determination and subsequent years as proposed. Set out below are the DACA deadlines for the FY 2014 through FY 2016 payment determinations.

Data Accuracy and Completeness Acknowledgment (DACA) Deadlines for FY 2014, FY 2015, AND FY 2016 Payment Determinations		
Payment Determination (Fiscal Year)	**Reporting Period for Services Provided (Calendar Year)**	**Data Accuracy and Completeness Acknowledgement Deadline**
FY 2014	Q4 2012 (October 1, 2012 – December 31, 2012) Q1 2013 (January 1, 2013 - March 31, 2013)	August 15, 2013
FY 2015	Q2 2013 (April 1, 2013 – June 30, 2013) Q3 2013 (July 1, 2013 – September 30, 2013) Q4 2013 (October 1, 2013 - December 31, 2013)	August 15, 2014
FY 2016	Q1 2014 (January 1, 2014 – March 31, 2014) Q2 2014 (April 1, 2014 – June 30, 2014) Q3 2014 (July 1, 2014 – September 30, 2014) Q4 2014 (October 1, 2014 - December 31, 2014)	August 15, 2015

8. Reconsideration and Appeals Procedures for the FY 2014 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28115), we proposed a reconsideration process whereby IPFs can request a reconsideration of their payment

update reduction in the event an IPF believes that its annual payment update has been incorrectly reduced for failure to report quality data under the IPFQR Program. We proposed to institute an annual reconsideration process similar to the Hospital IQR Program (74 FR 43892). We would not utilize reconsideration policies and procedures related to the Hospital IQR Program validation requirement because the IPFQR Program does not currently include an annual validation requirement for IPFs. For FY 2014 and subsequent years, we proposed that the deadline for IPFs to submit a request for reconsideration of their payment determination would be 30 days from the date identified on the payment determination notification letter. While we want to ensure that IPFs have an opportunity to request reconsiderations when warranted, we also need to balance this goal with our need to complete the reconsideration process in a timely manner and with the IPFs' need to obtain final decisions on their requests in a timely manner. We believe that a 30-day timeframe best achieves this balance.

We believe that requiring IPFs to submit a request for reconsideration prior to filing an appeal before the Provider Reimbursement Review Board (PRRB) is more efficient for both CMS and IPFs because it decreases the number of appeals by resolving issues earlier in the process. We proposed that, together with a request for reconsideration, an IPF must submit all documentation and evidence that supports its request for reconsideration. The documentation should include copies of any communication, such as e-mails, that the IPF believes demonstrates its compliance with the program requirements, as well as any other records that may support the IPF's rationale for seeking reconsideration. We proposed to codify the reconsideration

procedures that IPFs must follow at new § 412.434 under 42 CFR Part 412, Subpart N. Under these procedures, an IPF must submit to CMS, no later than 30 days from the date identified on the IPFQR Program payment determination notification letter provided to the IPF, a Reconsideration Request form containing the following information:

- The IPF's CMS Certification Number (CCN).
- The name of the IPF.
- Contact information for the IPF's chief executive officer and QualityNet system administrator, including each individual's name, e-mail address, telephone number, and physical mailing address.
- A summary of the reason(s), as set forth in the IPFQR Program Annual Payment Update Notification Letter, that CMS concluded the IPF did not meet the requirements of the IPFQR Program.
- A detailed explanation of why the IPF believes that it complied with the requirements of the IPFQR Program for the applicable fiscal year.
- Any evidence that supports the IPF's reconsideration request, such as e-mails and other documents.

Following receipt of a request for reconsideration, we will provide--

- An e-mail acknowledgment, using the contact information provided in the reconsideration request, to the CEO and the QualityNet Administrator that the request has been received; and

● Written notification to the hospital CEO, using the contact information provided in the reconsideration request, regarding our decision. We expect the process to take approximately 90 days from the receipt of the reconsideration request.

We proposed that IPFs must submit a request for reconsideration, as described previously, and receive a decision on that request from CMS before they can file an appeal with the PRRB. If dissatisfied with the decision rendered at the reconsideration level, IPFs can appeal the decision with the PRRB under 42 CFR Part 405, Subpart R. We proposed to codify this requirement at new § 412.434(c).

We intend to work with our Medicare administrative contractors to process updated IPF claims in an expeditious manner to pay IPFs when our annual payment update reduction decision is overturned in reconsideration or PRRB review. The timeframe for updating payment through retroactive claims processing widely varies, and is dependent on the number of IPFs, the number of affected claims, and the advance time needed by the Medicare administrative contractor.

We invited public comment on the proposed procedures for reconsideration and appeals.

Comment: One commenter supported the CMS proposal for reconsideration whereby IPFs are afforded 30 days from the date identified on the payment determination notification letter to file a request for reconsideration.

Response: We appreciate the commenter' support.

After consideration of the public comment we received, we are finalizing the policy on reconsideration and appeals procedures for the FY 2014 payment determination and subsequent years as proposed.

9. Waivers from Quality Reporting Requirements for the FY 2014 Payment Determination and Subsequent Years

In our experience with other quality reporting and/or performance programs, we have noted occasions when IPFs have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). It is our goal to avoid penalizing IPFs in such circumstances or to unduly increase their burden during these times. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28115), we proposed that, for FY 2014 and subsequent years, IPFs may request and we may grant waivers with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the facility may warrant. When waivers are granted, IPFs will not incur payment reductions for failure to comply with the requirements of the IPFQR Program.

Under the proposed process, in the event of extraordinary circumstances not within the control of the IPF, such as a natural disaster, the IPF may request a reporting extension or a complete waiver of the requirement to submit quality data for one or more quarters. Such facilities would submit a request form to CMS that would be made available on the QualityNet Web site. The following information should be noted on the form:

- The IPF's CCN;

- The IPF's name;
- Contact information for the IPF's CEO and any other designated personnel, including name, email address, telephone number, and mailing address (the address must be a physical address, not a post office box);
- The IPF's reason for requesting an extension or waiver;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the IPF will again be able to submit IPFQR Program data, and a justification for the proposed date.

We proposed that the request form must be signed by the IPF's CEO, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the request form, we would: (1) provide a written acknowledgement, using the contact information provided in the request, to the CEO and any additional designated IPF personnel, notifying them that the IPF's request has been received; and (2) provide a formal response to the CEO and any additional designated IPF personnel, using the contact information provided in the request, notifying them of our decision.

We indicated in the proposed rule that this proposal would not preclude us from granting waivers or extensions to IPFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, a hurricane or other natural disaster that could reasonably affect a facility's ability to compile or report data), affects an entire region or locale. If we make the determination to grant a waiver

or extension to IPFs in a region or locale, we proposed to communicate this decision through routine communication channels to IPFs and vendors, by means of memoranda, emails, and notices on the QualityNet Web site, among other means.

We invited public comment on this proposal.

Comment: Some commenters supported providing waivers when there are extraordinary circumstances beyond the IPF's control.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the requirements for waivers from the quality reporting requirements for the FY 2014 payment determination and subsequent years as proposed.

10. Electronic Health Records (EHRs)

Although for initial reporting, the opportunity to utilize EHRs for automatic data collection is not applicable because the proposed measures will be submitted as aggregate data, we encourage IPFs to take steps towards adoption of EHRs (also referred to as electronic medical records) that will allow for reporting of clinical quality data from EHRs directly to a CMS repository. We encourage IPFs that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by HHS. Although the IPFQR Program is in its initial implementation stages, we suggest that IPFs take due care and be diligent to ensure that their EHR systems accurately capture quality data and that, ideally, such systems provide point-of-care decision support that promotes optimal levels of clinical performance.

In the future, we will continue to work with standard-setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting.

We welcomed public comment on the adoption of EHRs for the IPFQR Program in the future.

Comment: One commenter urged CMS to encourage Congress to fund an extension of the EHR incentives to behavioral health in order to improve care coordination across mental health providers.

Response: We thank the commenter for the input. We will continue our efforts to minimize burden and at the same time, improve quality of care across all behavioral health settings by supporting innovative strategies such as the EHR in future years when funding is available.

Comment: Some commenters suggested that CMS not collect the IPFQR measure data on all patients until eMeasures are available because the proposed data collection and reporting would "add burden of already strapped resources at the local level."

Response: We thank the commenters for the input. We are committed to improving quality of care and health outcomes for Medicare beneficiaries who suffer from behavioral/mental conditions. We cannot meet the statutory requirements if we delay the implementation of the IPFQR Program.

We thank the commenters for their input on the EHRs and IPFQR Program.

IX. MedPAC Recommendations and Other Related Studies and Reports for the IPPS and the LTCH PPS

A. MedPAC Recommendations for the IPPS for FY 2013

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2012 "Report to the Congress: Medicare Payment Policy" and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2013 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653-7226, or visit MedPAC's Web site at: http://www.medpac.gov.

B. Studies and Reports on Reforming the Hospital Wage Index

1. Secretary's Report to Congress on Wage Index Reform

Section 3137(b) of the Affordable Care Act requires the Secretary of Health and Human Services to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act relating to the IPPS. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by MedPAC in its June 2007 report entitled "Report to Congress: Promoting Greater Efficiency in Medicare." This

report is available via the Internet at: http://www.medpac.gov/documents/jun07_entirereport.pdf, and was discussed in the FY 2009 IPPS final rule (73 FR 48567 through 48574), the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43824 and 43825), and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50158 and 50159).

In developing the Report to Congress required by section 3137(b) of the Affordable Care Act, CMS contracted with Acumen L.L.C. (Acumen) to review the June 2007 MedPAC report and recommend a methodology for an improved Medicare wage index system. (The Acumen reports are available via the Internet at: http://www.acumenllc.com/reports/cms. After consultation with relevant parties during the development of the plan (which included an April 12, 2011 special wage index reform open door forum, along with a review of electronically submitted comments and concerns), the Secretary submitted a "Report to Congress--Plan to Reform the Medicare Hospital Wage Index" that describes the concept of a Commuting Based Wage Index (CBWI) as a potential replacement to the current Medicare wage index methodology. The following is a summary of the highlights of the report. The complete report can be accessed on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html.

As discussed in section III.B. of the preamble of this final rule, the current wage index methodology relies on labor markets that are based on statistical area definitions (Core-Based Statistical Areas (CBSAs)) established by the Office of Management and Budget (OMB). Hospitals are grouped by geographic location into either an urban labor

market (that is, a metropolitan statistical area (MSA) or metropolitan division) or a statewide rural labor market (any area of a State that is not defined as urban). The current system establishes wage indexes for hospital labor market areas, not for individual hospitals. Many parties have argued that these definitions, in many instances, are not reflective of the true cost of labor for any given hospital, particularly for hospitals located on the periphery of labor markets or at labor market boundaries. Multiple exceptions and adjustments have been put into place in attempts to correct perceived inequities. However, many of these exceptions and adjustments may create or further exacerbate distortions in labor market values. The issue of "cliffs," or significant differences in wage index values between proximate hospitals, can often be attributed to one hospital benefiting from such an exception and adjustment when another hospital cannot.

On April 11, 2012, the Secretary submitted to Congress a report, "Plan to Reform the Medicare Hospital Wage Index." This broad-based plan for reforming the hospital wage index included a fundamental change in the description and definition of labor market areas. The concept, referred to as the commuting based wage index (CBWI), would improve upon Medicare's existing wage index method by using commuting data to define hospital labor market areas. The CBWI is based on data on the number of hospital workers commuting from home to work to define a hospital's labor market. To derive the CBWI, commuting flows would be used to identify the specific areas (for example, zip code or census tracts) from which a hospital hires its workers and to determine the proportion of its workers hired from each area. A CBWI system could use either current hospital cost report data or other alternative sources, such as the Bureau of Labor

Statistics (BLS) Occupational Employment Survey data, to calculate labor market area average wage values. While the current wage index system aggregates wage data within geographic CBSA-based areas where hospitals are located, the CBWI would aggregate wage data based upon where the hospital workers reside.

Once the hiring proportions by area and area wage levels are determined, the hospital's benchmark wage level would be calculated as the weighted average of these two elements. This value would then be divided by the national average. This calculation would result in a hospital-specific value, which reflects wage levels in the areas from which a hospital hires, accounting for variation in the proportion of workers hired from each area.

Using more precisely-defined labor markets, the CBWI values can vary for hospitals within the same CBSA or county and, thus, more precisely reflect wage differences within and across CBSA boundaries and address intra-area variation more precisely than the current system. Although the CBWI would allow wage index values to vary *within* a CBSA, the CBWI is less likely to produce large differences--or "cliffs"--between wage index values for nearby hospitals in adjacent CBSAs because nearby hospitals likely hire workers from areas in similar proportions.

Acumen found in its analysis that the CBWI system would more closely reflect hospitals' actual wages than the current CBSA-based system and the MedPAC proposal. As MedPAC suggested in its proposal, the exceptions and adjustments to the wage index system are the primary cause of the often significant "cliffs" between wage indexes of nearby hospitals. Acumen suggested the CBWI has the potential to reduce the need for

exceptions and adjustments and further manipulation of wage index values (as is central to the MedPAC proposal) to prevent these "cliffs" between labor market areas.

The Report to Congress detailed several findings relevant to implementation of a CBWI:

- Because the CBWI accounts for specific differences in hospitals' geographic hiring patterns, it would yield wage index values that more closely correlate to actual labor costs than either the current wage index system (with or without geographic reclassification) or a system that attempts to reduce wage index differences across geographic boundaries, such as MedPAC's proposed wage index based on Bureau of Labor Statistics (BLS) data for health care industry workers.

- While a CBWI could be constructed with the most recent Census commuting data, were the CBWI to be adopted, a more up-to-date reporting system for collecting commuting data from hospitals would have to be established so that the wage index calculations would accurately reflect the commuting patterns of hospital employees. We believe that creating a system of more up-to-date commuting data could be achieved with a modest addition to the current reporting requirements.

- Concerns about a CBWI leading to hospitals altering hiring patterns and distorting labor markets do not appear to be worse than under the current system and could be managed with minimal policy adjustments.

- As current statutory provisions governing the Medicare wage index and exceptions to that wage index were designed for the current MSA-based wage index system, their applicability would need to be reviewed if a CBWI were to be adopted.

- The Medicare statute has traditionally applied payment changes in a budget neutral manner. If a CBWI were to be adopted in a budget neutrally manner, payments for some providers would increase while payments for other providers would decrease.

The Secretary was directed to "consult with relevant affected parties" during the development of the plan. In a special Medicare wage index open door forum held on April 12, 2011, hospital and hospital association representatives presented several concerns, which included issues with commuting data availability, the continuation of certain exceptions and adjustment policies, and the impacts of the CBWI upon other nonhospital payment systems. Several commenters expressed concern that a CBWI could encourage providers to alter or manipulate hiring practices in order to improve wage index calculations. However, based upon our findings and analysis, we believe it is dubious whether any alteration of a hospital's employment patterns would improve its competitive advantage over other hospitals that employ workers in the same area. We also share a concern expressed by multiple commenters regarding whether a CBWI should be applied to other nonhospital payment systems. Currently, several other payment systems are based upon the Medicare pre-reclassified hospital wage index. It is not clear whether it would be advantageous, or even possible, to apply a CBWI to these provider types.

2. Institute of Medicine (IOM) Study on Medicare's Approach to Measuring Geographic Variations in Hospitals' Wage Costs

In addition to submitting the aforementioned Report to Congress, in April 2010, the Secretary commissioned the Institute of Medicine (IOM) to evaluate Medicare's

approach for measuring geographic variation in the wage costs faced by hospitals. The IOM's Phase I report, published in September 2011, is available via the Internet at: http://iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx. In that report, IOM's Committee on Geographic Adjustment Factors in Medicare Payment proposed a set of recommendations for modifying the hospital wage index in both the method used in its construction and the data used in its calculation.

In constructing the wage index, the IOM recommends altering the current labor market definitions to account for the out-commuting patterns of health care workers who travel to a place of employment in an MSA other than the one in which they live. The IOM's recommendation is based on its theory that county-to-MSA commuting patterns reveal the degree of integration of labor markets across geographically drawn boundaries (that is, MSAs) and a commuting-based smoothing adjustment to the wage index would more accurately measure the market wage each hospital faces. The IOM model uses workers' out-commuting patterns to smooth wage index values for hospitals in different counties, similar to the out-migration adjustment used in the current wage index system. The IOM also suggests that using out-commuting shares in the smoothing adjustment creates an index based on the wage levels of workers *living* in that area in which a hospital is located, as opposed to wage levels of workers *employed* in that area, as in the CBWI model. In calculating its smoothed wage index, the IOM uses the following four steps:

- Step 1 - Compute a wage index for each MSA, adhering to Medicare's current approach for calculating the average hourly wage (AHW) paid by all IPPS hospitals located in the MSA (this step replicates the current pre-reclassification wage index).
- Step 2 - Compute an area wage for each county equal to a weighted average of MSA-level AHWs, where the weight for each MSA measures the share of all hospital workers living in the county who commute to hospitals located in that MSA.
- Step 3 - Assign all hospitals located in the county a hospital wage index value equal to the county area wage index.
- Step 4 - Normalize wage indices to ensure budget neutrality, similar to the approach currently implemented by Medicare.

In addition, the IOM's wage index model uses hourly wage data from the BLS Occupational Employment Survey rather than from hospital cost reports. The IOM also recommends measuring hourly wages using data for all health care workers rather than only hospital workers and using a fuller set of occupations incorporated in the hospital wage index occupational mix adjustment. The IOM suggests that BLS data would reduce administrative burdens placed upon hospitals and, by broadening the array of reported occupations from what is currently covered in the hospital cost report, would achieve more accurate labor market definitions and reduce year-to-year volatility. The IOM encourages CMS to establish an ongoing agreement with the BLS to use occupational survey data specific to health care workers to calculate average hourly wage values. The IOM suggests, for instance, that the 5-year American Community Survey is a potential

source of the necessary commuting information, assuming CMS can arrange to obtain certain nonpublic "micro-data" from the BLS.

Preliminary findings demonstrate that the IOM hospital wage index method would result in the reduction in wage index "cliffs," and would diminish the need to maintain current wage index exceptions and adjustments. The IOM also recommends that the hospital wage values should be applied to other nonhospital health care providers, shifting to a single measurement of geographic variation to be used in multiple Medicare provider payment systems. However, we believe that, by creating a wage index that measures the wage level only of workers who live near a hospital rather than of all workers who could potentially work at the hospital (including those who live far away from the hospital), IOM's approach may have some problematic implications. First, some of the wage information used by the IOM index is based on workers employed outside of the hospital's pertinent labor market. Second, the IOM index neglects market-relevant information regarding the wages of workers employed at the hospital who live outside the county of the hospital's location. If the in-commuting workers come from high wage areas, this information should contribute to increasing the hospital's wage index values. Likewise, if such workers live in low wage areas, they should contribute to decreasing the hospital's wage index values.

We are aware of numerous concerns from hospital and hospital association representatives regarding whether the BLS Occupational Employment Survey data is an acceptable source for hospital wage index calculations. (We refer readers to a discussion of the BLS occupational survey data in the FY 2010 IPPS/RY 2010 LTCH PPS final rule

(74 FR 43824 and 43825).) While the IOM proposal suggested a more refined use of BLS data than did the previous MedPAC recommendation, there may be significant operational challenges in accessing and compiling health care sector specific wage, occupational mix, and commuting data from the available datasets. Additional research would be required to determine whether the IOM recommendation for applying its hospital wage index to nonhospital providers would be appropriate.

Comment: The AHA commented that, in June 2011, the AHA Board of Trustees created the AHA Area Wage Index Task Force to further review the CMS, MedPAC, and IOM reports, as well as examine other design issues around the wage index. The AHA anticipates issuing a report on the subject by early 2013. Most other commenters indicated they were withholding opinion pending an analysis of the AHA study. Many commenters supported the concept of significant wage reform, and some commenters indicated that an ideal wage index system would reduce or eliminate the need for wage index reclassifications.

Response: We look forward to reviewing the findings of the upcoming AHA report, and appreciate the commenters' continued interest and support in the wage index reform process.

Comment: MedPAC expressed concerns regarding several aspects of the CBWI methodology. MedPAC favored a methodology that includes a broader definition of labor inputs than one limited to hospital workers and is concerned that the CBWI could potentially create a "great circularity risk" due to its reliance on hospital-specific employment patterns.

MedPAC stated that the CBWI contradicts the following principles contained in the IOM report:

- Geographic adjustment for input price differences is intended to reflect the input prices faced by providers, not the costs incurred by providers.

- Geographic adjustment, where possible, should reflect the areawide input prices for labor faced by all employers operating in the same local market and should not be drawn exclusively from data on the prices paid by hospitals or health care practitioners.

Response: We disagree with MedPAC's assertion that the CBWI contradicts these certain key principles. The IOM principles refer to the characteristics of the wage data used in constructing the wage index, not the method used to group those data into wage areas that attempt to reflect the boundaries of labor markets. The advantage of the CBWI is its method for refining the boundaries of labor markets. The CBWI can be constructed with many different sources of wage data--the more closely the data reflect input prices faced by providers, the better; CBWI does not require that the wage data be limited to data from hospitals or health care practitioners. The empirical application of the CBWI described in the proposed rule was constructed with the CMS wage survey data that are currently used for the Medicare wage index. That choice facilitates comparisons of the CBWI to the current wage index by isolating the effect of the method for defining labor markets from the effect of the wage data. The CMS wage survey data are based on wages paid solely by hospitals, but they are adjusted for differences in the

occupational mix of nurses, in an attempt to make the reported wages more closely reflect input prices.

Regarding the increased risk of "circularity" and distortions in labor markets, MedPAC provides an example of a town with one hospital, with that hospital essentially setting its own wage index. MedPAC expresses its preference for methods that "draw on a bigger pool of workers (all workers in an entire MSA) and are therefore less influenced by an individual hospital's wages." However, we believe that these statements do not acknowledge that much of the impetus for geographic reclassification and other modifications of the current Medicare wage index result from inaccuracies in current MSA-based labor market boundaries. These boundary problems rarely would occur in areas where there are few hospitals, but in areas where many hospitals draw their employees from overlapping areas. By defining wage areas on the basis of areas from which hospitals draw their employees, the CBWI provides a method for refining boundaries that offers potential for addressing the central problem of the current wage index. We further point out that circularity issues exist within the current wage index system, as well as the existent current single provider MSAs. However, as discussed in the Report to Congress, we believe relatively minor policy revisions can be implemented to mitigate any related effects within a CBWI system, including expanding ZIP or census tract areas to ensure a minimum number of different hospital employees are represented in any given labor market.

Comment: MedPAC stated that "CMS should publish simulated data on a hospital-by-hospital basis to make sure that hospitals in the same city would not have materially different wage indexes under the proposed wage index system."

Response: The empirical application of the CBWI based on commuting data from the 2000 Census examined this relationship and found that the closer together two hospitals were, the more similar were their CBWI values ("Report to Congress: Plan to Reform the Medicare Wage Index - Technical Appendix A," April 2012, p. 6). We agree with MedPAC that further simulations would be helpful, but only if more up-to-date commuting pattern data were to be made available. We note that data are available to simulate or reconstruct the CBWI in the "Wage Index Reform" section of the CMS Web page at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/.

Comment: MedPAC asserted that the CBWI is not consistent with how hospital labor markets work because it "ignores well understood relationships between wage rates and commuting costs and implicitly assumes that workers will demand the same wage from a job with an hour commute as a job with a 10 minute commute."

Response: It is possible to adjust the CBWI for commuting costs, but it might be impractical to do so and would certainly add considerable complexity to the CBWI. Commuting times and costs may vary widely within an MSA, and we are not convinced that failing to account for commuting costs would be more of a problem for the CBWI than it is for an MSA-based wage index.

Comment: MedPAC stated that using the correlation of the wage index and actual wages is a poor measure of the validity of a wage index, noting that an index set equal to the hospital wage would have a correlation of 1.0.

Response: We agree that candidate wage index methodologies should not be measured solely based on their correlation with a hospital's observed wage, but the correlation does provide useful information describing the relationship between a hospital's wage index values and reported wages. The correlation coefficient assists in identifying whether sharp differences exist between actual and fitted wages; sizable differences would arise if a wage index induces artificial cliffs across boundaries that do not mirror actual circumstances. An R-squared statistic in a regression model would serve a similar role.

Comment: MedPAC stated that CMS erroneously reported the properties of the three proposals (CMS', IOM's and MedPAC's). MedPAC noted that the table in the proposed rule at 77 FR 28119 failed to include its recommendation that MedPAC's proposed hospital compensation index should be used in the home health and skilled nursing facility prospective payment systems. MedPAC also stated that "contrary to the claims in the table at . . . [77 FR] 28119, no occupational mix adjustment is necessary under MedPAC's proposal or the IOM proposal."

Response: We agree that we made an error in not including MedPAC's recommendation for nonhospital providers in the table in the proposed rule. Therefore, we have corrected this error in the table below. The "Occupational Mix" section of the table is intended to show how each of the wage index proposals would incorporate

occupational data, including those established in the BLS Occupational Employment Survey. We did not intend to imply that a separate occupational mix adjustment would be necessary under the MedPAC or IOM methodology. We have added a footnote in the table below to clarify this point.

COMPARISON OF WAGE INDEX REFORM PROPOSALS				
	Current Wage Index	IOM	MedPAC	CBWI
Labor Market Definition				
Labor Market Area	MSAs or Metropolitan Divisions/rural "rest of State" areas	MSAs or Metropolitan Divisions/rural "rest of State" areas	Blend of county and MSA labor market definitions (50/50).	Creates separate but linked labor-market for each hospital using small geographic areas (for example, zip codes).
Commuting Adjustment	Section 505 Out-Commuting Adjustment	Adjusts hospitals' wage index values based on the out-commuting patterns of health care workers.	None.	Uses in-commuting patterns relevant for individual hospitals to weight benchmark wages constructed for small geographic areas.
Other Adjustments	Multiple Reclassifications and/or Floors (for example, Frontier State floor, Lugar counties, MGCRB, and Section 508 reclassifications and special exceptions)	IOM proposes three smoothing specifications: (1) Apply to all counties; (2) Apply only to counties to which at least 10 percent of workers commute; (3) Apply only to counties to which at least 10 percent of workers commute and hospital wage index is higher than home-county hospital wage index.	Smoothing algorithm uses iterative process to eliminate large differences in index values across county boundaries.	None.
Measurement of Worker Wages				
Wage Data Source	Hospital cost reports	BLS Occupational Employment Survey	BLS Occupational Employment Survey	Any source of establishment wage data could potentially be used (for example, hospital cost reports, BLS Occupational Employment Survey).
Industry Sectors Used to Measure Wages	Hospitals	Health care sector	All Industries (for example, hospitals, other health care and nonhealth care sectors).	The CBWI could be implemented using any industry sector.

COMPARISON OF WAGE INDEX REFORM PROPOSALS				
	Current Wage Index	IOM	MedPAC	CBWI
Occupational Mix*	Occupational mix adjustment based on occupational categories of nurses reported on cost reports.	Occupational mix adjustment based on all occupations.	Occupational mix adjustment based on 30 occupations with the highest wage share in the hospital industry.	Occupational mix adjustment based on all occupations available in the wage data source selected.
Other Provider Settings				
Wage Index for Nonhospital Providers	Pre-floor, pre-reclassification version of the current hospital wage index. A version of this index with an occupational mix adjustment has also been used for payments for other specialized hospital inpatient services.	Use identical hospital wage index methodology, except create an industry-specific occupational mix adjustment for each provider type.	Use hospital compensation index for home health and skilled nursing facility prospective payment systems.	Considerations include: (1) Collect commuting data for each provider type and apply CBWI; (2) Apply CBWI framework, but use hospital wage and commuting data; or (3) Measure using a weighted average of nearby-hospital CBWI values.
* "Occupational Mix" refers to any occupationally weighted adjustment that is performed as a separate process during the wage index development process, or is included in an established wage data set (for example, BLS Occupational Employment Survey)				

X. Quality Improvement Organization (QIO) Regulation Changes Related to Provider and Practitioner Medical Record Deadlines and Claims Denials

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119 through 28120), we explained that QIOs have historically experienced difficulty in obtaining medical information in a timely manner from providers and even more difficulty obtaining this information in a timely manner from practitioners. Although the regulations at 42 CFR Part 476 refer to practitioners' responsibilities in certain instances, § 476.78, which relates to the submission of medical information, addresses only the obligations of providers and not practitioners. Moreover, we explained that while § 476.90 addresses

steps that a QIO may take when providers *or practitioners* fail to cooperate with the QIO, § 476.90(b) limits the QIO's authority to deny claims to providers for failing to respond to a QIO's request for information, and no similar provision exists for practitioners.

In light of the issues discussed above, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119 and 28120), we proposed several changes to the regulations at §§ 476.1, 476.78, and 476.90 to more clearly convey the responsibilities of providers and practitioners in submitting medical information and to specify the QIO's authority should the information not be received.

- We proposed to add a definition of "providers" under § 476.1 to clearly denote that certain requirements in Part 476 apply to health care facilities, institutions, and organizations involved in the delivery of health care services to Medicare beneficiaries.

- We proposed to change the section heading of § 476.78 from "Responsibilities of health care facilities" to "Responsibilities of providers and practitioners". In addition, we proposed to add references to "practitioners" in § 476.78(b)(2) so that the 21-day and 30-day timeframes for submittal of information apply equally to practitioners and providers. We also proposed one minor technical change to § 476.78 that is unrelated to the application of timeframes to providers or practitioners. We proposed to remove the sentence, "QIOs pay providers paid under the prospective payment system for the costs of photocopying records required by the QIO in accordance with the payment rate determined under the methodology described in

paragraph (c) of this section and for first-class postage for mailing the records to the QIO", because it is merely a reference to paragraph (c) of § 476.78.

- We proposed changes to § 476.90 that will provide improved instructions to QIOs when attempting to resolve issues associated with practitioners and providers that fail to submit medical information within the timeframes set forth in §476.78. These proposed changes included: changing the section heading from "Lack of cooperation by a health care facility or practitioner" to "Lack of cooperation by a provider or practitioner"; incorporating the broader term "provider" (as reflected in our proposed change to § 476.1) within § 476.90, as well as references to "practitioners", where appropriate. We proposed to add references to "practitioners" in § 476.90(a)(2) to denote that the QIO's authority includes the ability to make financial liability determinations for both providers and practitioners, and we proposed to add the word "may" to clarify that the QIO has the discretion to report a provider's or practitioner's failure to provide evidence of the medical necessity or quality of care provided to the Inspector General. In addition, we proposed modifications to § 476.90 (b) to denote that QIOs will also deny claims if practitioners fail to submit medical information as requested. We also proposed to add new language to § 476.90(b) to convey the right of providers and practitioners to request a reconsideration by the QIO of its decision to deny the claim based on the failure to receive the medical information, and that no further appeal rights exist beyond the QIO.

- We proposed to make a technical correction to a cross-reference to "§ 474.30(c)" that appears in § 476.90(a)(1). This cross-reference is to the Office of

Inspector General regulations that convey the obligations of providers and practitioners; these regulations are now located in 42 CFR 1004.10(c).

We invited public comment on our proposals, including the definition of "providers", the timeframes for practitioners and providers to follow in submitting medical information, the QIO's authority when medical information is not received, as well as the technical corrections. We did not receive any public comments on these proposed changes. Therefore, in this final rule, we are adopting the proposed changes as final.

XI. Other Required Information

A. Requests for Data from the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html**.** We listed the data files and the cost for each file, if applicable, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28120 through 28122).

Commenters interested in discussing any data used in constructing this final rule should contact Nisha Bhat at (410) 786-5320.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28122), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). We discuss and respond to any public comments we received in the relevant sections.

2. ICRs for Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of the proposed rule and this final rule discusses add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2014

must submit a formal request. A formal request includes a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold. We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. In FYs 2008, 2009, 2010, 2011, 2012, and 2013, we received 1, 4, 5, 3, 3, and 5 applications, respectively.

We did not receive any public comments regarding these information collections.

3. ICRs for the Occupational Mix Adjustment to the FY 2013 Index (Hospital Wage Index Occupational Mix Survey)

Section II.F. of the preamble of the proposed rule and this final rule discusses the occupational mix adjustment to the FY 2013 wage index. While the preamble does not contain any new ICRs, we note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Pub. L. 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data at least once every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program

in order to construct an occupational mix adjustment to the wage index. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; however, it is currently approved under OCN 0938-0907, with an expiration date of February 28, 2013.

We did not receive any public comments regarding these information collections.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.H.3. of the preamble of the proposed rule and this final rule discusses proposed revisions to the wage index based on hospital redesignations. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index or standardized payment amounts and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. While this requirement is subject to the PRA, the associated burden was previously approved under OCN 0938–0573. However, the information collection expired on December 31, 2011. We are currently seeking to reinstate the information collection and, as required by the PRA, will announce public notice and comment periods in the **Federal Register** separate from this rulemaking.

5. ICRs for Application for GME Resident Slots

The information collection requirements associated with the distribution of additional residency positions under section 5503 of the Affordable Care Act, addressed under section IV.I.3. of this preamble, are not subject to the Paperwork Reduction Act (44 U.S.C. Chapter 35), as stated in section 5503(c) of the Affordable Care Act. The information collection requirements associated with the preservation of resident cap positions from closed hospitals, addressed under section IV.I.4. of this preamble, also are not subject to the Paperwork Reduction Act , as stated in section 5506 of the Affordable Care Act.

We did not receive any public comments regarding these information collections.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Pub. L. 108-173. This program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a "starter set" of 10 quality measures. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938-0918. We are currently seeking reinstatement of the information collection and will publish the required 60-day and 30-day notices in the **Federal Register** to solicit public comments.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital

IQR measures was part of our implementation of section 5001(a) of the DRA. New section 1886(b)(3)(B)(viii)(III) of the Act, added by section 5001(a) of the DRA, requires that the Secretary expand the "starter set"' of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures "that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings." The burden associated with these reporting requirements was previously approved under OMB control number 0938-1022. We are currently seeking reinstatement of the information collection and will publish the required 60-day and 30-day notices in the **Federal Register** to solicit public comments.

For the FY 2015 payment updates, we are seeking OMB approval for a revised information collection request using the same OMB control number (0938-1022). In the revised request, we will add 1 chart-abstracted measure (Elective Delivery Prior to 39 Weeks Gestation), 1 survey-based measure, and 3 claims-based measures. In addition, we will remove 1 chart-abstracted measure (SCIP-VTE-1: Surgery patients with recommended venous thromboembolism prophylaxis) and 16 claims-based measures. We estimate that the changes to our FY 2015 payment determination measure set will result in a total collection burden to IPPS hospitals of approximately 6,750,000 hours per year.

With respect to the new chart-abstracted measure for the FY 2015 payment determination, we are adding add a chart-abstracted measure: Elective delivery Prior to 39 Completed Weeks Gestation: Percentage of babies electively delivered prior to 39 completed weeks gestation. Hospitals will be required to submit data on patients with

elective vaginal deliveries or elective cesarean sections at >=37 and <39 weeks of gestation completed. We estimate that IPPS hospitals will incur an additional 170,000 burden hours resulting from the addition of this measure. We estimate that hospitals will submit approximately 1,006,917 cases annually for this measure, and the information needed to calculate these measures requires an average of 10 minutes to abstract from medical records for each case.

We are also adding three new claims-based measures for the FY 2015 payment determination. We do not believe that these claims-based measures will create any additional burden for hospitals because they will be collected and calculated by CMS based on the Medicare FFS claims the hospitals have already submitted to CMS.

One additional survey measure will be added to the existing HCAHPS survey measures for the FY 2015 payment determination. Burden for HCAHPS data collection is approved through OMB No. 0938-0981.

We believe that the overall burden on hospitals will be reduced to some extent by the policy we finalized in the FY 2011 IPPS/LTCH PPS final rule to remove one chart-abstracted measures, SCIP-VTE-1: Surgery patients with recommended venous thromboembolism prophylaxis beginning with the FY 2015 payment determination. In addition, beginning with the FY 2015 payment determination, we are removing 16 claims-based measures. We estimate that the removal of these measures will reduce the total burden to hospitals by a total of 150,000 hours.

We are adding a structural measure for the FY 2016 payment determination, the Safe Surgery Checklist Use measure. This measure will require hospitals to report their

yes/no response regarding use of a safe surgery checklist. We estimate that 3,300 hospitals will spend about 2 minutes each to answer this question each year, resulting in an estimated total increase of 110 hours in terms of the total burden to hospitals each year.

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section VIII.B. of the preamble of this final rule, section 1866(k) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. To comply with the statutory mandate, we are implementing the PCHQR Program in an effort to improve the quality of care for inpatient cancer patients. It is our aim and goal to encourage PCHs to furnish high quality care in a manner that is effective and meaningful, while remaining mindful of the reporting burden created by the implementation of this new program. Therefore, we intend to reduce and avoid duplicative reporting efforts, whenever possible, by leveraging existing infrastructure.

For the FY 2014 program year, as we proposed, we are adopting five NQF-endorsed quality measures, two of which were developed by the CDC and three of which were developed by the American College of Surgeons' Commission on Cancer (ACoS/CoC).

TOPIC	QUALITY MEASSURES
Cancer-Specific Treatments	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive)

TOPIC	QUALITY MEASSURES
	colon cancer (NQF#0223)
	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer (NQF#0559)
	Adjuvant Hormonal Therapy (NQF#0220)
Healthcare Acquired Infections (HAIs)	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF#0139)
	National Healthcare Safety Network (NHSN)Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF#0138)

We estimate that 11 PCHs will submit data on approximately 27,273 cases annually for these measures, and it will require, on average, 2.5 hours for a PCH to abstract the information from medical records and submit it for each case.

Although PCHs have not previously reported data on quality measures to CMS, they have some familiarity and experience with the reporting of quality data. More specifically, out of the 11 existing PCHs, 10 (or 91 percent) are currently reporting the proposed cancer-specific measures to the ACoS/CoC. Likewise, a majority of the PCHs are currently submitting data on the HAI measures to the CDC. We believe that because the majority of the PCHs have demonstrated the ability to report these measures, the reporting requirements we are finalizing in this final rule for the PCHQR Program will not significantly impact PCHs.

Furthermore, we estimate that reporting the quality data to the CDC and the CMS contractor will not be costly to PCHs. In our burden calculation, we have included

the time used for chart abstraction and for training personnel on collection of chart-abstracted data, as well as training for submitting the data through these entities (CDC and the CMS contractor). We estimate that the annual hourly burden to each PCH for the collection, submission, and training of personnel for submitting all quality measure data will be approximately 6,293.5 hours per year for each PCH. The average hourly burden to each PCH will be approximately 524 hours per month. This final rule would affect all PCHs participating in Medicare. The facilities would have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the Notice of Participation form. The anticipated burden to these providers consists of the following: (1) the initial registration with the CDC, CMS contractor, and CMS QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection of data; and (4) the time required for entry of the data to the CDC and the CMS contractor database by the PCH's representative.

Comment: Commenters urged CMS to leverage with the ACoS/CoC infrastructure because the PCHQR Program could pose a "sizeable expense for each participating institution and a significant time investment."

Response: We are appreciative of the commenters' concerns surrounding administrative burden and duplicative reporting. We intend to align closely with the ACoS/CoC data infrastructure and apply consistent reporting format in an effort to minimize burden.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section VIII.C. of the preamble of the proposed rule and this final rule, we discuss requirements for the Hospital VBP Program. Specifically, in this final rule, for the FY 2015 program, we are removing a measure from the Clinical Process of Care domain. We are adding two additional measures in the Outcome domain, an AHRQ Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We also are adding a measure, Medicare Spending per Beneficiary, in the Efficiency domain. All of these additional measures are required for the Hospital IQR Program; therefore, their inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

9. ICRs for the Long Term Care Hospital Quality Reporting (LTCHQR) Program

In section VIII.D. of the preamble of this final rule, we discuss the implementation of section 3004(a) of the Affordable Care Act, which added section 1886(m)(5) to the Act. Section 1886(m)(5) of the Act provides that, for rate year 2014 and each subsequent rate year, in the case of an LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by 2 percentage points. The initial requirements for the LTCH Quality Reporting (LTCHQR) Program were finalized in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

In section VIII.D.3.d. of the preamble of this final rule, for FY 2015, we have finalized the use of three quality measures that were previously finalized for use in the LTCHQR Program in the FY 2012 IPPS/LTCH PPS final rule. These measures are: (1) Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened. We stated that the NQF had expanded the scope of endorsement of the CAUTI and CLABSI measures to additional care settings, including LTCHs. The revision of these measures has not changed the way that the data for these measures is to be collected.

In this final rule, we are finalizing our adoption of the expanded versions of the CAUTI and CLABSI measures for the FY 2014 payment determination and all subsequent fiscal year payment determinations. We are also retaining an application of the Pressure Ulcer measure for the FY 2014 and subsequent years payment determinations.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51780 through 51781), we estimated that the total yearly cost to all LTCH that are paid under the LTCH PPS to report these data (including: NHSN registration and training for the CAUTI and CLABSI quality measures; data submission for all three measures, and monitoring data submission) will be approximately $756,326. We believe that this remains a valid estimation of the total financial burden that all LTCHs will incur as a result of the LTCHQR Program, even considering that the CAUTI and CLABSI measures were reviewed and expanded by the NQF.

We do not believe that the burden estimate we made in the FY 2012 IPPS/LTCH PPS final rule is affected by the NQF's expansion of the CAUTI and CLABSI measures because these expanded measures are essentially the same measures that were adopted in the FY 2012 IPPS/LTCH PPS final rule. While the measures will now be calculated using a standardized infection ratio (SIR), the expansion of the CAUTI and CLABSI measures has made no differences in the way that these data are to be collected and reported by LTCHs. Thus, use of the expanded CAUTI and CLABSI measures will place no additional burden on LTCHs. In addition, we believe that this burden should remain relatively stable over the first several years of this quality reporting program, subject to normal inflationary increases, such as increased labor wage rates.

As stated in section VIII.D.3.d. of the preamble of this final rule, for the FY 2016 LTCHQR Program, we had proposed the addition of five new quality measure but are finalizing the addition of only two of these new quality measures to the LTCHQR Program measure set. The quality measures that we have finalized in this rule are: (1) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (2) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

Data for three of the LTCH measures, namely Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure, NHSN Central line- associated Bloodstream Infection (CLABSI) Outcome Measure, and Influenza Vaccination Coverage among Healthcare Personnel, will be collected via the CDC's NHSN online data submission

system (http://www.cdc.gov/nhsn/). As we proposed, LTCHs will report data on these measures according to measure specifications of these NQF-endorsed measures.

The NHSN is a secure, Internet-based surveillance system that is maintained and managed by CDC. Many LTCHs already submit data to the NHSN either voluntarily or as part of mandatory State reporting requirements for HAIs. There are currently 442 LTCHs in operation in the United States and, according to CDC, over 200 of these LTCHs already submit HAI data to NHSN. For these LTCHs, we believe the burden related to complying with the requirements of the quality reporting program will be reduced because of pre-existing familiarity with the NHSN submission process.

Further, the initial setup and acclimation to the NHSN system will have already occurred through the implementation of the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and the NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure for the FY 2014 LTCHQR Program payment determination. Even though these measures have been recently reviewed by the NQF and expanded to postacute care settings, including LTCHs, there has been no change in the way that the data for these measures is to be collected and reported to NHSN. Likewise, there has been no change in the registration and training requirements for providers that are new to the NHSN reporting system. In addition, LTCH providers will begin to use the NHSN system to report CAUTI and CLABSI data on October 1, 2012. By the time that any new measures are finalized and reporting of the same begins, LTCH providers should be very familiar and comfortable with the NHSN reporting system.

The burden associated with these quality measures is the time and effort associated with collecting and submitting the data concerning CAUTI, CLABSI, and Influenza Vaccination Coverage among Healthcare Personnel to NHSN for LTCHs that are not currently reporting such data. As we have stated above, for LTCHs that already submit data regarding these measures to NHSN, we believe there should be little, if any, additional burden. For LTCHs that submit data to NHSN for other HAIs, but not data for these three proposed measures, there may be some added burden. However, we believe that this burden will be significantly decreased because these LTCHs will already be enrolled in the NHSN system and will be already familiar with the NHSN data submission process. The CDC reports that 321 LTCHs are presently enrolled and are reporting data through the NHSN system and that 198 of these LTCHs are presently submitting data on the CAUTI measure, for example.

There are currently 442 LTCHs in the United States paid under the LTCH PPS. We estimate that each LTCH will submit approximately 12 NHSN submissions (6 CAUTI events and 6 CLABSI events) per month (144 events per LTCH annually). This equates to a total of approximately 63,648 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment will take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the data into the NHSN database. Based on this estimate, we expect each LTCH will expend 300 minutes (5 hours) per month and 60 hours per year reporting

to NHSN. Therefore, the total estimated annual hourly burden to all LTCHs in the United States for reporting to NHSN is 26,520 hours.

The estimated cost per submission is estimated at $12.07. These costs are estimated using an hourly wage for a registered nurse of $41.59 and a medical billing clerk/data entry person of $20.57 (U.S. Bureau of Labor Statistics data). Therefore, we estimate that the annual cost per each LTCH provider will be $1,739 and the total yearly cost to all LTCHs for the submission of CAUTI and CLABSI data to NHSN will be $768,497.[259] While these requirements are subject to the Paperwork Reduction Act, we believe the associated burden hours are accounted for in the information collection request currently approved, OCN 0920–0666.

We analyzed the information collection requirements for the FY 2014 LTCHQR Program quality reporting measure "Percent of Residents with Pressure Ulcers that are New or Worsened (NQF #0678)" in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51781). This same estimate applies to the measures affecting the FY 2015 payment determination as they are the same three (3) measures.

As stated in section VIII.D.3.d. of this final rule, the other new quality measure that we have finalized for addition to the LTCHQR Program is the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine. This measure is to be collected using the LTCH CARE Data Set. In order to do

[259] Nursing Time – 24 hours @ $41.59 per hour = $998.16; $998.16 x 442 LTCHs = approximately $441,187.
Admin Time – 36 hours @ $20.57 per hour = $740.52; $740.52 x 442 LTCHs = approximately $327,310.
TOTAL = $441,187 + $327,310 = $768,497.

so, the LTCH CARE Data Set will require modification with the addition of the item sets necessary to collect the data needed for this measure.

In the FY 2013 IPPS/LTCH PPS proposed rule collection of information section, we proposed that we would post the specific additional data elements that would need to be added to the LTCH CARE Data set in order to collect the data necessary to calculate the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine measure. We further proposed to post the corresponding modified technical data specifications for at a later date, on our LTCH Quality Reporting Program Web site.. We made this proposal because, we had not yet completed the necessary technical development of the data items and the modifications to the data collection instrument that LTCHs will use to submit the data for this new measure. Because the forms are still under development, we cannot make a complete burden estimate at this time. We proposed that reporting and submission of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine measure be incorporated into the existing data collection and submission framework of the LTCH CARE Data Set. This is the same data collection and submission framework that will be used by CMS to support providers for reporting on the Percent of Residents with Pressure Ulcers That Are New or Worsened measure.[260]

By building upon preexisting resources for data collection and submission, we intend to foster alignment between measures that helps to reduce the administrative

[260] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA Notice which appeared in the Federal Register on September 2, 2011 (Volume 76, Issue 171). The file number for the LTCH PRA package is CMS-10409.

burden related to data collection and submission. We anticipate that the initial setup and acclimation to the data collection by the LTCH CARE Data Set will have already occurred with the adoption of the Pressure Ulcer measure for the LTCHQR Program for the FY 2014 payment determination. Therefore, we believe the transition to reporting the four measures via the LTCH CARE Data Set may be less burdensome.

The delivery of high quality care in the LTCH setting is imperative. We believe that collecting quality data on all patients in the LTCH setting supports CMS' mission to ensure quality care for Medicare beneficiaries. Collecting data on all patients provides the most robust and accurate reflection of quality in the LTCH setting.

At this time, we have not completed development of the information collection instrument that LTCHs would have to submit to comply with the aforementioned reporting requirements regarding the measures proposed for data collection by the LTCH CARE Data Set for the FY 2016 LTCHQR payment determination. Because the forms are still under development, we cannot make a complete burden estimate at this time. Once the forms are available, we will prepare and submit the required Paperwork Reduction Act (PRA) package which will fully set forth the anticipated burden to LTCH providers as a result of the new data items (questions) that need to be added to the LTCH CARE Data Set. The PRA process provides for the publication of two PRA notices in the **Federal Register** which are followed by 60 and 30 day comment periods respectively. The PRA notice and comment process is similar to that provided for with the proposed and final rule notice and comment process. Therefore, even though it is not possible, at this time, for CMS to provide all of the necessary burden estimate

information related to the new measures that we proposed to add to the LTCHQR Program, stakeholders will still be afforded opportunities to submit public comments in accordance with the PRA rules and guidelines.

Comment: Several commenters expressed concern about CMS' burden estimate. They believed that 50 hours per LTCH per year (or roughly 20 minutes per patient) for submission of the pressure ulcer measure is unrealistic. Several commenters estimated that data collection and submission would take closer to 2 hours per patient. One commenter noted that in order for LTCHs to achieve the 20 minute estimate, CMS needs to reduce the amount of data collected for calculating the pressure ulcer measure. Several commenters noted that CMS' conclusion that reporting four measures via the LTCH CARE Data Set will not be burdensome because data collection using this data collection mechanism is a preexisting tool is flawed because CMS' burden estimate for the pressure ulcer measure is underestimated. Several commenters noted that LTCHs believe it will be necessary to hire at least one additional staff member in order to meet the reporting requirements. One commenter added that CMS was incorrect in its assumption that clerical staff will be able to collect these data, when many data will need to be collected by wound care or nursing staff (both of whom generally have higher wages). Another commenter argued that it is not necessary to complete the LTCH CARE Data Set for all patients and all care transitions.

Response: We acknowledge the commenters' concern regarding the number of data elements that are included on the LTCH Care Data Set and the amount of time that it may take to complete the LTCH CARE Data Set. We are sensitive to the commenters'

concern for the amount of time and money that they will have to expend to comply with the reporting pressure ulcer data.

In response to those concerns, we have carefully reviewed the LTCH CARE Data Set and our rationale for the collection quality measure data in the LTCH setting. We have given much consideration to the benefits of collecting quality measure data versus the burden that will be placed upon LTCH providers when required to report this data to CMS using the LTCH CARE Data Set or the National Healthcare Safety Network (NHSN). In addition, we considered the number and types of LTCHs that are present in the United States today and the effect that size, financial status, access to technical vendor services, and other factors that may have an impact upon each LTCHs abilities to comply with the demands of reporting quality data using the LTCH CARE Data Set. We further considered the likelihood of and degree of burden to which LTCHs of various sizes, corporate structure, financial status and varying specialties would be able to successfully comply with the requirements of the section 3004 of the Affordable Care Act for the LTCHQR Program.

For reasons that we explain in section VIII.D.3.a. of the preamble of this final rule, we are finalizing that certain data elements contained on the LTCH CARE Data Set will be voluntary. What we mean by this is that failure to submit data on these items will not cause CMS to find an LTCH provider to be in noncompliance with the rules and regulations of the LTCHQR Program. LTCHs can submit data on these items on a voluntary basis, and we strongly encourage this.

Under this policy , LTCHs will only be required to complete a subset of the data elements that comprise the LTCH CARE Data Set. For purposes of this discussion, we have broken down the items which make up the LTCH CARE Data Set into three categories and have deemed them to be either required or voluntary. These elements are: (1) a limited set of administrative items that are necessary in order to identify each LTCH and properly attribute patients to it for purposes of calculating the measure rate; (2) the data elements necessary to populate the pressure ulcer measure, consistent with the NQF-endorsed specifications for that measure; (3) the data elements necessary to enable CMS to validate that the pressure ulcer measure data elements were accurately reported. All other data elements on the LTCH Care Data Set can be completed on a voluntary basis but will have no impact on the measure rate calculations or on our determination of whether the LTCH has met the reporting requirements under the LTCHQR Program. We will post on the CMS Web site a detailed matrix that identifies which data elements will be required and which will be voluntary.

As noted above, we have decided to make a portion of the LTCH CARE Data Set voluntary. However, we are required by the Paperwork Reduction Act of 1995 to report the burden for information collection requests that are voluntary. Therefore, even though our position has changed with respect to how many of the LTCH CARE Data Set items are now considered to be required for successful reporting, this will not affect the burden estimate that we must render.

Although we have reviewed and made some adjustments to our policy related to the mandatory or voluntary nature of each item in the LTCH CARE Date set, we believe

that these adjustments have no effect on our previously stated burden estimates. Upon review of the burden calculations that we previously put forth in the proposed rule, we were not able to find any information that would lead us to believe that that it will take close to 2 hours per patient to complete the full LTCH CARE Data Set (including all required and voluntary items). Furthermore, we have not been able to find any facts that would lead us to believe that LTCHs would have to dedicate one full-time staff position to the responsibility for completion of a full LTCH CARE Data Set assessment for each patient, or for an assessment that does not include all of the voluntary items. The likelihood of the need for a dedicated staff person is further reduced by our decision to make a portion of the items on the LTCH CARE Data Set voluntary in nature. We have several rationales in support of our conclusions, which we will discuss below.

First, we note that the full LTCH CARE Data Set Admission Assessment consists of 29 data items (which shall now divided into required and voluntary categories). When we originally calculated our burden estimate for the LTCH CARE Data set, we considered burden information data pertaining to how long it took to complete similar data items on similar assessment instruments. Data obtained during the Post Acute Care Payment Reform Demonstration (PAC-PRD) included estimates of the response time necessary for each CARE tool item. PAC-PRD data revealed that it took approximately 0.7 minutes to complete each question on the CARE tool that was being used during this demonstration.

In addition, we also considered burden estimates from other data collection tools such as the Outcome and Assessment Information Set (OASIS-C). The OASIS-C is a

data collection instrument which is approved under OMB control number 0938-0760. The OASIS-C is used by home health providers for Medicare payment and quality reporting purposes. We have estimated that the time required to complete this information collection is estimated to average 0.7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed and complete and review the information collection. The time estimates for these quality data collection instruments are consistent with our previously stated time estimate of approximately 20 minutes for completion of the LTCH CARE Data Set or 0.7 minutes per response (either voluntary or required).

Second, the first 20 data items on the LTCH CARE Data Set consist of basic patient demographic information typically collected by most providers. A portion of these items, while not necessary for the calculation of the pressure ulcer measure, are required in order for the record to be accepted by the CMS online data submission system. Often, this information is provided to the LTCH by the transferring facility, or by the patient and/or their family members upon admission. Only rarely should the person responsible for the completion of the LTCH CARE Data Set have to elicit this information directly from the patient or their family members. Because the patient's demographic information should be readily available in the patient's medical records, we believe that it should take no more that the estimated 0.7 minutes per item to complete these particular data items, whether these items are required or voluntary (A0050 to A1820).

Third, many LTCHs are now using EHRs. With the recent movement towards use of EHRs and the advancement of this technology, those LTCHs using EHR technology may gain additional time efficiencies in the completion of the LTCH CARE Data Set by working with their vendors to pull the specified patient demographic data (A0050 to A1820) from their EHRs to populate the corresponding field of the LTCH-CARE data set. We are in the process of obtaining Logical Observation Identifiers Names & Codes (LOINC) codes for all LTCH-CARE data items to facilitate electronic interoperability.

Fourth, a review of the remaining nine data items of the LTCH CARE Data Set reveal that these are items related to a clinical physical assessment of various body systems or functions. Several of these items on the LTCH CARE Data Set that are necessary for the calculation of the pressure ulcer measure as well as matching of patient data at admission and discharge for the calculation of the pressure ulcer measure remain mandatory items, while others (items that are not necessary for the calculation of the pressure ulcer measure) are considered voluntary. We will post on our Web site a detailed matrix that identifies which data elements of the LTCH CARE Data Set are mandatory (that is, will be required), and which will be voluntary. This matrix will also be incorporated into the final LTCHQR Program Manual which will be posted on CMS LTCHQR Program Website and available for download from http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html. Each of these sections contain data items that are assessment-based and should be performed on an ongoing basis by clinical

staff for each patient as a routine part of safe and effective patient care, and irrespective of the requirements for completion of the LTCH CARE Data Set. Therefore, most, if not all LTCHs, should be assessing their patients for the information that is captured in the LTCH CARE Data Set [261] and documenting their findings in the medical record as part of their normal patient care.

As with the patient demographic questions, completion of the patient physical assessment data items may be possible through the use of EHR technology. Data required for the LTCH CARE Data Set could be electronically captured directly from the patient's electronic medical records and placed into the LTCH CARE Data Set to populate the data item fields. The time required for the LTCHs with the capability to complete the entire LTCH CARE Data Set in this manner may be significantly less that for those LTCHs that do not use this type of technology.

Finally, we do not believe that it should take more than 20 minutes to complete a full LTCH CARE Data Set assessment on each LTCH patient because, pursuant to PRA requirements, we are not required to include in our burden estimates, any time that a provider would spend in the performance of normal patient care. Nor are we required to factor into our burden estimate any other work that an LTCH provider would perform in the normal course of business (that is, if they had not been asked to collect the information that is the LTCH CARE Data Set). This principal would apply to all data

---

[261] Mandatory data elements are the administrative section, skin conditions section, and assessment of risk factors used as covariates for the NQF-endorsed Pressure Ulcer measure (NQF)678) of the LTCH CARE Data Set. The covariate items include: functional status assessment, bowel continence, active diagnosis such as diabetes and peripheral vascular disease, documentation of height and weight to calculate patient body mass index, and skin assessment to capture new or worsening of pressure ulcers (Stage 2, 3 or 4) between admission and discharge assessment.

items, whether they are voluntary or required, because pursuant to the Paperwork Reduction Act of 1995, we are obligated to report the burden for all information collection requests, whether they be voluntary or mandatory.

Collection of patient demographic information is done in the normal course of business, typically when a patient is received into an LTCH facility. Patient assessment, and more particularly, the skin assessments are performed and the results documented by the LTCH clinical staff on an ongoing basis during the patient's stay. To the extent that we ask LTCHs to provide any of this information to us on the LTCH CARE Data Set, this information is already being collected and documented during the normal course of business and in the normal course of patient care, and we are not required to factor it into our burden assessment.

Comment: Several commenters noted that CMS provided a burden estimate for NHSN data submission but did not provide data for the estimated level of burden for submission of LTCH CARE Data Set data for the newly proposed measures.

Response: In the FY 2013 IPPS/LTCH PPS proposed rule, we noted that we could not provide a burden estimate for the time that it will take to complete the LTCH CARE Data Set given the newly proposed measures selected for use in the LTCHQR Program, as the LTCH CARE Data set has not yet been updated to include the data items needed for the measures CMS is finalizing. We further explained that the data for four of these new measures is to be collected using the LTCH CARE Data Set. However, since the time of the publication of the proposed rule, we have elected not to proceed with three of the new measures that we had named in the proposed rule. We instead decided to

proceed with the addition of two new measures (that is, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), in addition to the three measures that were previously finalized for use in the LTCHQR Program.

The data for the staff influenza vaccination measure will be reported by LTCHs to NHSN. However, the addition of the inpatient influenza vaccination measure has required us to add additional item sets to the LTCH CARE Data Set. We are currently in the process of developing these new item sets but this work has not yet been completed. We cannot provide an accurate burden estimate for revised LTCH CARE Data Set which incorporates the new items sets until these new items have been completely developed.

We also stated in the FY 2013 IPPS/LTCH PPS proposed rule that, upon completion of the revised LTCH CARE Data Set (which will contain the new item sets), we will file a PRA package in which we will provide a complete burden estimate for the revised LTCH CARE Data Set. This PRA process will supply LTCH providers with not only one, but two separate notices and comment periods which will afford them with the opportunity to view PRA documents that we file and to submit public comments related to these PRA documents.

The PRA process provides for the publication of an initial 60 day PRA notice in the **Federal Register**. LTCHs will have 60 days from the date of publication of this 60 day PRA notice in which to file their public comments in response to the PRA documents that we file. These PRA documents will be posted on the CMS PRA Website.

After the expiration of the 60-day notice and comment period, we will respond to any comments that we receive. Thereafter, a second, 30 day PRA notice will be posted in the **Federal Register** which will begin the 30-day notice and comment period. This is an additional opportunity to file public comments in response to the second PRA publication and posting.

Comment: One commenter expressed concerned regarding the burden of inputting data into LASER because LASER was developed without user input.

Response: While the LTCHQR Program and the LASER program are new, the LASER program was developed by CMS contractors who have had extensive experience with the design, development, and implementation of similar data collection programs. These computer programs correspond to data collection instruments that are used by CMS to obtain data for payment and quality measurement purposes. One such program is the JIRVEN program that is used to collect data from the Inpatient Rehabilitation Facility Assessment- Patient Assessment Instrument (IRF-PAI). This instrument is used to determine IRF PPS payments and will also be used for the collection of IRF quality reporting program data beginning on October 1, 2012. Another such program is the RAVEN software, which is used to collect data for the Minimum Data Set, 3.0 (MDS 3.0). The MDS 3.0 data collection instrument is used in skilled nursing facilities to collect information that is used for payment and quality measurement purposes. CMS also offers another free software program to stakeholders, known as HAVEN, which is used to collect data for OASIS-C.

We believe that the CMS contractors who created the LASER program have used the past knowledge and experience, which they gained from development of similar data collection programs when creating the LASER program. In addition, during the design process for the LASER program, the contractors were in frequent contact with the various CMS subject matter experts and technical advisors, who provided them with information about the LTCH setting, so that the LASER program would be customized to fit the needs of the LTCH setting.

We disagree with the contention that we did not get user input during the creation of the LASER program, or that lack of input will cause increased burden to LTCHs. When the LASER program was being created, we made numerous attempts to reach out to the LTCH community to educate the community about the LTCHQR Program and to also seek input about various areas of the LTCHQR Program, including the development of the LASER program. We held a vendor calls on November 16, 2011 and June 28, 2012, during which the LTCH community and their vendors were invited to participate and share their questions and concerns about the LASER program.

We have also reached out to the LTCH community through the use of several different types of activities, including Open Door Forums, the posting of information on the LTCH Quality Reporting Program Web page (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html and a 2- day in-person training conference. LTCH Special Open Door Forums were held on September 21, 2011 and April 13, 2012. Open Door Forums provided an opportunity for

LTCHs to receive information about selected topics and to ask questions and seek information about the LTCH quality reporting program. A tape recording of each of these Open Door Forums was made available for a short period of time following the date of the presentation. Also, a transcript of each Open Door Forum is available at the CMS Open Door Forum website and the LTCHQR Program Web page.

Finally, we have posted informational updates about the status of the LTCHQR Program on an ongoing basis to the LTCHQR Program Web page. Information about the LASER data collection program for the LTCHQR Program also has been posted, including draft and final technical specifications.

In summary, we believe that the LASER Program was created by experienced CMS contractors with input from the LTCH vendors and provider community, as well as CMS subject matter experts, taking into account provider and vendor comments and interactions as outlined above, so we do not foresee any increased burden to providers caused by the method in which this program was created.

10. ICRs for the Ambulatory Surgical Center (ASC) Quality Reporting Program

In section VIII.E. of the preamble of the proposed rule and this final rule, we discuss the requirements for the ASCQR Program for payment determinations affecting CY 2014 and subsequent years. In section XIV.K. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement a quality reporting program for ASCs beginning with the CY 2014 payment determination. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554) for a detailed discussion of the ASCQR Program collection of

information requirements for the claims-based and structural measures for the CY 2014 and CY 2015 payment determinations.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal to consider an ASC to be participating in the ASCQR Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the program on their CY 2012 claims relating to the finalized measures.

For the CY 2015 payment determination and subsequent payment determination years, we proposed and are finalizing that once an ASC submits any quality measure data, it would be considered to be participating in the ASCQR Program. For the CY 2014 payment determination and subsequent payment determination years, if the ASC submits quality measure data, there is no additional action required by the ASC to indicate participation in the Program. Once an ASC submits quality measure data indicating its participation in the ASCQR Program, in order to withdraw, an ASC must complete and submit an online form indicating that it is withdrawing from the quality reporting program.

The burden associated with the requirements to withdraw from the program is the time and effort associated with accessing, completing, and submitting the online form. Based on the number of hospitals that have withdrawn from the Hospital OQR Program over the past 4 years, we estimate that 2 ASCs would withdraw per year and that an ASC would expend 30 minutes to access and complete the form, for a total burden of 1 hour per year.

For the CY 2015 payment determination, we proposed and are finalizing the requirement that ASCs identify and register a QualityNet administrator in order to set up accounts necessary to enter structural measure data. We estimate that, based upon previous experience with the Hospital OQR Program, it would take an ASC 10 hours to obtain, complete, and submit an application for a QualityNet administrator and then set up the necessary accounts for structural measure data entry. We estimate the total burden to meet these requirements to be 51,750 hours (10 hours x 5,175 ASCs). We previously discussed the burden associated with the data entry of structural measure information for the ASCQR Program in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554).

We proposed and are finalizing a process for an extension or waiver for submitting information required under the ASCQR Program due to extraordinary circumstances that are not within the ASC's control for the CY 2014 payment determination and subsequent payment determination years. We proposed and are finalizing that an ASC would complete a request form that would be available on the QualityNet Web site, supply requested information, and submit the request. The burden associated with these requirements is the time and effort associated with gathering required information as well as accessing, completing, and submitting the form. Based on the number of hospitals that have submitted a request for an extension or waiver from the Hospital OQR Program over the past 4 years, we estimate that 1 ASC per year would request an extension or waiver and that an ASC would expend 2 hours to gather required

information as well as access, complete, and submit the form, for a total burden of 2 hours per year.

We also proposed and are finalizing a reconsideration process that would apply to the CY 2014 payment determination and subsequent payment determination years under the ASC Quality Reporting Program. While there is burden associated with an ASC filing a reconsideration request, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals.

We requested public comments on these information collection requirements.

We did not receive any public comments regarding these information collections.

11. ICRs for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In section VIII.F. of the preamble of the proposed rule and this final rule, we discuss the implementation of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

Historically, IPFs have not been required to report quality data to CMS. However, they have been required to report quality measures to other entities such as TJC or State survey and certification organizations. Therefore, although IPFs have not reported on quality measures to CMS, they have some familiarity with and experience in reporting of quality data. More specifically, out of the 1,741 existing IPFs, 450 are currently reporting the proposed measures to TJC. This equates to 26.02 percent of IPFs that already report the measures on a regular basis. The fact that over one-quarter of the

IPFs have demonstrated the ability to report the measures indicates the proposed regulation would not significantly impact IPFs.

Furthermore, we estimate that reporting aggregated-level data on QualityNet will not be costly to IPFs. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data, aggregation of the data, as well as training for submitting the aggregate-level data through QualityNet. We estimate that the annual hourly burden to each IPF for the collection, submission, and training of personnel for submitting all quality measures is approximately 821 hours in a year for each IPF. The average hourly burden to each IPF is approximately 68 hours per month.

This rule would affect all IPFs participating in Medicare. The facilities would have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the data. The anticipated burden to these providers consists of the following: (1) the initial registration of the facility with QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection and aggregation of data; and (4) the time required for entry of the data into the QualityNet database by the IPF's representative.

This rule would affect all IPFs that currently do not already report data to CMS. These facilities will have to register with CMS and take the proper training in order to be adequately prepared to use the CMS QualityNet System for data submission.

Those IPFs that already report quality measures to the TJC will be minimally affected because the abstraction methods, population, sampling, and reporting approaches are similarly adopted by CMS. Therefore, IPFs that report the proposed IPFQR Program quality measures will experience a minimum burden.

We requested public comments on these information collection requirements.

We did not receive any public comments regarding these information collections.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 424

Conditions for Medicare payment.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV as follows:

PART 412--PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), and sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332).

2. Section 412.1 is amended by adding new paragraphs (a)(5) and (a)(6) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(5) This part implements section 1886(q) of the Act, which provides that, effective for discharges from an "applicable hospital" beginning on or after October 1, 2012, payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions, under the Hospital Readmissions Reduction Program. This reduction will be made through an adjustment to the hospital's base operating DRG payment amounts under the prospective payment system for inpatient operating costs.

(6) This part implements section 1886(o)(1)(B) of the Act, which directs the Secretary to begin to make value-based incentive payments under the Hospital Value-Based Purchasing Program to hospitals for discharges occurring on or after October 1, 2012, through an adjustment to the base operating DRG payment amounts under the prospective payment system for inpatient operating costs.

* * * * *

3. Section 412.64 is amended--

a. Revising paragraph (d)(1)(iv).

b. Revising the introductory text of paragraph (h)(4).

c. Revising paragraph (h)(4)(v).

d. Adding a new paragraph (h)(4)(vi).

The revisions and addition read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(iv) For fiscal years 2012 and 2013, the percentage increase in the market basket index less a multifactor productivity adjustment (as determined by CMS) and less 0.1 percentage point for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before October 1, 2013, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology.

* * * * *

(v) The product determined under paragraph (h)(4)(iv) of this section is the minimum wage index value for the State, except as provided under paragraph (h)(4)(vi) of this section;

(vi) For discharges on or after October 1, 2012 and before October 1, 2013, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

(A) CMS estimates a percentage representing the average percentage increase in wage index for hospitals receiving the rural floor due to such floor.

(B) For each all-urban State, CMS makes a onetime determination of the lowest hospital wage index in the State (including all adjustments to the hospital's wage index, except for the rural floor, the rural floor budget neutrality, and the outmigration adjustment) and increases this wage index by the percentage determined under paragraph (h)(4)(vi)(A) of this section, the result of which establishes the alternative minimum wage index value for the State.

* * * * *

4. Section 412.92 is amended by--

a. Revising paragraph (b)(2)(i).

b. Adding paragraphs (b)(2)(v) and (b)(3)(iv).

The revision and additions read as follows:

§ 412.92 Special treatment: Sole community hospitals.

* * * * *

(b) * * *

(2) * * * (i) Sole community hospital status is effective 30 days after the date of CMS' written notification of approval, except as provided in paragraph (b)(2)(v) of this section.

* * * * *

(v) If a hospital that is classified as an MDH under § 412.108 applies for classification as a sole community hospital because its status under the MDH program

expires with the expiration of the MDH program, and that hospital's sole community hospital status is approved, the effective date of approval of sole community hospital status is the day following the expiration date of the MDH program if the hospital--

(A) Applies for classification as a sole community hospital prior to 30 days before the expiration of the MDH program; and

(B) Requests that sole community hospital status be effective with the expiration of the MDH program.

(3) * * *

(iv) A sole community hospital must report to the fiscal intermediary or MAC any factor or information that could have affected its initial classification as a sole community hospital.

(A) If CMS determines that a sole community hospital has failed to comply with the requirement of paragraph ((b)(3)(iv) of this section, CMS may cancel the hospital's classification as a sole community hospital effective with the date the hospital failed to meet the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.

(B) Effective on or after October 1, 2012, if a hospital reports to CMS any factor or information that could have affected its initial determination and CMS determines that the hospital should not have qualified for sole community hospital status, CMS will cancel the sole community hospital status effective 30 days from the date of the determination.

* * * * *

5. Section 412.105 is amended by revising paragraph (b)(4) to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(b) * * *

(4) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or inpatient hospice services.

* * * * *

6. Section 412.140 is amended by revising paragraphs (a)(3)(i) and (b) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Review (IQR) Program.

(a) * * *

(3) * * *

(i) A hospital that would like to participate in the program for the first time (and to which paragraph (a)(3)(ii) of this section does not apply), or that previously withdrew from the program and would now like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the calendar year preceding the first quarter of the calendar year in which data submission is required for any given fiscal year.

* * * * *

(b) Withdrawal from the Hospital IQR Program. A subsection (d) hospital may withdraw from the Hospital IQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital must submit the withdrawal form by May 15 prior to the start of the payment year affected. For example, if a hospital seeks to withdraw from the FY 2015 payment determination, the hospital must submit the withdrawal form to CMS by May 15, 2014.

* * * * *

7. Subpart I is added to part 412 to read as follows:

SUBPART I--ADJUSTMENTS TO THE BASE OPERATING DRG PAYMENT AMOUNTS UNDER THE PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT OPERATING COSTS

Sec.

412.150 Basis and scope of subpart.

Payment Adjustments under the Hospital Readmissions Reduction Program

412.152 Definitions for the Hospital Readmissions Reduction Program.

412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

412.155 - 412.159 [Reserved]

Incentive Payments under the Hospital Value-Based Purchasing Program

412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program.

412.161-Applicability of the Hospital Value-Based Purchasing (VBP) Program

412.162 Process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program.

412.163 Process for making hospital-specific performance information under the Hospital Value-Based Purchasing (VBP) Program available to the public.

412.164 Measure selection under the Hospital Value-Based Purchasing (VBP) Program.

412.165 Performance standards under the Hospital Value-Based Purchasing (VBP) Program.

412.167 Appeal under the Hospital Value-Based Purchasing (VBP) Program.

412.168 - 412.169 [Reserved]

Subpart I--Adjustments to the Base Operating DRG Payment Amounts Under the Prospective Payment Systems for Inpatient Operating Costs

§ 412.150 Basis and scope of subpart.

(a) Section 1886(q) of the Act requires the Secretary to establish a Hospital Readmissions Reduction program, under which payments to applicable hospitals are reduced in order to account for certain excess readmissions, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Readmission Reductions Program are specified in §§ 412.152 and 412.154.

(b) Section 1886(o) of the Act requires the Secretary to establish a Value-Based Purchasing (VBP) Program for inpatient hospitals (Hospital VBP Program), which requires CMS to make value-based incentive payments to hospitals that meet performance standards for applicable performance periods, effective for discharges

beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Value-Based Purchasing Program are specified in §§ 412.160 through 412.167.

Payment Adjustments under the Hospital Readmissions Reduction Program

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

As used in this section and in § 412.154, the following definitions apply:

Aggregate payments for all discharges is, for a hospital for the applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.

Aggregate payments for excess readmissions is, for a hospital for the applicable period, the sum, for the applicable conditions, of the product for each applicable condition of:

(1) The base operating DRG payment amount for the hospital for the applicable period for such condition;

(2) The number of admissions for such condition for the hospital for the applicable period; and

(3) The excess readmission ratio for the hospital for the applicable period minus 1.

Applicable condition is a condition or procedure selected by the Secretary among conditions and procedures for which:

(1) Readmissions represent conditions or procedures that are high volume or high expenditures; and

(2) Measures of such readmissions have been endorsed by the entity with a contract under section 1890 and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).

Applicable hospital is a hospital described in section 1886(d)(1)(B) of the Act or a hospital in Maryland that is paid under section 1814(b)(3) of the Act and that, absent the waiver specified by section 1814(b)(3) of the Act, would have been paid under the hospital inpatient prospective payment system.

Applicable period is, with respect to a fiscal year, the 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program.

Base operating DRG payment amount is the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Value-Based Purchasing Program, as specified under § 412.162. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, and a low volume of discharges under § 412.101.

Excess readmissions ratio is a hospital-specific ratio for each applicable condition for an applicable period , which is the ratio (but not less than 1.0) of risk-adjusted readmissions based on actual readmissions for an applicable hospital for each applicable

condition to the risk-adjusted expected readmissions for the applicable hospital for the applicable condition.

Floor adjustment factor is the value that the readmissions adjustment factor cannot be less than for a given fiscal year. The floor adjustment factor is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Readmission is the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period of 30 days from the date of such discharge.

Readmissions adjustment factor is equal to the greater of:

(1) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges; or

(2) The floor adjustment factor.

Wage-adjusted DRG operating payment is the applicable average standardized amount adjusted for resource utilization by the applicable MS-DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment for hospitals located in Alaska and Hawaii). This amount includes an applicable payment adjustment for transfers under § 412.4(f).

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

(a) Scope. This section sets forth the requirements for determining the payment adjustments under the Hospital Readmissions Reduction Program for applicable hospitals to account for excess readmissions in the hospital.

(b) Payment adjustment. (1) General. To account for excess readmissions, except as provided for in paragraph (d) of this section, an applicable hospital's base operating DRG payment amount is adjusted for each discharge occurring during the fiscal year. The payment adjustment for each discharge is determined by subtracting the product of the base operating DRG payment amount (as defined in § 412.152) for such discharge by the hospital's readmission payment adjustment factor for the fiscal year (determined under paragraph (c) of this section) from the base operating DRG payment amount for such discharge.

(2) Special treatment for sole community hospitals. In the case of a sole community hospital that receives payments under § 412.92(d) based on the hospital-specific rate, the difference between the hospital-specific rate payment and the Federal rate payment determined under subpart D of this part is not affected by this payment adjustment.

(c) Methodology to calculate the readmissions payment adjustment factor. A hospital's readmissions payment adjustment factor is the higher of the ratio described in paragraph (c)(1) of this section or the floor adjustment factor set forth in paragraph (c)(2) of this section.

(1) Ratio. The ratio is equal to 1 minus the ratio of the aggregate payments for excess readmissions as defined in § 412.152 and the aggregate payments for all discharges as defined in § 412.152.

(2) Floor adjustment factor. The floor adjustment factor is:

(i) For FY 2013, 0.99;

(ii) For FY 2014, 0.98; and

(iii) For FY 2015 and subsequent fiscal years, 0.97.

(d) Hospitals paid under section 1814(b)(3) of the Act (certain Maryland hospitals). The Secretary will consider whether to exempt Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the provisions of section 1814(b)(3) of the Act, would be paid under section 1886(d) of the Act from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings for the Hospital Readmissions Reduction Program as applied to hospitals described in section 1886(d)(1)(B) of the Act.

(1) CMS will establish criteria for evaluation of Maryland's annual report to the Secretary to determine whether Maryland will be exempted from the program for a given fiscal year.

(2) Maryland's annual report to the Secretary and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually.

(e) Limitations on review. There is no administrative or judicial review under this subpart of the following:

(1) The determination of base operating DRG payment amounts.

(2) The methodology for determining the adjustment factor under paragraph (c) of this section, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges.

(3) The applicable period.

(4) The applicable conditions.

(f) Reporting of hospital-specific information. CMS will make information available to the public regarding readmissions rates of each applicable hospital (as defined in § 412.152) under the Hospital Readmissions Reduction Program.

(1) To ensure that an applicable hospital has the opportunity to review and submit corrections for its excess readmission ratios for the applicable conditions for a fiscal year that are used to determine its readmissions payment adjustment factor under paragraph (c) of this section, CMS will provide each applicable hospital with confidential hospital-specific reports and discharge level information used in the calculation of its excess readmission ratios.

(2) Applicable hospitals will have a period of 30 days after receipt of the information provided in paragraph (f)(1) of this section to review and submit corrections for the excess readmission ratios for each applicable condition that are used to calculate the readmissions payment adjustment factor under paragraph (c) of this section for the fiscal year.

(3) The administrative claims data used to calculate an applicable hospital's excess readmission ratios for the applicable conditions for a fiscal year are not subject to review and correction under paragraph (f)(1) of this section.

(4) CMS will post the excess readmission ratios for the applicable conditions for a fiscal year for each applicable hospital on the *Hospital Compare* Web site.

§§ 412.155-412.159 [Reserved]

Incentive Payments under the Hospital Value-Based Purchasing Program

§ 412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program.

As used in this section and in §§ 412.161 through 412.167:

Achievement threshold (or achievement performance standard) means the median (50^{th} percentile) of hospital performance on a measure during a baseline period with respect to a fiscal year.

Applicable percent means the following:

(1) For FY 2013, 1.0 percent;

(2) For FY 2014, 1.25 percent;

(3) For FY 2015, 1.50 percent;

(4) For FY 2016, 1.75 percent; and

(5) For FY 2017 and subsequent fiscal years, 2.0 percent.

Base operating DRG payment amount means the following:

(1) With respect to a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act), the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Readmissions Reduction Program, as specified under § 412.154. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a

disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, or a low volume of discharges under § 412.101.

(2) With respect to a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) or a sole community hospital that receives payments under § 412.92(d), the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, or a low volume of discharges under § 412.101. This amount also does not include the difference between the hospital-specific payment rate and the Federal payment rate determined under subpart D of this part.

(3) With respect to a hospital that is paid under section 1814(b)(3) of the Act, the payment amount under section 1814(b)(3) of the Act.

Benchmark means the arithmetic mean of the top decile of hospital performance on a measure during the baseline period with respect to a fiscal year.

Cited for deficiencies that pose immediate jeopardy means that, during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least two surveys using the Form CMS-2567, Statement of Deficiencies and Plan of Correction.

Domain means a grouping of measures used for purposes of calculating the Total Performance Score for each hospital with respect to a fiscal year.

Domain score means the total number of points awarded to a hospital for a domain.

Hospital means a hospital described in section 1886(d)(1)(B) of the Act, but does not include a hospital, with respect to a fiscal year, for which one or more of the following applies:

(1) The hospital is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act for the fiscal year;

(2) The Secretary cited the hospital for deficiencies that pose immediate jeopardy to the health or safety of patients during the performance period that applies with respect to the fiscal year;

(3) There are not a minimum number of measures that apply to the hospital for the performance period for the fiscal year; or

(4) There are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

Immediate jeopardy has the same meaning as that term is defined in §489.3 of this chapter.

Improvement threshold (or improvement performance standard) means an individual hospital's performance level on a measure during the baseline period with respect to a fiscal year.

Linear Exchange Function is the means to translate a hospital's total performance score into a value-based incentive payment percentage such that:

(1) Each eligible hospital's value-based incentive payment percentage is based on its total performance score; and

(2) The total amount of value-based incentive payments to all hospitals in a fiscal year is equal to the total amount available for value-based incentive payments in such fiscal year.

Performance period means the time period during which data are collected for the purpose of calculating hospital performance on measures with respect to a fiscal year.

Performance standards are the levels of performance that hospitals must meet or exceed in order to earn points under the Hospital VBP Program.

Total Performance Score means the numeric score ranging from 0 to 100 awarded to each hospital based on its performance under the Hospital VBP Program with respect to a fiscal year.

Value-based incentive payment adjustment factor is the number that will be multiplied by the base operating DRG payment amount for each discharge from a hospital, during a fiscal year, in order to adjust the hospital's payment as a result of its performance under the Hospital VBP Program.

Value-based incentive payment percentage means the percentage of the base operating DRG payment amount for each discharge that a hospital has earned with respect to a fiscal year, based on its Total Performance Score for that fiscal year.

Wage-adjusted DRG operating payment is the applicable average standardized amount adjusted for--

(1) Resource utilization by the applicable MS-DRG relative weight;

(2) Differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment for hospitals located in Alaska and Hawaii); and

(3) Any applicable payment adjustment for transfers under § 412.4(f).

§ 412.161 Applicability of the Hospital Value-Based Purchasing (VBP) Program

(a) General rule. Except as provided in paragraph (b) of this section, the Hospital VBP Program applies to hospitals, as that term is defined in § 412.160.

(b) Special rule for hospitals paid under section 1814 of the Act. The Secretary may exempt hospitals paid under section 1814 of the Act from the requirements of the Hospital VBP Program for a fiscal year if the State submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program.

§ 412.162 Process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program.

(a) General. If a hospital meets or exceeds the performance standards that apply to the Hospital VBP Program for a fiscal year, CMS will make value-based incentive payments to the hospital under the requirements and conditions specified in this section.

(b) Value-based incentive payment amount. (1) Available amount. The value-based incentive payment amount for a discharge is the portion of the payment amount that is attributable to the Hospital VBP Program. The total amount available for value based incentive payments to all hospitals for a fiscal year is equal to the total

amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

(2) Calculation of the value-based incentive payment amount. The value-based incentive payment amount is calculated by multiplying the base operating DRG payment amount by the value-based incentive payment percentage.

(3) Calculation of the value-based incentive payment percentage. The value-based incentive payment percentage is calculated as the product of: the applicable percent as defined in §412.160, the hospital's Total Performance Score divided by 100, and the exchange function slope.

(c) Methodology to calculate the value-based incentive payment adjustment factor. The value-based incentive payment adjustment factor for each discharge is determined by subtracting the applicable percent as specified in §412.160 from the value-based incentive payment percentage and then adding that difference to one.

§ 412.163 Process for making hospital-specific performance information under the Hospital Value-Based Purchasing (VBP) Program available to the public.

(a) CMS will make information available to the public regarding the performance of each hospital under the Hospital VBP Program.

(b) To ensure that a hospital has the opportunity to review and submit corrections for the information to be made public under this section, CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its performance with respect to each measure, condition, and domain, and the calculation of its Total Performance Score.

(c) Hospitals will have a period of 30 days after CMS provides the information specified in paragraph (b) of this section to review and submit corrections for the information.

(d) CMS will post the information specified in paragraph (b) for each hospital on the Hospital Compare Web site.

§ 412.164 Measure selection under the Hospital Value-Based Purchasing (VBP) Program.

(a) CMS will select measures, other than measures of readmissions, for purposes of the Hospital VBP Program. The measures will be a subset of the measures specified under section 1886(b)(3)(B)(viii) of the Act (the Hospital Inpatient Quality Reporting Program).

(b) CMS will post data on each measure on the Hospital Compare Web site for at least 1 year prior to the beginning of a performance period for the measure under the Hospital VBP Program.

§ 412.165 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.

(a) Points awarded based on hospital performance. (1) CMS will award points to hospitals for performance on each measure for which the hospital reports the applicable minimum number of cases during the applicable performance period.

(2) CMS will award from 1 to 9 points for achievement to each hospital whose performance on a measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark for that measure.

(3) CMS will award from 0 to 9 points for improvement to each hospital whose performance on a measure during the applicable performance period exceeds the improvement threshold but is less than the benchmark for that measure.

(4) CMS will award 10 points to a hospital whose performance on a measure during the applicable performance period meets or exceeds the benchmark for that measure.

(b) Calculation of the Total Performance Score. The hospital's Total Performance Score for a program year is calculated as follows:

(1) CMS will calculate a domain score for a hospital when it reports the minimum number of measures in the domain.

(2) CMS will sum all points awarded for each measure in a domain to calculate an unweighted domain score.

(3) CMS will normalize each domain score to ensure that it is expressed as a percentage of points earned out of 100.

(4) CMS will weight the domain scores with the finalized domain weights for each fiscal year.

(5) The sum of the weighted domain scores is the hospital's Total Performance Score for the fiscal year.

§ 412.167 Appeal under the Hospital Value-Based Purchasing (VBP) Program.

(a) A hospital may appeal the following issues:

(1) CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;

(2) Whether the achievement/improvement points were calculated correctly;

(3) Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;

(4) Whether CMS correctly calculated the domain scores, including the normalization calculation;

(5) Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;

(6) Whether CMS calculated the HCAHPS consistency points correctly;

(7) Whether the correct domain scores were used to calculate the Total Performance Score;

(8) Whether each domain was weighted properly;

(9) Whether the weighted domain scores were properly summed to arrive at the Total Performance Score; and,

(10) Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

(b) Appeals must be submitted within 30 days of CMS' decision to deny a corrections request under § 412.163 or within 30 days of the conclusion of the review and corrections period, as applicable, and must contain the following information:

(1) Hospital's CMS Certification Number (CCN).

(2) Hospital name.

(3) Hospital's basis for requesting an appeal. This must identify the hospital's specific reason(s) for appealing the hospital's Total Performance Score or performance assessment with respect to the performance standards.

(4) CEO contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box).

(5) QualityNet System Administrator contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box).

(c) Limitations on review. There is no administrative or judicial review of the following:

(1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount.

(2) The determination of the amount of funding available for value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act.

(3) The establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act.

(4) The measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act.

(5) The methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores.

(6) The validation methodology that is specified under section 1886(b)(3)(B)(viii)(XI) of the Act.

§§ 412.168 – 412.169 [Reserved].

8. Section 412.424 is amended by adding a new paragraph (d)(1)(vi) to read as follows:

§ 412.424 Methodology for calculating the Federal per diem payment amount.

* * * * *

(d) * * *

(1) * * *

(vi) Applicable percentage change for fiscal year 2014 payment determination and for subsequent years. (A) In the case of an inpatient psychiatric facility that is paid under the prospective payment system in § 412.1(a)(2) that does not submit quality data to CMS, in the form and manner and at a time specified by CMS, the applicable annual update to a Federal standard rate is reduced by 2.0 percentage points.

(B) Any reduction in the applicable annual update to a Federal standard rate will apply only to the fiscal year involved and will not be taken into account in computing the annual payment update for a subsequent year.

* * * * *

9. Section 412.434 is added to subpart N to read as follows:

§ 412.434 Reconsideration and appeals procedures of Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program decisions.

(a) An inpatient psychiatric facility may request reconsideration of a decision by CMS that the inpatient psychiatric facility has not met the requirements of the IPFQR Program for a particular fiscal year. An inpatient psychiatric facility must submit a reconsideration request to CMS no later than 30 days from the date identified on the IPFQR Program Annual Payment Update Notification Letter provided to the inpatient psychiatric facility.

(b) A reconsideration request must contain the following information:

(1) The inpatient psychiatric facility's CMS Certification Number (CCN);

(2) The name of the inpatient psychiatric facility;

(3) Contact information for the inpatient psychiatric facility's chief executive officer and QualityNet system administrator, including each individual's name, e-mail address, telephone number, and physical mailing address;

(4) A summary of the reason(s), as set forth in the IPFQR Program Annual Payment Update Notification Letter, that CMS concluded the inpatient psychiatric facility did not meet the requirements of the IPFQR Program;

(5) A detailed explanation of why the inpatient psychiatric facility believes that it complied with the requirements of the IPFQR Program for the applicable fiscal year; and

(6) Any evidence that supports the inpatient psychiatric facility's reconsideration request, such as e-mails and other documents.

(c) An inpatient psychiatric facility that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R of this chapter.

10. Section 412.523 is amended by--

a. Adding a new paragraph (c)(3)(ix).

b. Revising paragraph (d)(3).

The addition and revision read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(ix) For long-term care hospital prospective payment system fiscal year beginning October 1, 2012, and ending September 30, 2013. (A) The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2012, and ending September 30, 2013, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.8 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(B) With respect to discharges occurring on or after October 1, 2012 and before December 29, 2012, payments are based on the standard Federal rate in paragraph (c)(3)(ix)(A) of this section without regard to the adjustment provided for under paragraph (d)(3)(ii) of this section.

* * * * *

(d) * * *

(3)(i) General. The Secretary reviews payments under this prospective payment system and may make a one-time prospective adjustment to the long-term care hospital prospective payment system rates no earlier than December 29, 2012, so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.

(ii) Adjustment to the standard Federal rate. The standard Federal rate determined in paragraph (c)(3) of this section is permanently adjusted by 3.75 percent to account for the estimated difference between projected aggregate payments in FY 2003 made under the prospective payment system implemented under this subpart and the projected aggregate payments that would have been made in FY 2003 under Part 413 of this chapter without regard to the implementation of the prospective payment system implemented under this subpart, excluding the effects of sections 1886(b)(2)(E) and (b)(3)(J) of the Act. This adjustment is transitioned over 3 years beginning in FY 2013.

(iii) Special rule for certain discharges occurring during FY 2013. The adjustment applied under paragraph (d)(3)(ii) of this section is not applicable when making payments under this subpart for discharges occurring on or after October 1, 2012, and on or before December 28, 2012.

* * * * *

11. Section 412.529 is amended by revising paragraph (d)(4)(i)(C) to read as follows:

§ 412.529 Special payment provisions for short-stay outliers.

* * * * *

(d) * * *

(4) * * *

(i) * * *

(C) The payment amount specified under paragraph (d)(4)(i)(B) of this section may not exceed the full amount comparable to what would otherwise be paid under the hospital inpatient prospective payment system determined under paragraph (d)(4)(i)(A) of this section.

* * * * *

12. Section 412.534 is amended by--

a. In the following paragraphs, removing the date "October 1, 2012" and adding in its place the date "October 1, 2013":

1. Paragraph (c)(1) heading;

2. Paragraph (c)(1)(i);

3. Paragraph (c)(1)(ii);

4. Paragraph (c)(2) heading;

5. Paragraph (d)(1) heading;

6. Paragraph (d)(1)(i);

7. Paragraph (d)(2) heading;

8. Paragraph (e)(1) heading;

9. Paragraph (e)(1)(i); and

10. Paragraph (e)(2) heading.

b. Revising paragraph (c)(3).

c. Revising paragraph (d)(3).

d. Revising paragraph (e)(3).

e. Revising paragraphs (h)(4) and (h)(5).

f. Adding a new paragraph (h)(6).

The revisions and addition read as follows:

§ 412.534 Special payment provisions for long-term care hospitals within hospitals and satellites of long-term care hospitals.

* * * * *

(c) * * *

(3) For a long-term care hospital satellite facility described in § 412.22(h)(3)(i), payments are determined as follows:

(i) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012, and for cost reporting period beginning on or after October 1, 2012 and before October 1, 2013, payment will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 50 percent.

(ii) For cost reporting periods beginning on or after July 1, 2012, and before October 1, 2012, for discharges occurring on or after October 1, 2012, and before the

beginning of the next cost reporting period, payment will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 50 percent.

(iii) In determining the percentage of patients admitted to a satellite from the co-located hospital, patients on whose behalf an outlier payment was made to the co-located hospital are not counted toward the 50-percent threshold.

(d) * * *

(3) For cost reporting periods beginning on or after July 1, 2007, and before July 1, 2012, and beginning on or after October 1, 2012, and before October 1, 2013, payment for a long-term care hospital satellite facility described in § 412.22(h)(3)(i) are determined as follows:

(i) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012, and for cost reporting period beginning on or after October 1, 2012 and before October 1, 2013, payment will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 75 percent.

(ii) For cost reporting periods beginning on or after July 1, 2012, and before October 1, 2012, for discharges occurring on or after October 1, 2012, and before the beginning of the next cost reporting period, payment will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 75 percent..

(iii) In determining the percentage of patients admitted to a satellite from the co-located hospital, patients on whose behalf an outlier payment was made to the co-located hospital are not counted toward the 75-percent threshold.

(e) * * *

(3) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, payments for a long-term care hospital satellite facility described in § 412.22(h)(3)(i) are determined as follows::

(i) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012, and for cost reporting period beginning on or after October 1, 2012 and before October 1, 2013, payment will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 75 percent.

(ii) For cost reporting periods beginning on or after July 1, 2012, and before October 1, 2012, for discharges occurring on or after October 1, 2012, and before the beginning of the next cost reporting period, payment will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 75 percent.

(iii) In determining the percentage of patients admitted to a satellite from the co-located hospital, patients on whose behalf an outlier payment was made to the co-located hospital are not counted toward the 75-percent threshold.

* * * * *

(h) * * *

(4) Except as provided in paragraph (h)(6) of this section, for a long-term care hospital described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f), the policies set forth in this paragraph (h) and in § 412.536 do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012, and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.

(5) Except as provided in paragraph (h)(6) of this section, for a long-term care hospital or satellite facility that, as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Act at the off-campus location, the policies set forth in this paragraph (h) and in § 412.536 do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012, and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.

(6) For long-term care hospitals and satellite facilities with cost reporting periods beginning on or after July 1, 2012 and before October 1, 2012.

(i) Payments to long-term care hospitals and satellite facilities described in paragraphs (h)(4) and (h)(5) of this section are determined using the methodology specified in paragraph (c)(1) of this section for discharges occurring prior to October 1, 2012 during the hospital's or satellite facility's cost reporting period beginning on or after July 1, 2012 and before October 1, 2012. Such policies will not be

applied to discharges occurring on or after October 1, 2012 and before the beginning of the hospital's or satellite facility's next cost reporting period.

(ii) In determining the percentage of Medicare discharges admitted from the co-located hospital under this paragraph, patients on whose behalf a Medicare high-cost outlier payment was made at the co-located referring hospital are not counted toward that threshold.

13. Section 412.536 is amended by revising the introductory text of paragraph (a)(2) and adding a new paragraph (a)(3) to read as follows:

§ 412.536 Special payment provisions for long-term care hospitals and satellites of long-term care hospitals that discharged Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite of the long-term care hospital.

(a) * * *

(2) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012, and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013, the policies set forth in this section are not applicable to discharges from:

* * * * *

(3) For certain long-term care hospitals with cost reporting periods beginning on or after July 1, 2012 and before October 1, 2012--

(i) Payments to long-term care hospitals described in paragraph (a)(1)(iv) of this section are determined using the methodology specified in either paragraph (b)(1) or

paragraph (b)(2) of this section, except that such policies will not be applied to discharges occurring on or after October 1, 2012, and before October 1, 2012.

(ii) In determining whether the percentage of long-term care hospital discharges during a long-term care hospital's cost reporting period beginning on or after July 1, 2012 and before July 1, 2013 exceeds the 25 percent threshold, those discharges occurring on or after October 1, 2012, and before October 1, 2013, will not be counted towards that threshold.

(iii) In determining the percentage of Medicare discharges admitted to the long-term care hospital from any referring hospital not co-located with the long-term care hospital or with the satellite facility of a long-term care hospital under paragraphs (b)(1) and (b)(2) of this section, patients on whose behalf a Medicare high cost outlier payment was made to the referring hospital are not counted toward the 25 percent threshold from that referring hospital.

* * * * *

PART 413--PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

14. The authority citation for Part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d),

1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106-133 (113 Stat. 1501A-332).

15. Section 413.24 is amended by revising paragraph (a) to read as follows:

§ 413.24 Adequate cost data and cost finding.

(a) Principle. Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting, except for--

(1) Governmental institutions which operate on a cash basis method of accounting. Cost data based on such basis of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

(2) Costs of qualified defined benefit pension plans shall be reported on a cash basis method of accounting, as described at § 413.100(c)(2)(vii)(D) for cost reporting periods beginning on or after October 1, 2011.

* * * * *

16. Section 413.79 is amended by--

a. Revising paragraphs (e)(1), (e)(2), (e)(3), and (e)(4).

b. Adding a new paragraph (e)(5).

c. Revising paragraph (f)(7)(i)(B).

d. Redesignating paragraphs (n)(2)(ii) and (n)(2)(iii) as paragraphs (n)(2)(iii) and paragraph (n)(2)(iv), respectively.

e. Adding new paragraph (n)(2)(ii).

f. Revising newly redesignated paragraphs (n)(2)(iii) and (n)(2)(iv).

The revisions and addition read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(e) * * *

(1) If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted for new residency training programs based on the sum of the products of the highest number of FTE residents in any program year during the third year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program. If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted for new residency training programs based on the sum of the products of the highest number of

FTE residents in any program year during the fifth year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program.

(i) If a hospital begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, and if the residents are spending portions of a program year (or years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each qualifying hospital's cap for a new medical residency training program(s) is equal to the sum of the products of the highest number of FTE residents in any program year during the third year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program and the number of years the residents are training at each respective hospital. If a hospital begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, and if the residents are spending portions of a program (or years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each qualifying hospital's cap for new residency training program (s) is equal to the sum of the products of three factors (limited to the number of accredited slots for each program):

(A) The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence at all of the hospitals to which the residents in the program rotate;

(B) The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

(C) The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

(ii) If a hospital begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's first new residency program(s), the hospital's cap may be temporarily adjusted during each of the first 3 years of the hospital's first new residency program using the actual number of residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year. If a hospital begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, prior to the implementation of the hospital's adjustment to its FTE cap beginning with the sixth year of the hospital's first new residency program(s), the hospital's cap may be adjusted temporarily during each of the first 5 years of the hospital's first new residency program using the actual number of FTE residents participating in the new program. The

adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(iii) If a hospital begins training residents in a new medical residency training program for the first time on or after January 1, 1995, but before October 1, 2012, the cap will not be adjusted for new programs established more than 3 years after residents begin training in the first new program, or if a hospital begins training residents in a new medical residency training program for the first time on or after October 1, 2012, the cap will not be adjusted for new programs established more than 5 years after residents begin training in the first new program.

(iv) Effective for Medicare GME affiliation agreements entered into on or after October 1, 2005, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.

(v) A rural hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap.

(2) If a hospital had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, the hospital's unweighted FTE cap may be adjusted for a new medical residency training program(s) established on or after January 1, 1995, and on or before August 5, 1997. The adjustment to the hospital's FTE resident cap for new residency training programs is based on the sum of the product

of the highest number of FTE residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete each program based on the minimum accredited length for the type of program.

(i) If the residents are spending portions of a program year (or years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each respective hospital's cap for each program is equal to the product of the highest number of FTE residents in any program year during the third year of each program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program and the number of years the residents are training at each respective hospital.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program, the hospital's cap may be temporarily adjusted during each of the first 3 years of the hospital's new residency program, using the actual number of FTE residents in the new programs. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(3) If a rural hospital participates in new medical residency training programs, regardless of whether the rural hospital had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, the hospital's unweighted FTE cap may be adjusted in the same manner described in paragraph (e)(2) of this section to reflect the increase for residents training in a new medical residency training program(s) established after August 5, 1997 and before October 1, 2012. If a

rural hospital participates in new medical residency training programs on or after October 1, 2012, the hospital's unweighted FTE cap is adjusted in accordance with paragraph (e)(1) of this section, except that the adjustment is based on the sum of the products of the highest number of FTE residents in any program year during the fifth year of each new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program.

(4) A hospital seeking an adjustment to its FTE cap must provide documentation to its fiscal intermediary justifying the adjustment.

(5) The cap will not be adjusted for expansion of existing or previously existing programs.

(f) * * *

(7) * * *

(i) * * *

(B) Specify the effective period of the emergency Medicare GME affiliation agreement (which must, in any event, terminate at the conclusion of four academic years following the academic year in which the section 1135 emergency period began).

* * * * *

(n) * * *

(2) * * *

(ii) If a hospital receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section, and does not use all of that increase in its final (12-

month or partial) cost report of the 5-year period beginning July 1, 2011 and ending June 30, 2016, the Medicare contractor will remove the applicable unused slots, and the hospital's increase in the otherwise applicable FTE resident cap received under paragraph (n)(1) of this section will be reduced for portions of cost reporting periods on or after July 1, 2016. The number of applicable unused slots is equal to the difference between the increase in the otherwise applicable FTE resident cap and the applicable slots used. In determining the applicable slots used, the following amounts are added, as relevant:

(A) If a hospital uses the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section to expand an existing program(s), the used slots are equal to the lesser of the number of slots used for an expansion(s) in the fourth 12-month cost report or the final cost report.

(B) If a hospital uses the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section to start a new program(s), the used slots are equal to the number of slots used for a new program(s) in the final cost report.

(C) The portion, if any, of the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section used for cap relief, subject to the requirements in paragraph (n)(2)(i) of this section.

(iii) CMS may determine whether a hospital has met the requirements under paragraphs (n)(2)(i) and (n)(2)(ii) of this section during the 5-year period of July 1, 2011, through June 30, 2016, in such manner and at such time as CMS determines appropriate, including at the end of such 5-year period.

(iv) In a case where the Medicare contractor determines that a hospital did not meet the requirements under paragraphs (n)(2)(i), (n)(2)(ii), and (n)(2)(iii) of this section in a cost reporting period within the 5-year time period, the Medicare contractor will reduce the otherwise applicable FTE resident cap of the hospital by the amount by which such limit was increased under paragraph (n)(1) of this section from the earliest cost reporting period that is reopenable in which it would be determined that the hospital did not meet the requirements.

* * * * *

17. Section 413.100 is amended by adding a new paragraph (c)(2)(vii)(D) to read as follows:

§ 413.100 Special treatment of certain accrued costs.

* * * * *

(c) * * *

(2) * * *

(vii) * * *

(D) Exception: Qualified defined benefit pension plans, which are funded deferred compensation arrangements, shall be reported on a cash accounting basis as follows:

(1) The allowable pension cost shall be equal to the amount of actual pension contributions funded during the hospital's current Medicare cost reporting period, plus any contributions funded in a prior period and carried forward, subject to the limit under paragraph (c)(2)(vii)(D)*(2)* of this section.

(2) Except as provided in paragraph (c)(2)(vii)(D)*(3)* of this section, the allowable pension cost shall not exceed 150 percent of the average contribution(s) funded during the three consecutive Medicare cost reporting periods that produce the highest average contribution(s), out of the five most recent Medicare cost reporting periods (ending with the current cost reporting period). Contributions in excess of the limit may be carried forward to future period(s). In the case of a newly adopted pension plan, the 5-year look-back period and/or the 3-year averaging period will be limited to the number of cost reporting periods the provider sponsored a qualified defined benefit pension plan.

(3) A waiver of the limit imposed under paragraph (c)(2)(vii)(D)*(2)* of this section may be granted for a specific Medicare cost reporting period for all or a portion of the contributions in excess of the limit imposed under paragraph (c)(2)(vii)(D)*(2)* of this section if it is determined that such excess costs are reasonable and necessary for that period.

* * * * *

PART 424--CONDITIONS FOR MEDICARE PAYMENT

18. The authority citation for Part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

19. Section 424.30 is revised to read as follows:

§ 424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished

on a prepaid capitation basis by an MA organization, or through cost settlement with either a health maintenance organization (HMO), a competitive medical plan (CMP), or a health care prepayment plan (HCPP), or as part of a demonstration. Therefore, claims must be filed by hospitals seeking IME payment under § 412.105(g) of this chapter, and/or direct GME payment under § 413.76(c) of this chapter, and/or nursing or allied health education payment under § 413.87 of this chapter associated with inpatient services furnished on a prepaid capitation basis by an MA organization. Hospitals that must report patient data for purposes of the DSH payment adjustment under § 412.106 of this chapter for inpatient services furnished on a prepaid capitation basis by an MA organization, or through cost settlement with an HMO/CMP, or as part of a demonstration, are required to file claims by submitting no pay bills for such inpatients. Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in subpart E of this part.

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

20. The authority citation for Part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

21. Section 476.1 is amended by adding a definition of "Provider" in alphabetical order, to read as follows:

§ 476.1 Definitions.

* * * * *

Provider means a health care facility, institution, or organization, including but not limited to a hospital, involved in the delivery of health care services for which payment may be made in whole or in part under Title XVIII of the Act.

* * * * *

22. Section 476.78 is amended by revising the section heading and the introductory text of paragraph (b)(2) to read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) Providers and practitioners must provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. When the QIO does postadmission, preprocedure review, the provider must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers and practitioners must--

* * * * *

23. Section 476.90 is revised to read as follows:

§ 476.90 Lack of cooperation by a provider or practitioner.

(a) If a provider or practitioner refuses to allow a QIO to enter and perform the duties and functions required under its contract with CMS, the QIO may—

(1) Determine that the provider or practitioner has failed to comply with the requirements of 42 CFR 1004.10(c) and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the provider or practitioner, and may report the matter to the HHS Inspector General.

(b) If a QIO gives a provider or practitioner sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if the provider or practitioner does not respond in a timely manner, the QIO will deny the claim. A provider or practitioner may request that the QIO reconsider its decision to deny the claim. No further appeal rights are available.

CMS-1588-F

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; Program No. 93.774, Medicare--Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance)

Dated: July 27, 2012

Marilyn Tavenner,

Acting Administrator, Centers for

Medicare & Medicaid Services

Dated: July 31, 2012

Kathleen Sebelius,

Secretary.

BILLING CODE 4120-01-P

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, and Rate-of-Increase Percentages Effective with Cost Reporting Periods Beginning on or after October 1, 2012 and Payment Rates for LTCHs Effective for Discharges Occurring on or after October 1, 2012

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2013 for acute care hospitals. We also are setting forth the rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS for FY 2013. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are finalizing the rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS that are effective for cost reporting periods beginning on or after October 1, 2012.

In addition, we are setting forth a description of the methods and data we used to determine the standard Federal rate that would be applicable to Medicare LTCHs for FY 2013.

In general, except for SCHs and hospitals located in Puerto Rico, for FY 2013, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge.

We note that, as discussed in section IV.G. of the preamble of this final rule, section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). (Under prior law, the MDH program was to be in effect through the end of FY 2011 only.) Therefore, due to the expiration of the MDH program beginning with FY 2013, we are not including hospitals that are currently MDHs (until October 1, 2012) in our update of the hospital-specific rates for FY 2013.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2013. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2013. In section IV. of this Addendum, we are setting forth our changes for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2013. In section V. of this Addendum, we are making changes in the determination of the standard Federal rate for

LTCHs paid under the LTCH PPS for FY 2013. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the Internet.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2013

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors used for determining the prospective payment rates for FY 2013.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.

- The labor-related share that is applied to the standardized amounts and Puerto Rico-specific standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act.

- An update of 1.8 percent for all areas (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent less an adjustment of 0.7 percentage point for MFP and less 0.1 percentage point), as required by section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. For hospitals that fail to submit data, in a form and manner, and at the time, specified by the Secretary relating to the quality of

inpatient care furnished by the hospital, pursuant to section 1886(b)(3)(B)(viii) of the Act, the update is –0.2 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.7 percentage point for MFP, and less 0.1 percentage point).

- An update of 1.8 percent to the Puerto Rico-specific standardized amount (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent less an adjustment of 0.7 percentage point for MFP and less 0.1 percentage point), in accordance with section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Pub. L. 108-173, which sets the update to the Puerto Rico-specific standardized amount equal to the applicable percentage increase set forth under section 1886(b)(3)(B)(i) of the Act.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.

- An adjustment to ensure the wage index changes are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act. We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62 percent labor-related share in certain circumstances) had not been enacted.

- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2012 budget neutrality factor and applying a revised factor.

- An adjustment to ensure the effects of the rural community hospital demonstration program required under section 410A of Pub. L. 108-173, as amended by sections 3123 and

10313 of Pub. L. 111-148, which extended the demonstration program for an additional 5 years, are budget neutral as required under section 410A(c)(2) of Pub. L. 108-173.

- An adjustment to remove the FY 2012 outlier offset and apply an offset for FY 2013, as provided for under section 1886(d)(3)(B) of the Act.

- As discussed below and in section II.D. of the preamble of this final rule, an adjustment to meet the requirements of sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110-90 to adjust the standardized amounts to offset the estimated amount of the increase in aggregate payments (including interest) due to the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009. As discussed below, for FY 2013, we are making an adjustment to the standardized amounts to complete the necessary adjustments required by the provisions of sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110-90. (We note as discussed in greater detail in section II.D. of the preamble of this final rule, at this time, we are not finalizing our proposed adjustment to the standardized amount for FY 2013 to offset the estimated amount of the increase in aggregate payments due to the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2010.)

Beginning in FY 2008, we applied the budget neutrality adjustment for the rural floor to the hospital wage indices rather than the standardized amount. As we did for FY 2012, for FY 2013, we are continuing to apply the rural floor budget neutrality adjustment to hospital wage indices rather than the standardized amount. Consistent with section 3141 of the Affordable Care Act, instead of applying a State level rural floor budget neutrality adjustment to the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2013 wage index for the rural floor. We note that, as finalized in the FY 2012 IPPS/LTCH PPS final rule,

we extended the imputed floor through FY 2013 (76 FR 51593). Therefore, for this final rule, we are continuing to include the imputed floor in calculating the uniform, national rural floor budget neutrality adjustment to the wage indices. Thus, the imputed floor is reflected in the FY 2013 wage index. Additionally, in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed an alternative temporary methodology for computing the imputed floor index in section II.G.2. of the preamble of that proposed rule. We are finalizing that alternative methodology and have included this alternative methodology in our calculation of rural floor budget neutrality in this final rule.

We note that, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51788 through 51790), we finalized an adjustment of 1.1 percent to the standardized amount (that is, a factor of 1.011) in light of the *Cape Cod* decision. The adjustment is a one-time permanent adjustment that is left permanently on the standardized amount.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. For Puerto Rico hospitals, the Puerto Rico-specific standardized amount is based on per discharge averages of adjusted target amounts from a base period (section 1886(d)(9)(B)(i) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d)(9) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS. The

September 1, 1987 final rule (52 FR 33043 and 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

In accordance with section 1886(d)(3)(E) of the Act, the Secretary estimates, from time-to-time, the proportion of hospitals' costs that are attributable to wages and wage-related costs. In general, the standardized amount is divided into labor-related and nonlabor-related amounts; only the proportion considered to be the labor-related amount is adjusted by the wage index. Section 1886(d)(3)(E) of the Act requires that 62 percent of the standardized amount be adjusted by the wage index, unless doing so would result in lower payments to a hospital than would otherwise be made. (Section 1886(d)(9)(C)(iv)(II) of the Act extends this provision to the labor-related share for hospitals located in Puerto Rico.)

For FY 2013, we are continuing to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2012, for the national standardized amounts and 62.1 percent for the Puerto Rico-specific standardized amount. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent for all IPPS hospitals whose wage index values are less than or equal to 1.0000. For all IPPS hospitals whose wage indices are greater than 1.0000, we are applying the wage index to a labor-related share of 68.8 percent of the national standardized amount. For FY 2013, all Puerto Rico hospitals have a

wage index less than 1.0. Therefore, the national labor-related share is 62 percent because the wage index for all Puerto Rico hospitals is less than 1.0.

For hospitals located in Puerto Rico, we are applying a labor-related share of 62.1 percent if its Puerto Rico-specific wage index is greater than 1.0000. For hospitals located in Puerto Rico whose Puerto-Rico specific wage index values are less than or equal to 1.0000, we are applying a labor share of 62 percent.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the Internet.

2. Computing the Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Section 1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific urban and rural area rates. Accordingly, we are calculating the FY 2013 national standardized amount and Puerto Rico-specific rate irrespective of whether a hospital is located in an urban or rural location.

3. Updating the Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. As discussed in section IV.H. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are reducing the FY 2013 applicable percentage increase (which is based on the second quarter 2012 forecast of the FY 2006-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2013) of 0.7 percent, which is calculated based on IHS Global Insight, Inc.'s (IGI's) second quarter 2012 forecast. In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are further updating the standardized amount for FY 2013 by the estimated market basket percentage increase less 0.1 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of Act, as added and amended by sections 3401(a) and 10319(a) the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services comprising routine, ancillary, and special care unit hospital inpatient services. Based on IGI's 2012 second quarter forecast of the hospital market basket increase (as discussed in Appendix B of this final rule), the most recent forecast of the hospital market basket increase for FY 2013 is 2.6 percent. Thus, for FY 2013, the update to the average standardized amount is 1.8 percent for hospitals in all areas (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent less an adjustment of 0.7 percentage point for MFP and less 0.1 percentage point). For hospitals that do not submit quality data pursuant to section 1886(b)(3)(B)(viii) of the Act, the estimated update to the operating

standardized amount is -0.2 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.7 percentage point for MFP, and less 0.1 percentage point). The standardized amounts in Tables 1A through 1C that are published in section VI. of this Addendum and available via the Internet reflect these differential amounts.

Section 401(c) of Pub. L. 108-173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth under section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are finalizing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.8 percent.

Although the update factors for FY 2013 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2013 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our proposed recommendations in the **Federal Register** for public comment. Our final recommendation on the update factors is set forth in Appendix B of this final rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are adjusting the FY 2013 standardized amount to remove the effects of the FY 2012 geographic reclassifications and outlier payments before applying the FY 2013 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2013 payment policies.

We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS-DRG classifications, recalibration of the MS-DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

In order to appropriately estimate aggregate payments in our modeling, we make several inclusions and exclusions so that the appropriate universe of claims and charges are included. We discuss IME Medicare Advantage payment amounts, fee-for-service only claims, and charges for anti-hemophilic blood factor and organ acquisition below.

First, consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include

Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total "operating DRG payments," which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

Second, consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a "Claim Type" of 60 (which is a field on the MedPAR file that indicates a claim is a fee-for-service claim).

Third, consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of "3" for blood clotting with a revenue code of "0636" from the covered charge field for the budget neutrality adjustments. We also removed organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

Comment: One commenter noted that it is still likely that CMS is including charges for anti-hemophilic blood factor (which are paid separately under the IPPS) in the MedPAR claims used to determine the budget neutrality adjustments. The commenter explained that the majority of patients receiving blood clotting drugs have a pharmacy indicator of "5", which denotes "general drugs and/or IV therapy and blood clotting drugs." The commenter searched the MedPAR file and found 67,548 claims reporting patients receiving blood clotting drugs and 843

of these claims had a pharmacy indicator of "3". From the subset of 843 claims, 5 had pharmacy charges in excess of $100,000 and 724 claims had pharmacy charges greater than $100,000 with a pharmacy indicator of "5". The commenter noted that the bulk of these 843 claims contain a pharmacy indicator of "5"; however, the MedPAR file as currently constructed does not allow for the separation of anti-hemophilic blood factor charges from other pharmacy charges. The commenter concluded that the inclusion of all pharmacy charges with a pharmacy indicator of "5" is inappropriate.

Response: We appreciate the commenter's concern regarding including charges that may not be appropriate to include within our modeling. As acknowledged by the commenter, the MedPAR file as currently constructed does not allow for the separation of anti-hemophilic blood factor charges from other pharmacy charges. We will explore the possibility of uniquely identifying anti-hemophilic blood factor pharmacy charges within the MedPAR file for future rulemaking.

Section 3021 of the Affordable Care Act, codified under section 1115A of the Act, authorizes CMS to test innovative payment and service delivery models with the goal of reducing Medicare program expenditures while preserving or enhancing the quality of care furnished to individuals. Because initiatives established under this authority could result in IPPS hospitals receiving a payment that is different from what they otherwise would receive under the IPPS, we believe it is important to identify how these initiatives are addressed in the context of our budget neutrality calculations.

The Bundled Payments for Care Improvement (BPCI) initiative, developed by CMS' Center for Medicare and Medicaid Innovation under the authority of section 3021 of the Affordable Care Act (codified under section 1115A of the Act), will test four payment models

that link payments for multiple services during an episode of care. On August 23, 2011, CMS invited providers to apply to help develop and test four models of bundling payments under the BPCI. We refer readers to section IV.H.4. of the preamble of this final rule for a discussion on the BPCI initiative. We note that under Models 1, 2, and 4, participating IPPS hospitals could receive a payment for all or selected IPPS claims under the BPCI that differs from payments they would otherwise receive under the IPPS. We also note that Model 3 addresses payments for related readmissions and postacute care services. Therefore, we believe it is not necessary to address the treatment of any data for participating hospitals in Model 3.

In the proposed rule, for purposes of computing the budget neutrality calculations to determine the average standardized amount, we proposed to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS-DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis). In essence, we would continue to treat these hospitals the same as in prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these three bundled payment models (that is, we would treat these hospitals as if they are not participating in Model 1, Model 2, or Model 4 under the BPCI initiative). We stated that we believe it is appropriate to include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act (in addition to the reconciliation payment the hospital may receive under Model 2 of the BPCI initiative). Moreover, the Secretary has the authority to make appropriate adjustments for payment amounts under section 1886(d)(5)(I)(i) of the Act to include all applicable data from these "subsection

(d)" hospitals in our IPPS ratesetting calculations. We further stated that we believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS short-term acute care hospitals and their data within the IPPS ratesetting calculations because excluding these hospitals would diminish the number of providers used to determine the IPPS rates, which could cause fluctuations to the IPPS rates and could produce instability in the IPPS rates. We did not receive any public comments on this proposal and, therefore, we are finalizing our proposal as presented in the FY 2013 IPPS proposed rule (77 FR 28138 through 28139) and summarized above without modification. Specifically, we are adopting as final our methodology to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS-DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis).

The Affordable Care Act established the Hospital Readmissions Reduction Program and the Hospital Value-Based Purchasing (VBP) Program which adjust payments to certain IPPS hospitals beginning with discharges on or after October 1, 2012. Because the adjustments made under these programs affect the estimation of aggregate IPPS payments, in the proposed rule we stated that we believe it is appropriate to include adjustments for these programs within our budget neutrality calculations. We discuss the treatment of these two programs in the context of budget neutrality adjustments below.

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new subsection (q) to section 1886 of the Act. Section 1886(q) of the Act establishes the "Hospital Readmissions Reduction Program" effective for discharges from an "applicable hospital" beginning on or after October 1, 2012, under which payments to

those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Under the Hospital Readmissions Reduction Program under section 1886(q) of the Act, payments for discharges from an "applicable hospital" will be in an amount equal to the product of the "base operating DRG payment amount" and an "adjustment factor" that accounts for excess readmissions for the hospital for the fiscal year, for discharges beginning on October 1, 2012. (The statute also specifies that any applicable add-on payments for IME, DSH, outliers and low-volume hospitals provided for under sections 1886(d)(5)(A), (d)(5)(B), (d)(5)(F), and (d)(12) of the Act, respectively, are not affected by the adjustment for excess readmissions under the Hospital Readmissions Reduction Program.) In other words, payment under section 1886(q) is the base operating DRG payment amount multiplied by the adjustment factor, calculated separately from any outliers, IME, DSH, or low-volume payment adjustment the hospital may otherwise receive. We refer readers to section IV.A. of the preamble of this final rule for full details of our implementation of the Hospital Readmissions Reduction Program for FY 2013, including definitions of the "base operating DRG payment amount." Under current law, the Hospital Readmissions Reduction Program under section 1886(q) of the Act is not budget neutral.

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program under which, beginning in FY 2013, value-based incentive payments will be made in a fiscal year to eligible subsection (d) hospitals that meet performance standards established for a performance period for that fiscal year. As specified under section 1886(o)(7)(B)(i) of the Act, the cost of these value-based incentive payments are funded by a reduction applied to each eligible hospital's base-operating DRG payment amount, for each discharge occurring in the fiscal year, beginning with FY 2013. For FY 2013, the reduction

amount is equal to 1.00 percent. As required by section 1886(o)(7)(A) of the Act, the total amount of allocated funds available for value-based incentive payments with respect to a fiscal year is equal to the total amount of estimated base-operating DRG payment reductions (the applicable percent reduction for FY 2013 is 1.0), as estimated by the Secretary. We refer readers to section VIII.C. of the preamble of this final rule for details regarding our implementation of the Hospital VBP Program, including the definition of the "base operating DRG payment amount."

Unlike the Hospital Readmissions Reduction Program (where an adjustment factor is applied to reduce the base-operating DRG payment amount for excess readmissions), the Hospital VBP Program is estimated to have no effect on overall payments. As mentioned above, for FY 2013, the total amount of the funding pool for value-based incentive payments is estimated to equal the total amount of the eligible hospitals' base-operating DRG payment amount reductions. In other words, the funding pool that CMS sets aside for the Hospital VBP Program is then equally redistributed by applying the hospital VBP adjustment. However, both the hospital readmissions payment adjustment (reduction) and the hospital VBP adjustment (redistribution) are applied on a claim by claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations. For example, when we calculate the budget neutrality factor for MS-DRG reclassification and recalibration of the relative weights, we compare aggregate payments estimated using the prior year's GROUPER and relative weights to estimated payments using the new GROUPER and relative weights. (We refer readers to section II.4.a. of this Addendum for full details.) Other factors, such as the DSH and IME payment adjustments, are the same on both

sides of the comparison because we are only seeking to ensure that aggregate payments do not increase or decrease as a result of the changes of MS-DRG reclassification and recalibration. In order to properly sum aggregate payments on each side of the comparison, we proposed to apply the hospital readmissions payment adjustment and the hospital VBP adjustment on each side of the comparison. We did not receive any public comments on this proposal. Therefore, to assure that aggregate payments are estimated correctly in light of the effects of the Hospital Readmissions Reduction Program and the Hospital VBP Program, we are finalizing our proposal as presented in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28138 through 28139) without modification, and are applying the readmissions payment adjustment and the Hospital VBP payment adjustment on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the proposed rule, for the purpose of modeling the aggregate payments for excess readmissions and the readmissions adjustment factors, we used excess readmission ratios for the applicable hospitals from the 3-year period of July 1, 2007, to June 30, 2010 (the 3-year period preceding the FY 2013 "applicable period" of July 1, 2008, to June 30, 2011, that was finalized in last year's rulemaking (76 FR 51671 through 51672), because the underlying data from this period had already been made available to the public on the Hospital Compare Web site (as of July 2011). At that time, the data from the 3-year applicable period of July 1, 2008, to June 30, 2011, for FY 2013 had not been through the review and correction process required by section 1886(q)(6) of the Act. As we indicated in the proposed rule, for this final rule, we are using excess readmission ratios based on admissions for the finalized applicable period of July 1, 2008, to June 30, 2011, to calculate the aggregate payments for excess readmissions and ultimately to calculate the readmissions payment adjustment factors for FY 2013, because

applicable hospitals have had the opportunity to review and correct these data before the data were made public under our proposal set forth in the proposed rule regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act (as discussed in section IV.A.3.d. of the preamble of this final rule).

a. Recalibration of MS-DRG Relative Weights and Updated Wage Index--Budget Neutrality Adjustment

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.H. of the preamble of this final rule, we normalized the recalibrated MS-DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage

index less than or equal to 1.0, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indices less than or equal to 1.0 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2013, we are adjusting 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.F. of the preamble of this final rule.

For FY 2013, to comply with the requirement that MS-DRG reclassification and recalibration of the relative weights be budget neutral for the Puerto Rico standardized amount and the hospital-specific rates, we used FY 2011 discharge data to simulate payments and compared aggregate payments using the FY 2012 labor-related share percentages, the FY 2012 relative weights, and the FY 2012 pre-reclassified wage data and applied the FY 2013 hospital readmissions payment adjustments and estimated FY 2013 hospital VBP payment adjustments to aggregate payments using the FY 2012 labor-related share percentages, the FY 2013 relative weights, and the FY 2012 pre-reclassified wage data and applied the same hospital readmissions payment adjustments and estimated hospital VBP adjustments. Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.998431. As discussed in section IV. of this Addendum, we also are applying the MS-DRG reclassification and recalibration budget

neutrality factor of 0.998431 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2012.

In order to meet the statutory requirements that we do not take into account the labor-related share of 62 percent when computing wage index budget neutrality, it was necessary to use a three-step process to comply with the requirements that MS-DRG reclassification and recalibration of the relative weights and the updated wage index and labor-related share have no effect on aggregate payments for IPPS hospitals. We first determined an MS- DRG reclassification and recalibration budget neutrality factor of 0.998431 (by using the same methodology described above to determine the MS-DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates). Secondly, to compute a budget neutrality factor for wage index and labor-related share changes, we used FY 2011 discharge data to simulate payments and compared aggregate payments using FY 2013 relative weights and FY 2012 pre-reclassified wage indices, applied the FY 2012 labor-related share of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) and applied the FY 2013 hospital readmissions payment adjustment and the FY 2013 estimated hospital VBP payment adjustment when estimating aggregate payments using the FY 2013 relative weights and the FY 2013 pre-reclassified wage indices, applied the labor-related share for FY 2013 of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0), and applied the same FY 2013 hospital readmissions payment adjustments and estimated FY 2013 hospital VBP payment adjustments. In addition, we applied the MS-DRG reclassification and recalibration budget neutrality factor (derived in the first step) to the rates that were used to simulate payments for this comparison of aggregate payments from FY 2012 to FY 2013. By applying this methodology, we determined a

budget neutrality factor of 1.000331 for changes to the wage index. Finally, we multiplied the MS-DRG reclassification and recalibration budget neutrality factor of 0.998431(derived in the first step) by the budget neutrality factor of 1.000331 for changes to the wage index (derived in the second step) to determine the MS-DRG reclassification and recalibration and updated wage index budget neutrality factor of 0.998761.

b. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that, effective with discharges occurring on or after October 1, 1988, certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account "in applying any budget neutrality adjustment with respect to such index" under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality factor for FY 2013, we used FY 2011 discharge data to simulate payments and compared total IPPS payments with FY 2013 relative weights, FY 2013 labor-related share percentages, and FY 2013 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act and applied the FY 2013 hospital readmissions payment

adjustments and the estimated FY 2013 hospital VBP payment adjustments to total IPPS payments with FY 2013 relative weights, FY 2013 labor-related share percentages, and FY 2013 wage data after such reclassifications and applied the same hospital readmissions payment adjustments and the estimated hospital VBP payment adjustments. Based on these simulations, we calculated an adjustment factor of 0.991276 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The FY 2013 budget neutrality adjustment factor is applied to the standardized amount after removing the effects of the FY 2012 budget neutrality adjustment factor. We note that, the FY 2013 budget neutrality adjustment reflects FY 2013 wage index reclassifications approved by the MGCRB or the Administrator.

c. Rural Floor and Imputed Floor Budget Neutrality Adjustment

As noted above, as discussed in section III.G. 2.b. of the preamble of this final rule, in the FY 2012 IPPS/LTCH PPS final rule, we extended the imputed floor through FY 2013. We make an adjustment to the wage index to ensure that aggregate payments to hospitals after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105-33) and the imputed floor under § 412.64(h)(4) of the regulations are not affected. In addition, we note in section III.G.2.b. of the preamble of this final rule, we are finalizing our proposal to use an alternative temporary methodology for computing the imputed floor index. In the proposed rule, we did not apply this alternative in our calculation of the proposed uniform, national rural floor budget neutrality adjustment to the wage indices because the projected impact of that proposal was estimated at less than $5 million and, therefore, would have a negligible impact on the adjustment. For this final rule, consistent with our methodology for treating the imputed floor, we have included this alternative methodology for computing the imputed floor index in the

calculation of the uniform, national rural floor budget neutrality adjustment in this final rule. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this final rule, the budget neutrality adjustment for the rural and imputed floors is a national adjustment to the wage index.

Since FY 2012, there has been one hospital in rural Puerto Rico. Therefore, similar to our calculation in the FY 2012 IPPS/LTCH final rule (76 FR 51593), for FY 2013, we are calculating a national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals located in Puerto Rico which receive 75 percent of the national standardized amount) and a rural Puerto Rico-specific wage index (which is used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals located in Puerto Rico that receive 25 percent of the Puerto Rico-specific standardized amount). Because this rural Puerto Rico hospital still has no established wage data, our calculation is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). A complete discussion regarding the computation of the rural Puerto Rico wage index can be found in the FY 2012 IPPS/LTCH PPS final rule.

To calculate the national rural floor and imputed floor budget neutrality adjustment factor and Puerto Rico-specific rural floor budget neutrality adjustment factor, we used FY 2011 discharge data and FY 2013 post-reclassified national and Puerto Rico-specific wage indices to simulate IPPS payments. First, we compared the national and Puerto Rico-specific simulated payments without the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to the national and Puerto Rico-specific simulated payments with the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to determine the national rural budget neutrality adjustment factor of 0.991340 and the Puerto Rico-specific budget neutrality

adjustment factor of 0.987620. The national adjustment is applied to the national wage indices to produce a national rural floor budget neutral wage index and the Puerto Rico-specific adjustment is applied to the Puerto Rico-specific wage indices to produce a Puerto Rico-specific rural floor budget neutral wage index.

d. Case-Mix Budget Neutrality Adjustment

Below we summarize the adjustments to the FY 2013 payment rates to account for the effect of changes in documentation and coding that do not reflect real changes in case-mix. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our proposals and final policies (including our historical adjustments to the payment rates) to eliminate the estimated effect of changes in documentation and coding that do not reflect real changes in case-mix.

(1) Prospective Adjustments for Documentation and Coding in FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Pub. L. 110-90 and Section 1886(d)(3)(A)(vi) of the Act

Section 7(b)(1)(A) of Pub. L. 110-90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Pub. L. 110-90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes.

For FY 2013, as proposed, we are finalizing a -1.9 percent adjustment to the standardized amount to complete the adjustment required under section 7(b)(1)(A) of Pub. L. 110-90. We

refer readers to section II.D. of the preamble of this final rule for a complete discussion on our historical adjustments and the FY 2013 adjustment to the standardized amount pursuant to section 7(b)(1)(A) of Pub. L. 110-90.

(2) Prospective Adjustments for Documentation and Coding in FY 2010 Authorized by Section 1886(d)(3)(A)(vi) of the Act

Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts if the Secretary determines such adjustments to be necessary for any subsequent fiscal years in order to eliminate the effect of coding or classification changes that do not reflect real changes in case mix. After reviewing public comments and recommendations received from MedPAC, we analyzed claims data in FY 2010 to determine whether any additional adjustment would be required to ensure that the introduction of MS-DRGs was implemented in a budget neutral manner. As discussed in section II.D. of the preamble of this final rule, our analysis showed a documentation and coding effect in FY 2010 of 0.8 percent, and we proposed to make an additional -0.8 percent adjustment to account for the effects of documentation and coding that did not reflect an increase in case-mix severity in FY 2010.

As discussed earlier in this preamble, we are not finalizing an additional -0.8 percent adjustment to the FY 2013 standardized amount to account for documentation and coding that did not reflect an actual increase in case-mix in FY 2010. (However, as discussed above, we still are making an adjustment of -1.9 percent to the standardized amount, accounting for all documentation and coding effects observed between FY 2008 though FY 2009.)

(3) Recoupment or Repayment Adjustment for Documentation and Coding in FY 2008 and FY 2009 Authorized by Section 7(b)(1)(B) of Pub. L. 110-90

Section 7(b)(1)(B) of Pub. L. 110-90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Pub. L. 110-90. This determination must be based on a retrospective evaluation of claims data. As discussed in section II.D.5. of the preamble of this final rule, we determined that an aggregate adjustment of -5.8 percent in FYs 2011 and 2012 would be necessary in order to meet these statutory requirements.

In the FY 2011 IPPS/LTCH PPS final rule, for FY 2011, we made an adjustment to the standardized amount of -2.9 percent, representing approximately half of the required adjustment. For FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Pub. L. 110-90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining -2.9 percent adjustment, in addition to removing the effect of the -2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Therefore, the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009 has been completed within the required statutory timeframes. However, to avoid continuing the -2.9 percent adjustment finalized in FY 2012, for FY 2013, we are finalizing the +2.9 percent adjustment to the standardized amount as we proposed. This adjustment removes the one-time -2.9 percent adjustment implemented in FY 2012.

(4) Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

As discussed in section II.D.9. of the preamble of this final rule, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we

applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate, based on the then most recently available data (FY 2009 claims paid through March 2010), was that for documentation and coding changes that occurred over FY 2008 and FY 2009, a cumulative adjustment of -2.6 percent was required to eliminate the full effect of the documentation and coding changes on future payments based on the Puerto Rico-specific standardized amount. In FY 2011, as finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), we applied an adjustment of -2.6 percent to the Puerto Rico-specific standardized amount. Therefore, because the Puerto Rico-specific standardized amount received a full prospective adjustment of -2.6 percent in FY 2011, in section II.D.9. of the preamble of this final rule, as we proposed, we are not making any further adjustment for FY 2013. For a complete discussion on our policy, we refer readers to section II.D.9. of the preamble of this final rule.

We note that, based upon our analysis of FY 2010 claims data; we found no significant additional effect of documentation and coding that would warrant any additional adjustment to the Puerto Rico-specific standardized amount.

e. Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.K. of the preamble to this final rule, section 410A of Pub. L. 108-173 originally required the Secretary to establish a demonstration program that modifies reimbursement for inpatient services for up to 15 small rural hospitals. Section 410A(c)(2) of Pub. L. 108-173 requires that "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented."

Sections 3123 and 10313 of the Affordable Care Act extended the demonstration program for an additional 5-year period, and allowed up to 30 hospitals to participate in 20 States with low population densities determined by the Secretary. (In determining which States to include in the expansion, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period.) In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51700 through 51705), in order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration program as described in section IV.K. of that final rule. In other words, we applied budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration program , consistent with past practice. We stated that we believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration…was not implemented," but does not identify the range across which aggregate payments must be held equal.

For FY 2013, for the 23 hospitals participating in the demonstration program, we are adjusting the national IPPS payment rates according to the methodology set forth elsewhere in this final rule. For this final rule, the estimated amount for the adjustment to the national IPPS payment rates for FY 2013 is $34, 288,129. (For the proposed rule, the estimated amount for the adjustment to the national IPPS payment rates for FY 2013 was $35,077,708.) Accordingly, to account for the estimated costs of the demonstration program for the specific time periods as explained in detail in section IV.K. of the preamble of this final rule, for FY 2013, we computed

a factor of 0.999677 for the rural community hospital demonstration program budget neutrality adjustment that will be applied to the IPPS standard Federal payment rate.

In the proposed rule, we stated that if updated data became available prior to the publication of the FY 2013 IPPS/LTCH PPS final rule, we would use that data, to the extent appropriate, to estimate the costs of the demonstration program in FY 2013. Therefore, this estimated budget neutrality offset amount in this final rule reflects updated data.

In addition, we proposed in the proposed rule that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (2007, 2008, 2009, or 2010) were made available prior to this FY 2013 IPPS/LTCH PPS final rule, we would incorporate into the FY 2013 budget neutrality offset amount the difference between the final cost of the demonstration in any of these years (as described previously) and the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. Because settled cost reports are not available for these years, we are not incorporating into the FY 2013 budget neutrality offset amount the difference between the final cost of the demonstration in any of these years and the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. We expect that the settled cost reports will be available prior to the FY 2014 IPPS /LTCH PPS proposed rule, and that we will be able to propose to make this adjustment at the appropriate time.

f. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for "outlier" cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the "outlier

threshold" or "fixed-loss" amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the outlier threshold as the outlier "fixed-loss cost threshold." To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2013 is 80 percent, the same marginal cost factor we have used since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amount applicable to hospitals located in Puerto Rico to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS Web site at: http://www.cms.hhs.gov/Medicare/Medicare-

Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=AcuteInpatientPPS/04_outlier.asp#TopOfPage.

(1) FY 2013 Outlier Fixed-Loss Cost Threshold

For FY 2013, we proposed to continue to use the same methodology that we first used for FY 2009 (73 FR 48763 through 48766) to calculate the outlier threshold. Similar to the methodology used in the FY 2009 IPPS final rule, for FY 2013, we proposed to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). As we have done in the past, to calculate the proposed FY 2013 outlier threshold, we simulated payments by applying proposed FY 2013 payment rates and policies using cases from the FY 2011 MedPAR file. Therefore, in order to determine the proposed FY 2013 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2011 to FY 2013.

We also proposed to continue to use a refined methodology that takes into account the lower inflation in hospital charges that are occurring as a result of the outlier final rule (68 FR 34494), which changed our methodology for determining outlier payments by implementing the use of more current CCRs. Our refined methodology uses more recent data that reflect the rate-of-change in hospital charges under the new outlier policy.

Using the most recent data available, we calculated the 1-year average annualized rate-of-change in charges per case from the last quarter of FY 2010 in combination with the first quarter of FY 2011 (July 1, 2010, through December 31, 2010) to the last quarter of FY 2011 in combination with the first quarter of FY 2012 (July 1, 2011, through December 31, 2011). This rate-of-change was 6.8 percent (1.068003) or 14.06 percent (1.140630) over 2 years. As we have done in the past, we established the proposed FY 2013 outlier threshold using hospital CCRs

from the December 2011 update to the Provider-Specific File (PSF)--the most recent available data at the time of the proposed rule.

As discussed in the FY 2007 IPPS final rule (71 FR 48150), we worked with the Office of Actuary to derive the methodology described below to develop the CCR adjustment factor. For FY 2013, we proposed to continue to use the same methodology to calculate the CCR adjustment by using the FY 2011 operating cost per discharge increase in combination with the actual FY 2011 operating market basket percentage increase determined by IHS Global Insight, Inc. (IGI), as well as the charge inflation factor described above to estimate the adjustment to the CCRs. (We note that, the FY 2011 actual (otherwise referred to as "final") operating market basket percentage increase reflects historical data, whereas the published FY 2011 operating market basket update factor was based on IGI's 2010 second quarter forecast with historical data through the first quarter of 2010. We also note that, while the FY 2011 published operating market basket update was based on the FY 2002-based IPPS market basket, the actual or "final" market basket percentage increase is based on the FY 2006-based IPPS market basket. Similarly, the FY 2011 published capital market basket update factor was based on the FY 2002-based capital market basket and the actual or "final" capital market basket percentage increase is based on the FY 2006-based capital market basket.) By using the operating market basket percentage increase and the increase in the average cost per discharge from hospital cost reports, we are using two different measures of cost inflation.

Under our proposal to continue to use the same methodology to calculate the CCR adjustment for FY 2013, we determined the proposed adjustment by taking the percentage increase in the operating costs per discharge from FY 2009 to FY 2010 (1.0160) from the cost report and dividing it by the final operating market basket percentage increase from FY 2010

(1.0210). This operation removes the measure of pure price increase (the market basket) from the percentage increase in operating cost per discharge, leaving the nonprice factors in the cost increase (for example, quantity and changes in the mix of goods and services). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the operating market basket percentage increase and the increase in cost per case from the cost report (the FY 2007 to FY 2008 percentage increase of operating costs per discharge of 1.0505 divided by the FY 2008 final operating market basket percentage increase of 1.0400, and the FY 2008 to FY 2009 percentage increase of operating costs per discharge of 1.0295 divided by the FY 2009 final operating market basket percentage increase of 1.0260). For FY 2013, we averaged the differentials calculated for FY 2008, FY 2009, and FY 2010, which resulted in a mean ratio of 1.0029. We multiplied the 3-year average of 1.0029 by the FY 2011 final operating market basket percentage increase of 1.0270, which resulted in an operating cost inflation factor of 2.99 percent or 1.029948. We then divided the operating cost inflation factor by the 1-year average change in charges (1.068003) and we proposed to apply an adjustment factor of 0.964368 to the operating CCRs from the PSF (calculation performed on unrounded numbers).

As stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a fiscal intermediary or MAC to tentatively settle a cost report from the fiscal year end of a hospital's cost reporting period. The average "age" of hospitals' CCRs from the time the fiscal intermediary or the MAC inserts the CCR in the PSF until the beginning of FY 2009 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

We used the same methodology for the capital CCRs and determined the proposed adjustment by taking the percentage increase in the capital costs per discharge from FY 2009 to FY 2010 (1.0102) from the cost report and dividing it by the final capital market basket percentage increase from FY 2010 (1.010). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the capital market basket percentage increase and the increase in cost per case from the cost report (the FY 2007 to FY 2008 percentage increase of capital costs per discharge of 1.0809 divided by the FY 2008 final capital market basket percentage increase of 1.0150, and the FY 2008 to FY 2009 percentage increase of capital costs per discharge of 1.0499 divided by the FY 2009 final capital market basket percentage increase of 1.0150). For FY 2013, we averaged the differentials calculated for FY 2008, FY 2009, and FY 2010, which resulted in a mean ratio of 1.0332. We multiplied the 3-year average of 1.0332 by the FY 2011 final capital market basket percentage increase of 1.0120, which resulted in a capital cost inflation factor of 4.56 percent or 1.045567. We then divided the capital cost inflation factor by the 1-year average change in charges (1.068003) and we proposed to apply an adjustment factor of 0.978993 to the capital CCRs from the PSF (calculation performed on unrounded numbers). We proposed to use the same charge inflation factor for the capital CCRs that was used for the operating CCRs. The charge inflation factor is based on the overall billed charges. Therefore, we believe it is appropriate to apply the charge factor to both the operating and capital CCRs.

As stated above, for FY 2013, we applied the proposed FY 2013 rates and policies using cases from the FY 2011 MedPAR files in calculating the proposed outlier threshold.

As discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.G.3. of the preamble of this final rule, in

accordance with section 10324(a) of the Affordable Care Act, beginning in FY 2011, we created a wage index floor of 1.00 for all hospitals located in States determined to be frontier States. We noted that the frontier State floor adjustments will be calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State will receive a wage index lesser than 1.00 due to the rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2013, it was necessary to apply this provision by adjusting the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2013. If we did not take into account this provision, our estimate of total FY 2013 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

In the proposed rule, we stated that our estimate of the cumulative effect of changes in documentation and coding due to the adoption of the MS-DRGs of 5.4 percent from FY 2008 and FY 2009 and 0.8 percent from FY 2010 is already included within the claims data (FY 2011 MedPAR files) used to calculate the proposed FY 2013 outlier threshold. We also stated in the proposed rule that we estimated that there would be no continued changes in documentation and coding in FYs 2011 and 2012. Therefore, the cumulative effect of documentation and coding that has occurred is already reflected within the FY 2011 MedPAR claims data, and we did not believe there was any need to inflate FY 2011 claims data for any additional case-mix growth projected to have occurred since FY 2010.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2013 outlier payments, we did not propose to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We indicated that we continue to believe that, due to the policy implemented in the June 9, 2003 outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also noted that reconciliation occurs because hospitals' actual CCRs for the cost reporting period are different than the interim CCRs used to calculate outlier payments when a bill is processed. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we proposed not to make any assumptions about the effects of reconciliation on the outlier threshold calculation.

As described in sections IV.A. and VIII.B., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. As we discussed in the proposed rule, we do not believe it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our proposed definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under proposed § 412.152 and the Hospital VBP Program under proposed § 412.160, we indicated that outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG

payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP adjustment). Consequently, we proposed to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

Using this methodology, we proposed an outlier fixed-loss cost threshold for FY 2013 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $27,425.

We note that on June 11, 2012, we published a correction notice to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 34326 through 34331). In that correction notice, we stated that we inadvertently applied the incorrect adjustment factors to the operating and capital cost-to-charge ratios (CCRs) from the PSF when performing the calculation of the proposed FY 2013 outlier fixed-loss cost threshold for the proposed rule. The correction of this error resulted in a decrease in the proposed outlier fixed-loss cost threshold of approximately $1,000, which resulted in a corrected proposed FY 2013 outlier fixed-loss cost threshold of $26,337.

We also noted in that correction notice that the corrected proposed FY 2013 outlier fixed-loss cost threshold represented a $3,952 (or 17.7 percent) increase from the final FY 2012 outlier fixed-loss cost threshold of $22,385. Since FY 2009, the outlier fixed-loss cost threshold has been between $20,185 and $23,140. Therefore, we were concerned about this large increase in the outlier fixed-loss cost threshold from FY 2012.

In the proposed rule, we further noted that the proposed 2-year charge inflation factor of 14.06 percent applied to the FY 2011 MedPAR claims used to compute the FY 2013 outlier fixed-loss cost threshold is higher than the 2-year charge inflation factor of 7.94 percent applied to the FY 2010 MedPAR claims used to compute the FY 2012 final outlier fixed-loss cost

threshold. We stated that we believe that a large increase in the charge inflation factor for FY 2013 (from FY 2012) increased projected total outlier payments. With an increase in projected outlier payments, in order for CMS to meet the 5.1 percent target, it would be necessary to reduce the amount of outlier payments by raising the outlier fixed-loss cost threshold. Therefore, in addition to being concerned about the large increase in the fixed-loss threshold proposed for FY 2013 compared to FY 2012, we were concerned about this large charge inflation increase and how it potentially affected the proposed FY 2013 outlier fixed-loss cost threshold. As described above, to determine the 1-year average annualized rate-of-change in charges per case, we currently use a methodology that compares the average charge per case from the most recent 6-month period of MedPAR data that are available to the same 6-month period of MedPAR data from the prior year. We adopted this methodology in the FY 2005 IPPS final rule (69 FR 49277) as a result of the special circumstances surrounding the revisions to the outlier payment methodology at that time. In that rule, we stated that we would continue to consider other methodologies for determining charge inflation when calculating the outlier threshold in the future. We welcomed public comment on possible modifications to our current methodologies, including the possibility of looking at a larger time period beyond 6 months to determine the average charge per case to measure the charge inflation factor.

In addition, as pointed out by commenters who responded to the policies presented in last year's final rule (76 FR 51793 through 51795), in this year's proposed rule we noted that CMS has not met the 5.1 percent target for some time and the commenters have recommended enhancements to the methodology to improve the calculation of the outlier fixed-loss cost threshold. Commenters have focused on CMS' underestimation of actual outlier payments. Since FY 2009, we have used the same methodology to calculate the outlier fixed-loss cost

threshold. While we have been reluctant to make changes to our methodology, as discussed below, our proposed estimate for FY 2011 was that outlier payments would be approximately 4.7 percent of actual total MS-DRG payments and for FY 2012 outlier payments would be approximately 6.0 percent of actual total MS-DRG payments (we have revised both of these estimates for the final rule using the latest data available as discussed below). In the proposed rule, we stated that while these estimates differ--with one being under the target and one above the target--they draw attention to the potential for improving our estimation methodology so that we meet the 5.1 percent target. We welcomed public comment on ways to enhance the accuracy of our methodology to calculate the FY 2013 outlier fixed-loss cost threshold, especially additional analyses that could inform potential technical improvements.

Comment: Commenters analyzed the CCRs used in the proposed rule to calculate the outlier fixed-loss cost threshold and found that CMS used outdated CCRs for the proposed rule. The commenters attempted to match the CCRs from the proposed rule impact file to the CCRs in the March 2012 PSF update with an effective date prior to January 15, 2012, and found that the CCRs in the impact file matched the CCRs in the March 2012 PSF update for only 200 providers. The commenter used CMS' methodology to calculate the outlier fixed-loss cost threshold and determined that the proposed outlier fixed-loss cost threshold should have been $23,780 for FY 2013.

Response: We appreciate the commenters pointing out this error. After further research, we discovered that we inadvertently removed all CCRs from the December 2011 PSF update that had an effective date after December 2010. Therefore, we used "outdated" CCRs to calculate the proposed outlier fixed-loss cost threshold. After this error was brought to our attention, we calculated the proposed outlier fixed-loss cost threshold with the "best available"

CCRs. Specifically, we used operating and capital CCRs from the latest effective date in the December 2011 update of the PSF and determined that the proposed outlier fixed-loss cost threshold for FY 2013 should have been $23,630.

Comment: Many commenters expressed concern that CMS is still not reaching the 5.1 percent target for outlier payments and believed there is still room for improvement. The commenters made various suggestions to improve the current methodology used to calculate the outlier threshold.

Several commenters suggested three alternative methodologies (discussed below) to adjust the CCRs, while other commenters only recommended the first and third options listed below. The commenters that suggested the three methodologies stated that they believed that a 1-year CCR adjustment is not appropriate since hospitals have different fiscal year ends and, therefore, different adjustments should be applied to the CCRs.

The first methodology the commenters recommended was for CMS to project CCRs over periods of time based on variations in hospital cost reporting fiscal year ends rather than 1 year in order to better reflect the CCRs as they are expected to exist during FY 2013 (we received similar comments in response to the policies presented in last year's rule recommending the adoption of this methodology to adjust the CCRs (75 FR 51793)). Using this methodology to adjust the CCRs, the commenters determined an outlier fixed-loss cost threshold for FY 2013 of $23,190.

The second methodology suggested by commenters was similar to the first methodology but projected CCRs by quarter rather than using hospital cost reporting fiscal year ends. For example, commenters suggested that CCRs in the PSF from June 2011 through September 2011 be projected 2 years from June 2013 through September 2013. Using this

methodology to adjust the CCRs, the commenters determined an outlier fixed-loss cost threshold for FY 2013 of $23,195.

The third methodology recommended by commenters used historical CCR data from the PSF to compute a rate-of-change in CCRs. Under this approach, the average case-weighted operating and capital CCR from October 2010 was compared to the average case-weighted operating and capital CCR from October 2011, and determined a -2.73 percent reduction for the operating CCRs and a -2.25 percent reduction for the capital CCRs. Although this adjustment would still be based on 1 year's data, the commenters believed that the use of historical data to adjust the CCRs is consistent with CMS' estimation of charge inflation.

Similar to comments received in response to the policies presented last year (76 FR 51793 through 51794), one commenter suggested that, if CMS did not incorporate the changes described above to its methodology for estimating outlier payments, it would recommend incorporating an "estimate adjustment factor" into the outlier projections. This commenter explained that outlier payments have been underpaid in every year since FY 2003. Based on estimated actual payments determined by the commenter's data analysis, the commenter asserted that the underpayment has exceeded 0.5 percent in all years since FY 2003. The commenter recommended that CMS determine an outlier fixed-loss cost threshold that would maintain the 5.1 percent target by applying an "estimate adjustment factor" when determining the outlier fixed-loss cost threshold. The commenter provided an example by taking the average variance of 0.68 percentage point in the actual payment from FY 2009 and FY 2011. Based on this factor, CMS would model the threshold to a level of 5.78 percent (5.1 percent plus 0.68 percent). If CMS were to estimate that it made outlier payments in excess of the 5.1 percent target, then the "estimate adjustment factor" would be negative. The commenter stated that this would fulfill the

statutory requirement under section 1886(d)(5)(A) of the Act that requires CMS to establish thresholds such that outlier payments will be projected to achieve at least 5.1 percent of DRG payments and would more closely achieve a result that is fully consistent with the statute.

Some commenters noted that some hospitals are at a financial disadvantage compared to others and outliers should not be among the reasons of this disadvantage. The commenters recommended that CMS lower the threshold, thereby increasing the chance that CMS will pay within the congressionally mandated target range of 5 to 6 percent. Another commenter, from a society representing transplant surgeons, applauded CMS' recognition and concern for the large increase in the outlier threshold. The commenter was concerned that the large increase in the outlier fixed-loss cost threshold may affect the reimbursement for transplant cases because these cases are typically high in costs and, therefore, reach outlier payment status. The commenter requested that CMS study the rapid rise in the outlier fixed-loss cost threshold while assuring stability in the outlier fixed-loss cost threshold and authorizing appropriate additional payment to transplant centers facing extraordinarily resource-intensive cases. Other commenters recommended that CMS maintain the outlier fixed-loss cost threshold from FY 2012 for FY 2013 until CMS develops a more reliable methodology for determining the outlier fixed-loss cost threshold.

Response: We appreciate the commenters providing multiple alternative methodologies to adjust the CCRs used in our outlier fixed-loss cost threshold. Due to the many options the commenters presented, we believe the most prudent approach is to study the merits of each methodology and, if appropriate, make a proposal in next year's proposed rule if we believe making a change to our current methodology would improve our methodology for projecting the outlier fixed-loss cost threshold. As we have stated in prior years, using our current

methodology, it is possible that some of the CCRs in the March 2012 PSF will be used in FY 2013 for actual outlier payments, while other CCRs may be 1 year old. Therefore, we apply a 1-year adjustment to the CCRs. The adjusted CCR is applied throughout the fiscal year within the outlier model. For this final rule, we are continuing to use the methodology we have used since FY 2009 to adjust the CCRs used to determine the outlier fixed-loss cost threshold. However, as stated above, we intend to study the merits of the commenters' suggestions for future rulemaking.

With regard to the comment that CMS implement an "estimate adjustment factor", as we stated last year, further analysis by CMS is necessary to determine if the commenter's approach to applying such a factor is appropriate. We will consider the commenter's suggestion to apply an "estimate adjustment factor" (in conjunction with analyzing the alternative methodologies to adjust the CCRs discussed above), for future rulemaking if, based on our analysis, we determine that application of an "estimate adjustment factor" is appropriate and consistent with the statute.

Also, as noted above, section 1886(d)(5)(A)(iv) of the Act requires outlier payments to be not less than 5 percent nor more than 6 percent of total estimated or projected payments. Therefore, we cannot adopt the commenter's suggestion to maintain the FY 2012 outlier fixed-loss cost threshold for FY 2013 because setting a threshold that is based on the current fiscal year for the coming fiscal year is inconsistent with the statute.

Comment: Commenters noted that from FYs 2007 through 2011, in each rulemaking cycle the final threshold is always significantly lower than the proposed threshold. The commenters believed this decline is most likely the result of using more recently updated CCRs

in the calculations for the final rule. The commenter emphasized the need for CMS to use the most recent data available when it calculates the outlier fixed-loss cost threshold.

One commenter recommended that CMS use the June 2012 PSF update instead of the March 2012 update to the PSF to calculate the outlier fixed-loss cost threshold for the final rule. The commenter explained that there was a delay in hospitals filing the form CMS 2552-10 cost reports and the March 2012 update to the PSF does not contain CCRs from these cost reports. The commenter stated that the June 2012 PSF is probably the first update that would contain updated CCRs from the CMS 2552-10 cost reports.

Response: CMS' historical policy is to use the best available data when setting the payment rates and factors in both the proposed and final rules. Sometimes there are variables that change between the proposed and final rule due to the availability of more recent data, such as the charge inflation factor and the CCR adjustment factors that can cause fluctuations in the threshold amount. Other factors such as changes to the wage indexes and market basket increase can also cause the outlier fixed-loss cost threshold to fluctuate between the proposed and final rule each year. CMS uses the latest data that is available at the time of the proposed and final rule, such as the most recent update of MedPAR claims data and CCRs from the most recent update of the PSF.

With regard to the commenters recommendation to use the June 2012 PSF update, this file was not available in time for the FY 2013 final rule and, therefore, we used the latest data available, which was the March 2012 PSF update.

Comment: One commenter was concerned that CMS did not include outlier reconciliations in developing the outlier fixed-loss cost threshold, and its failure to provide objective data concerning the number of hospitals that have been subjected to reconciliation and

the amount recovered during this process. The commenter searched Worksheet E, Part A, line 24.99 and line 52 and provided a summary table of operating outlier dollars (total of $82,080,928) recovered through the reconciliation process. The commenter concluded that absent the disclosure of data showing that these recoveries were immaterial, the commenter requested that CMS consider these recoveries in its determination of the outlier fixed-loss cost threshold.

Response: We received a similar comment in response to the policies presented in last year's rule, and we appreciate the commenter, again, informing us of its concern regarding our policy of not including outlier reconciliation within the development of the outlier fixed-loss cost threshold. However, as stated above, we continue to believe that, due to the policy implemented in the June 9, 2003 outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also noted that reconciliation occurs because hospitals' actual CCRs for the cost reporting period are different than the interim CCRs used to calculate outlier payments when a bill is processed. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we proposed and are again finalizing our policy not to make any assumptions about the effects of reconciliation on the outlier threshold calculation.

Also, outlier reconciliation is a function of the cost report and Medicare contractors record the outlier reconciliation amount on each provider's cost report (and are not required to report these data to CMS outside of the cost report settlement process). Therefore, the outlier reconciliation data that the commenter is requesting is publicly available through the cost report.

Since the effective date of Change Request 7192 on April 1, 2011, we have approved the reconciliation of outlier payments for some providers. Other providers that were flagged for outlier reconciliation are still under review for approval. In addition, some providers flagged for outlier reconciliation may experience a delay in reconciling their outlier payments due to circumstances that prevent the Medicare contractor from finalizing the hospital's cost report (such as other payments that may need to be reconciled aside from outlier payments).

We note that, we did not receive any public comments on possible modifications to our current charge inflation methodology or the possibility of looking at a larger time period beyond 6 months to determine the average charge per case to measure the charge inflation factor.

Because we are not making any changes to our methodology for this final rule, for FY 2013, we are using the same methodology we proposed to calculate the outlier threshold for FY 2013 (using the most recent data available at the time of this final rule).

Using the most recent data available, we calculated the 1-year average annualized rate-of-change in charges per case from the first quarter of FY 2011 in combination with the second quarter of FY 2011 (October 1, 2010, through March 31, 2011) to the first quarter of FY 2012 in combination with the second quarter of FY 2012 (October 1, 2011 through March 31, 2011). This rate-of-change was 4.24 percent (1.042411) or 8.94 percent (1.0866203) over 2 years. As we have done in the past, we established the final FY 2013 outlier threshold using hospital CCRs from the March 2012 update to the PSF--the most recent available data at the time of this final rule.

For FY 2013, we calculated the CCR adjustment by using the FY 2011 operating cost per discharge increase in combination with the actual FY 2011 operating market basket percentage increase determined by IHS Global Insight, Inc. (IGI), as well as the charge inflation factor

described above to estimate the adjustment to the CCRs. (As noted above, the FY 2011 actual (otherwise referred to as "final") operating market basket percentage increase reflects historical data, whereas the published FY 2011 operating market basket update factor was based on IGI's 2010 second quarter forecast with historical data through the first quarter of 2010. As also noted above, while the FY 2011 published operating market basket update was based on the FY 2002-based IPPS market basket, the actual or "final" market basket percentage increase is based on the FY 2006-based IPPS market basket. Similarly, the FY 2011 published capital market basket update factor was based on the FY 2002-based capital market basket and the actual or "final" capital market basket percentage increase is based on the FY 2006-based capital market basket.) By using the operating market basket percentage increase and the increase in the average cost per discharge from hospital cost reports, we are using two different measures of cost inflation. For FY 2013, we determined the adjustment by taking the percentage increase in the operating costs per discharge from FY 2009 to FY 2010 (1.0290) from the cost report and divided it by the final operating market basket percentage increase from FY 2010 (1.0160). This operation removes the measure of pure price increase (the market basket) from the percentage increase in operating cost per discharge, leaving the nonprice factors in the cost increase (for example, quantity and changes in the mix of goods and services). We repeated this calculation for 2 prior years to determine the 3-year average of the rate-of-adjusted change in costs between the operating market basket percentage increase and the increase in cost per case from the cost report (the FY 2007 to FY 2008 percentage increase of operating costs per discharge of 1.0505 divided by the FY 2008 final operating market basket percentage increase of 1.0400, and the FY 2008 to FY 2009 percentage increase of operating costs per discharge of 1.0295 divided by FY 2009 final operating market basket percentage increase of 1.0260). For FY 2013, we averaged the

differentials calculated for FY 2008, FY 2009, and FY 2010, which resulted in a mean ratio of 1.0029. We multiplied the 3-year average of 1.0029 by the FY 2011 final operating market basket percentage increase of 1.0270, which resulted in an operating cost inflation factor of 2.99 percent or 1.029948. We then divided the operating cost inflation factor by the 1-year average change in charges (1.042411) and applied an adjustment factor of 0.988044 to the operating CCRs from the PSF (calculation performed on unrounded numbers).

We used the same methodology for the capital CCRs and determined the adjustment by taking the percentage increase in the capital costs per discharge from FY 2009 to FY 2010 (1.0102) from the cost report and dividing it by the final capital market basket percentage increase from FY 2010 (1.010). We repeated this calculation for 2 prior years to determine the 3-year average of the rate-of-adjusted change in costs between the capital market basket percentage increase and the increase in cost per case from the cost report (the FY 2007 to FY 2008 percentage increase of capital costs per discharge of 1.0809 divided by the FY 2008 final capital market basket percentage increase of 1.0150, and the FY 2008 to FY 2009 percentage increase of capital costs per discharge of 1.0499 divided by the FY 2009 final capital market basket percentage increase of 1.0150). For FY 2013, we averaged the differentials calculated for FY 2008, FY 2009, and FY 2010, which resulted in a mean ratio of 1.0332. We multiplied the 3-year average of 1.0332 by the FY 2010 final capital market basket percentage increase of 1.0120, which resulted in a capital cost inflation factor of 4.56 percent or 1.045567. We then divided the capital cost inflation factor by the 1-year average change in charges (1.042411) and applied an adjustment factor of 1.003028 to the capital CCRs from the PSF (calculation performed on unrounded numbers). We are using the same charge inflation factor for the capital

CCRs that was used for the operating CCRs. The charge inflation factor is based on the overall billed charges.

As stated above, for FY 2013, we applied the final FY 2013 payment rates and policies using cases from the FY 2011 MedPAR file in calculating the final outlier fixed-loss cost threshold for FY 2013.

As discussed in section III.B.3. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.F. of the preamble of this final rule, in accordance with section 10324(a) of the Affordable Care Act, beginning in FY 2011, we created a wage index floor of 1.00 for all hospitals located in States determined to be frontier States. We noted that the frontier State floor adjustments will be calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State will receive a wage index lesser than 1.00 due to the rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the final outlier fixed-loss cost threshold for FY 2013, it was necessary to apply this provision by adjusting the wage index of those eligible hospitals in a frontier State when calculating the outlier fixed-loss cost threshold that results in outlier payments being 5.1 percent of total payments for FY 2013. If we did not take into account this provision, our estimate of total FY 2013 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

Also, for this final rule, the cumulative effect of documentation and coding that we estimate has occurred is already reflected within the FY 2011 MedPAR claims data, and we did not believe there was any need to inflate FY 2011 claims data for any additional case-mix growth projected to have occurred since FY 2010.

As discussed above, in our projection of FY 2013 outlier payments, we did not make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. Also, we are finalizing our proposal to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

Using this methodology, we calculated a final outlier fixed-loss cost threshold for FY 2013 equal to the prospective payment rate for the MS-DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $21,821. We note, that the final outlier fixed-loss cost threshold is $1,089 less than the revised corrected proposed threshold amount ($23,630) mentioned above (which used the correct CCRs from December 2010 PSF update and properly adjusted the CCRs). We believe this decrease is attributable to the reduction in the charge inflation factor from 14.06 percent in the proposed rule to 8.94 percent in this final rule (a reduction of 5.12 percentage points). A lower charge inflation factor decreases the projected total outlier payments. With a decrease in projected outlier payments, in order for CMS to meet the 5.1 percent target, it would be necessary to increase the amount of outlier payments by reducing the outlier fixed-loss cost threshold.

In addition, at this time, we are not finalizing our proposal to make an adjustment to the standardized amounts to offset the estimated amount of the increase in aggregate payments due to the effect of documentation and coding that did not reflect real changes in case-mix for

discharges occurring during FY 2010. Therefore, an increase to the standardized amount relative to the proposed rule also decreases the projected total outlier payments, which requires a reduction in the outlier fixed-loss cost threshold in order to increase the amount of outlier payments. Also, the final outlier fixed-loss cost threshold of $21,821 is $1,369 less than the outlier fixed-loss cost threshold of $23,190 requested by the commenters above. Because we are using the most recent available CCR data to calculate the final outlier fixed-loss cost threshold and the final outlier fixed-loss cost threshold is much lower than the threshold amount requested by the commenters, as discussed above, we believe it is prudent to closely analyze the commenters' suggestions on modifying the methodology to calculate the outlier fixed-loss cost threshold and how to improve our estimation of the outlier payout from prior years after this final rule so that, if warranted, we can make any proposals related to these issues in a future rulemaking.

(2) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2013 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 6.38 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are reducing the FY 2013 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that are applied to the standardized amount based on the FY 2013 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate
National	0.948999	0.936209
Puerto Rico	0.944760	0.925579

We are applying the outlier adjustment factors to the FY 2013 rates after removing the effects of the FY 2012 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the fiscal intermediary or MAC computes operating CCRs greater than 1.146 or capital CCRs greater than 0.166, or hospitals for which the fiscal intermediary or MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the Internet) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the fiscal intermediary or MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2012, these statewide average ratios will

replace the ratios posted on the Internet at http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp#TopOfPage. Table 8B listed in section VI. of this Addendum (and available via the Internet) contains the comparable statewide average capital CCRs. Again, the CCRs in Tables 8A and 8B will be used during FY 2013 when hospital-specific CCRs based on the latest settled cost report are either not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their fiscal intermediary or MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the fiscal intermediary or MAC can avoid possible overpayments or underpayments at cost report settlement, thus ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. Additionally, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions

on outlier reconciliation, we refer readers to the CMS Web site: http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.

(3) FY 2011 and FY 2012 Outlier Payments

In the FY 2012 IPPS final rule (76 FR 51795 through 51796), we stated that, based on available data, we estimated that actual FY 2011 outlier payments would be approximately 4.7 percent of actual total MS-DRG payments. This estimate was computed based on simulations using the FY 2010 MedPAR file (discharge data for FY 2010 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2011 claims, but instead reflected the application of FY 2011 payment rates and policies to available FY 2010 claims.

Our current estimate, using available FY 2011 claims data, is that actual outlier payments for FY 2011 were approximately 4.8 percent of actual total MS-DRG payments. Thus, the data indicate that, for FY 2011, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2011. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not plan to make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2011 are equal to 5.1 percent of total MS-DRG payments.

In the proposed rule, we estimated that actual outlier payments for FY 2012 will be approximately 6.0 percent of actual total MS-DRG payments, approximately 0.9 percentage point higher than the 5.1 percent we projected when setting the outlier policies for FY 2012. This estimate of 6.0 percent was based on simulations using the FY 2011 MedPAR file (discharge data for FY 2011 claims). We note that, similar to our error in estimating the proposed outlier fixed-loss cost threshold, this estimate was incorrect because we inadvertently used CCRs with an effective date prior to December 2010. For this final rule, using the latest CCRs from the

March 2012 update of the PSF, we estimate that actual outlier payments for FY 2012 will be approximately 5.0 percent of actual total MS-DRG payments, approximately 0.1 percentage point lower than the 5.1 percent we projected when setting the outlier policies for FY 2012. This estimate of 5.0 percent is based on simulations using the FY 2011 MedPAR file (discharge data for FY 2011 claims).

Comment: Commenters disagreed with CMS' use of modeled data versus actual payment data to compute the outlier payment percentage for FY 2011. The commenters stated that they performed their own analyses using actual payment information in the MedPAR file, which resulted in outlier payments being 4.42 percent of actual MSDRG payments for FY 2011. The commenters recommended that CMS determine the FY 2011 outlier payment percentage using actual payments rather than modeled payments.

The commenters disagreed with CMS' reasons presented in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50431) for using modeled data instead of actual data. In that final rule, CMS supported its decision to use modeled data in part because "while accurate at the time the MedPAR file is constructed, claims can be cancelled, edited and resubmitted to NCH after the MedPAR file is built, and, therefore, the payment field shown on MedPAR is subject to change and does not necessarily represent the final payment on that claim." The commenters stated that while this is true, the argument applies equally to modeling payments from the MedPAR data. The commenters explained that if a claim is cancelled after the MedPAR file is built, the modeled payment for that claim will be included in overall estimates.

The commenters further noted that, in the FY 2011 IPPS/LTCH PPS final rule, CMS expressed concern that SCHs and MDHs complicate the use of the payment field shown on the MedPAR file (75 FR 50431). The commenter disagreed with CMS and stated that CMS'

argument is valid for determining the DRG-based operating payments needed to calculate outlier payment levels; however, the SCH/MDH argument does not apply to outlier payments. The commenters claimed that "the PRICER program determines outlier payments for all hospitals, including SCH/MDHs, based on the Federal rate only." The commenters added that "the outlier payments are recorded in the "OUTLIER AMOUNT" field (and not included in the DRG PRICE)." Therefore, the commenters asserted that "obtaining the outlier payments directly from the MedPAR file does not introduce complications related to the SCH/MDH status." Moreover, the commenters stated, "that SCH/MDH hospitals represent a small percent of hospitals overall."

The commenters also believed that CMS' estimate is not as accurate as it could be. The commenter noted that CMS' statement in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51796) indicates that CMS estimated outlier payments for FY 2010 using a single CCR. The commenter stated that they were perplexed that CMS would not use the actual CCRs utilized in the actual payment process given that they are readily available in the PSF.

Using actual payment data, the commenter computed an outlier payout of 4.74 percent and 4.13 percent for FY 2009 and FY 2010 respectively, versus the 5.3 percent and 4.7 percent that CMS published in the FY 2011 and FY 2012 final rules. The commenter concluded that using modeled data has consistently overestimated outlier payments. The commenter recommended that CMS publish in the final rule the outlier percentage for FYs 2009 through 2011 based on actual payments.

Response: We responded to similar comments in response to policies presented in last year's final rule and refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51796).

Comment: One commenter was not aware that in determining the FY 2011 outlier payout, CMS first identifies SCHs then sums up the total Federal payments and hospital-specific

rate (HSP) payments and then excludes from the outlier calculation those SCHs whose HSP payments were greater than their Federal payments. Using actual payments, the commenter performed a similar edit for SCHs and an edit for MDHs (by excluding 75 percent of their standard Federal rate based on MS-DRG and outlier payments). Using the payment amounts on the claims, the commenter determined an outlier payout of 4.39 percent for FY 2011. The commenter also modeled the FY 2011 outlier payout by incorporating the same edit described above for SCHs and MDHs, and used CCRs that were in effect during FY 2011 from the March 2012 PSF update, and DSH and IME factors from the FY 2011 final rule impact file. The commenter used FY 2011 payment rates and determined a modeled outlier payout of 4.42 percent for FY 2011. The commenter noted that the modeled outlier percentage of 4.42 was very close to the actual outlier payment percentage of 4.39. The commenter added that using this model, an outlier fixed-loss cost threshold of $20,055 would have resulted in an outlier payout of 5.1 percent for FY 2011 versus CMS' final FY 2011 outlier fixed-loss cost threshold of $23,075 (which represents a 15 percent error in setting the threshold).

The commenter also used cost report data from the March 2012 HCRIS update to analyze the historical actual outlier payout from 2003 through 2010. To determine the outlier payout for each year, the commenter summed up total MS-DRG payments and outlier payments for each fiscal year based on cost report begin dates within the fiscal year. The commenters stated that CMS did not meet the 5.1 percent target in any of these fiscal years.

The commenter also stated that it is important for CMS to assess how closely the prior year's threshold achieved its target. The commenter explained that if outlier payments from the prior year closely approximate the target, unless there are policy changes imposed by Congress or the agency or indications that demographic or public health factors had an impact on inpatient

service intensity, then there is little need for dramatic change to the threshold from the prior year for the upcoming fiscal year.

The commenter modeled the FY 2012 outlier payout by using FY 2011 MedPAR data and inflating the charges by 6.8 percent. The commenter used the FY 2012 IPPS/LTCH PPS final rule impact file for payment variables and FY 2012 payment rules and determined an outlier payment of 5.8 percent. In the proposed rule, CMS calculated a 6.0 percent outlier payout for FY 2012. The commenter believed that the reason for this high outlier payout is due to the use of out of date CCRs. The commenter explained that they used CCRs from the March 2012 PSF update for the first three quarters of FY 2012 and projected forward CCRs by 1 year for the last quarter of FY 2012. The commenter noted that the estimate of 5.8 percent may still be too high because it is expected that many hospitals will have their CCRs updated in the last quarter of FY 2012 due to the delay in filing form CMS 2552-10 cost reports (and CCRs tend to trend lower over time which would lower the threshold). The commenter noted that this delay probably impacts the estimated FY 2012 outlier payout because hospitals did not have their CCR updated in the PSF, which caused relatively "older" CCRs to be used for payment of outliers longer than normal. (These older CCRs typically are higher than more recent updated CCRs, which would result in higher outlier payments during FY 2012.)

Response: We appreciate the commenter's analysis above. We believe it is necessary to annually recompute the outlier fixed-loss cost threshold because section 1886(d)(5)(A)(iv) of the Act requires outlier payments to be not less than 5 percent nor more than 6 percent of total estimated or projected payments. Additionally, aside from the statute, there are many variables such as the market basket increase, wage index, charge inflation factor and other adjustments to the standardized amount that could affect the outlier fixed-loss cost threshold from one year to

the next, which warrants an annual recalculation of the outlier fixed-loss cost threshold factoring in these changes so that we can meet our target of a 5.1 percent outlier payout. However, we recognize the commenter's concerns with our methodology for calculating the outlier fixed-loss cost threshold and our calculation of the outlier payout from prior years. Therefore, as stated above, we plan to closely analyze the commenters' suggestions for modifying the methodology to calculate the outlier fixed-loss cost threshold amount and to improve our estimation of the outlier payout from prior years after this final rule so that, if warranted, we can make any proposals on these issues in a future rulemaking.

5. FY 2013 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the Internet) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2013. The Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is the labor-related share of 68.8 percent, and Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals (other than those in Puerto Rico) whose wage indices are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increase of 1.8 percent for FY 2013, and an update of –0.2 percent for hospitals that fail to submit quality data consistent with section 1886(b)(3)(B)(viii) of the Act.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the discharge-weighted average of the national large urban standardized amount (this amount is set forth in Table 1A). The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2013 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). This table also includes the Puerto Rico standardized amounts. The labor-related share applied to the Puerto Rico-specific standardized amount is the labor-related share of 62.1 percent, or 62 percent, depending on which provides higher payments to the hospital.
(Section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Pub. L. 108-173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.)

The following table illustrates the changes from the FY 2012 national standardized amount. The second column shows the changes from the FY 2012 standardized amounts for hospitals that satisfy the quality data submission requirement and, therefore, receive the full update of 1.8 percent. The third column shows the changes for hospitals receiving the reduced update of -0.2 percent. The first row of the table shows the updated (through FY 2012) average standardized amount after restoring the FY 2012 offsets for outlier payments, demonstration budget neutrality, the geographic reclassification budget neutrality, and the retrospective documentation and coding adjustment under section 7(b)(1)(B) of Pub. L. 110-90. The

MS-DRG reclassification and recalibration wage index budget neutrality factors are cumulative. Therefore, those FY 2012 factors are not removed from this table.

COMPARISON OF FY 2012 STANDARDIZED AMOUNTS TO THE FY 2013 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE

	Full Update (1.8 percent); Wage index is greater than 1.0000	**Full Update (1.8 percent); Wage index is less than or equal to 1.0000**	**Reduced Update (-0.2 percent); Wage index is greater than 1.0000**	**Reduced Update (-0.2 percent); Wage index is less than or equal to 1.0000**
FY 2012 Base Rate, after removing geographic reclassification budget neutrality, rural community hospital demonstration program budget neutrality, cumulative FY 2008 and FY 2009 documentation and coding adjustment, FY 2012 documentation and coding recoupment, and outlier offset (based on the labor-related share percentage for FY 2012)	Labor: $4,060.65 Nonlabor: $1,841.46	Labor: $3,659.31 Nonlabor: $2,242.80	Labor: $4,060.65 Nonlabor: $1,841.46	Labor: $3,659.31 Nonlabor: $2,242.80
FY 2013 Update Factor	1.018	1.018	0.998	0.998
FY 2013 MS-DRG Recalibration and Wage Index Budget Neutrality Factor	0.998761	0.998761	0.998761	0.998761
FY 2013 Reclassification Budget Neutrality Factor	0.991276	0.991276	0.991276	0.991276
FY 2013 Rural Community Demonstration Program Budget Neutrality Factor	0.999677	0.999677	0.999677	0.999677
FY 2013 Operating Outlier Factor	0.948999	0.948999	0.948999	0.948999
Documentation and coding adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110-90	0.9478	0.9478	0.9478	0.9478
National Standardized Amount for FY 2013	Labor: $3,679.95 Nonlabor: $1,668.81	Labor: $3,316.23 Nonlabor:$2,032.53	Labor: $3,607.65 Nonlabor: $1,636.02	Labor: $3,251.08 Nonlabor: $1,992.59

The following table illustrates the changes from the FY 2012 Puerto Rico-specific payment rate for hospitals located in Puerto Rico. The second column shows the changes from

the FY 2012 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index greater than 1.0000. The third column shows the changes from the FY 2012 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index less than 1.0000. The first row of the table shows the updated (through FY 2012) Puerto Rico-specific payment rate after restoring the FY 2012 offsets for Puerto Rico-specific outlier payments, rural community hospital demonstration program budget neutrality, and the geographic reclassification budget neutrality. The MS-DRG recalibration budget neutrality factor is cumulative and is not removed from this table.

COMPARISON OF FY 2012 PUERTO RICO-SPECIFIC PAYMENT RATE TO THE FY 2013 PUERTO RICO-SPECIFIC PAYMENT RATE

	Update (1.8 percent); Wage index is greater than 1.0000	**Update (1.8 percent); Wage index is less than or equal to 1.0000**
FY 2012 Puerto Rico Base Rate, after removing geographic reclassification budget neutrality, the rural community hospital demonstration program budget neutrality, Puerto Rico outlier offset (based on the Puerto Rico specific labor-related share percentage for FY 2012)	Labor: $1,643.77 Nonlabor: $1,003.21	Labor: $1,641.13 Nonlabor: $1,005.85
FY 2013 Update Factor	1.018	1.018
FY 2013 MS-DRG Recalibration Budget Neutrality Factor	0.998431	0.998431
FY 2013 Reclassification Budget Neutrality Factor	0.991276	0.991276
FY 2013 Rural Community Hospital Demonstration Program Budget Neutrality Factor	0.999677	0.999677
FY 2013 Puerto Rico Operating Outlier Factor	0.944760	0.944760
Puerto Rico-Specific Payment Rate for FY 2013	Labor: $1,564.17 Nonlabor: $954.62	Labor: $1,561.65 Nonlabor:$957.14

B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet), contain the labor-related and nonlabor-related shares that we used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2013. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national and Puerto Rico prospective payment rates, respectively, to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2013 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make "such adjustments . . . as the Secretary deems appropriate" to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) Web site at http://www.opm.gov/oca/cola/rates.asp to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28145 and 28146), we explained that sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111-84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. We further explained in the proposed rule that, beginning in FY 2012, as OPM transitioned away from COLAs, we continued to use the same "frozen" COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA

factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule for a more detailed discussion of our rationale for continuing to use the frozen COLAs.

In the FY 2013 IPPS/LTCH PPS proposed rule, for FY 2013, we proposed to continue to use the same COLA factors that are used to adjust payments in FY 2012 (as originally used to adjust payments in FY 2011, which are based on OPM's 2009 COLA factors), and we also proposed a methodology to update the COLA factors published by OPM beginning in FY 2014. Specifically, we proposed to update the COLA factors published by OPM that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) by using the comparison of the growth in the overall CPI relative to the growth in the CPI in Anchorage and Honolulu to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. We noted that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent, and we have exercised our discretionary authority to adjust Alaska and Hawaii payments by incorporating this cap. We again refer readers to the FY 2013 IPPS/LTCH PPS proposed rule for a more detailed discussion of our methodology. Lastly, as we stated in the proposed rule, we are updating the COLA factors based on our methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket. The labor-related share of the IPPS market basket is currently not scheduled to be updated until FY 2014.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposals without modification. Specifically, we are adopting as final our proposed methodology to update the COLA factors annually beginning in FY 2014. We also are finalizing our proposal for FY 2013 to continue to use the same COLA factors used to adjust payments in FY 2012. Therefore, the COLA factors which will be used to adjust the nonlabor-related portion

of the standardized amount for hospitals located in Alaska and Hawaii for FY 2013 remain unchanged from FY 2012. The table below shows the COLA factors that we are establishing for FY 2013:

FY 2013 Cost-of-Living Adjustment Factors:
Alaska and Hawaii Hospitals

Area	Cost of Living Adjustment Factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

C. Calculation of the Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2013

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs, for FY 2013 equals the Federal rate. (As noted above, due to the expiration of the MDH program, beginning with FY 2013, we are not including MDHs in our discussion of the update of the hospital-specific rates for FY 2013.)

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the

updated hospital-specific rate based on the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2013 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for hospitals located in Puerto Rico for FY 2013 equals 25 percent of the Puerto Rico-specific payment rate plus 75 percent of the applicable national rate.

1. Federal Rate

The Federal rate is determined as follows:

Step 1--Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data (full update for hospitals submitting quality data; update including a -2.0 percent adjustment for hospitals that did not submit these data).

Step 2--Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3--For hospitals in Alaska and Hawaii, multiply the nonlabor-related portion of the standardized amount by the applicable cost-of-living adjustment factor.

Step 4--Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if applicable, under Step 3).

Step 5--Multiply the final amount from Step 4 by the relative weight corresponding to the applicable MS-DRG (Table 5 listed in section VI. of this Addendum and available via the Internet).

The Federal rate as determined in Step 5 may then be further adjusted if the hospital qualifies for either the IME or DSH adjustment. In addition, for hospitals that qualify for a low-

volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b), the payment in Step 5 would be increased by the formula described in section IV.D. of the preamble of this final rule. Finally, the base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886 (q) and 1886(o) of the Act, respectively.

2. Hospital-Specific Rate (Applicable Only to SCHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that currently SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

We note that, in the FY 2012 IPPS/LTCH final rule (76 FR 51799), we finalized an adjustment of 0.9 percent to the hospital-specific rate (that is, a factor of 1.009) in light of the *Cape Cod* decision. The adjustment is a one-time permanent adjustment to the hospital-specific rates.

b. Updating the FY 1982, FY 1987, FY 1996 and FY 2006 Hospital-Specific Rate for FY 2013

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the applicable percentage increase to the hospital-specific rates applicable to SCHs is 1.8 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent less an adjustment of 0.7 percentage point for MFP and less 0.1 percentage point) for hospitals that submit quality data or –0.2 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.7 percentage point for MFP, and less 0.1 percentage point) for hospitals that fail to submit quality data. For a complete discussion of the applicable percentage increase applicable to the hospital-specific rates for SCHs, we refer readers to section IV.B. of the preamble of this final rule.

In addition, because SCHs use the same MS-DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS-DRG classifications and the recalibration of the MS-DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, a SCH's hospital-specific rate is adjusted by the MS-DRG reclassification and recalibration budget neutrality factor of 0.998431, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate an SCH will receive for its discharges beginning on or after October 1, 2012.

c. Documentation and Coding Adjustment to the FY 2013 Hospital-Specific Rate for SCHs

As discussed in section II.D. of the preamble of this final rule, because hospitals paid based in whole or in part on the hospital-specific rate (that is, SCHs and, until October 1, 2012, MDHs) use the same MS-DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patients' severity of illness. Under section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rate should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patients' severity of illness. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50426) and in section II.D. of the preamble of this final rule, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS-DRGs to all other hospitals. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates to ensure rates are not increased in a manner that does not reflect real changes in case-mix, and using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act.

As we discuss in section II.D. of the preamble of this final rule, we have determined that a cumulative adjustment of -5.4 percent is required to eliminate the full effect of changes in documentation and coding that occurred in FY 2008 and FY 2009 on future payments to SCHs.

Currently, we have made cumulative adjustments to the hospital-specific rates to account for 4.9 percent of the 5.4 percent effect of changes in documentation and coding that occurred in FY 2008 and FY 2009. (For FY 2011, we established a prospective adjustment of -2.9 percent to the hospital-specific rates, and, for FY 2012, we established a prospective adjustment to the hospital-specific rates of -2.0 percent.) In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51499), we indicated that, because the -2.0 percent adjustment we made in FY 2012 did not reflect the entire remaining required adjustment amount of -2.5 percent, an additional -0.5 percent adjustment to the hospital-specific rates would be required in a future rulemaking.

In this final rule, as we proposed, we are finalizing a -0.5 percent prospective adjustment to the hospital-specific rate to account for the remainder of the 5.4 percent effect of documentation and coding that occurred in FY 2008 and FY 2009. We continue to believe that hospitals paid based on their hospital-specific rate (that is, SCHs and, until October 1, 2012, MDHs) had the same opportunity to benefit from improvements in documentation and coding that did not reflect an increase in patient severity, and we continue to believe that any resulting adjustments should be applied similarly to all subsection (d) hospitals, when possible.

As discussed in section II.D. of the preamble of this final rule, consistent with our policy for IPPS hospitals based upon a review of FY 2010 claims data using the same methodology, we proposed to make an additional -0.8 percent adjustment to the hospital-specific rates to account for documentation and coding that did not reflect an actual increase in case-mix in FY 2010. In the proposed rule, we stated that we believe that a full prospective adjustment is the most appropriate means to take into account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between different IPPS hospitals paid using the MS-DRG system. Therefore, as discussed in more detail in the preamble of this final

rule, we proposed a combined adjustment of -1.3 percent (-0.5 percent + -0.8 percent) to the hospital-specific rates, accounting for all documentation and coding effects observed between FY 2008 though FY 2010.

As discussed in section II.D. of the preamble of this final rule, we are not finalizing an additional -0.8 percent adjustment to the FY 2013 hospital-specific rates to account for documentation and coding that did not reflect an actual increase in case-mix in FY 2010. However, as stated above, we are making an adjustment of -0.5 percent to the hospital-specific rates, accounting for all documentation and coding effects observed during FY 2008 and FY 2009.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or after October 1, 2012, and before October 1, 2013

Section 1886(d)(9)(E)(iv) of the Act provides that, effective for discharges occurring on or after October 1, 2004, hospitals located in Puerto Rico are paid based on a blend of 75 percent of the national prospective payment rate and 25 percent of the Puerto Rico-specific rate.

a. Puerto Rico-Specific Rate

The Puerto Rico-specific prospective payment rate is determined as follows:

Step 1- Select the applicable average standardized amount considering the applicable wage index (obtained from Table 1C published in section VI. of this Addendum and available via the Internet).

Step 2 - Multiply the labor-related portion of the standardized amount by the applicable Puerto Rico-specific wage index.

Step 3 - Add the amount from Step 2 and the nonlabor-related portion of the standardized amount.

Step 4 - Multiply the amount from Step 3 by the applicable MS-DRG relative weight (obtained from Table 5 listed in section VI. of this Addendum and available via the Internet).

Step 5 - Multiply the result in Step 4 by 25 percent.

b. National Prospective Payment Rate

The national prospective payment rate is determined as follows:

Step 1 - Select the applicable average standardized amount.

Step 2--Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3 - Add the amount from Step 2 and the nonlabor-related portion of the national average standardized amount.

Step 4 - Multiply the amount from Step 3 by the applicable MS-DRG relative weight (obtained from Table 5 listed in section VI. of this Addendum and available via the Internet).

Step 5 - Multiply the result in Step 4 by 75 percent.

The sum of the Puerto Rico-specific rate and the national prospective payment rate computed above equals the prospective payment for a given discharge for a hospital located in Puerto Rico. This rate is then further adjusted if the hospital qualifies for either the IME or DSH adjustment.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2013

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, hospitals were paid during a 10-year transition period (which extended through FY 2001) to change the payment methodology for Medicare acute care hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we used to determine the capital Federal rate for FY 2013, which is effective for discharges occurring on or after October 1, 2012.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except "new" hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment

factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed below in section III.A.4. of this Addendum, there is no longer a need for an exceptions payment adjustment factor.) Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for blended payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. In accordance with section 1886(d)(9)(A) of the Act, under the IPPS for acute care hospital operating costs, hospitals located in Puerto Rico are paid for operating costs under a special payment formula. Effective October 1, 2004, in accordance with section 504 of Pub. L. 108-173, the methodology for operating payments made to hospitals located in Puerto Rico under the IPPS was revised to make payments based on a blend of 25 percent of the applicable standardized amount specific to Puerto Rico hospitals and 75 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges occurring on or after October 1, 2004, we also revised the methodology for computing capital payments made to hospitals located in Puerto Rico to be based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the national capital Federal rate (69 FR 49185).

A. Determination of Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2013. In particular, we explain why the FY 2013 capital Federal rate increases approximately 1.0 percent, compared to the FY 2012 capital Federal rate. As discussed in the impact analysis in Appendix A to this final rule, we estimate that capital payments per discharge will increase 1.8 percent during that same period. Because capital payments constitute about 10 percent of hospital payments, a percent change in the capital Federal rate yields only about a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate-of-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2013 under that framework is 1.2 percent based on the best data available at this time. The update factor under that framework is based on a projected 1.2 percent increase in the CIPI, a 0.0 percent adjustment for intensity, a 0.0 percent adjustment for case-mix, a 0.0 percent adjustment for the FY 2011 DRG reclassification and recalibration, and a forecast error correction of 0.0 percent. As discussed below in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2013 CIPI projection in that same section of this Addendum. (We note that, as discussed in section V.C. of the preamble of this final rule, at this time, we are not finalizing our proposal to apply a -0.8 percent adjustment to the capital Federal rate in FY 2013 to account for the effect

of changes in documentation and coding under the MS-DRGs that do not correspond to changes in real increases in patients' severity of illness.) Below we describe the policy adjustments that we are applying in the update framework for FY 2013.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patients changes ("real" case-mix change);
- Changes in hospital documentation and coding of patient records result in higher weighted DRG assignments ("coding effects"); and
- The annual DRG reclassification and recalibration changes may not be budget neutral ("reclassification effect").

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2013, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will also equal 0.5 percent for FY 2013. The net

adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the net adjustment for case-mix change in FY 2013 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2011 DRG reclassification and recalibration as part of our update for FY 2013. We estimate that FY 2011 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are making a 0.0 percent adjustment for reclassification and recalibration in the update framework for FY 2013.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast

error. A forecast error of 0.0 percentage point was calculated for the FY 2013 update. That is, current historical data indicate that the forecasted FY 2011 CIPI (1.2 percent) used in calculating the FY 2011 update factor is the same as the actual realized price increases (1.2 percent). Because we estimate forecast error for the FY 2011 CIPI, we are making a 0.0 percent adjustment for forecast error in the update for FY 2013.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CIPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2013 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2013, we are using an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2005 and extending through FY 2010. Based on these data, we estimated that case-mix constant intensity declined during FYs 2005 through 2010. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2013. Therefore, we are making a 0.0 percent adjustment for intensity in the update for FY 2013.

Above, we described the basis of the components used to develop the 1.2 percent capital update factor under the capital update framework for FY 2013 as shown in the table below.

CMS FY 2013 Update Factor to the Capital Federal Rate

Capital Input Price Index	1.2
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	-0.5
Projected Case-Mix Change	0.5
Subtotal	1.2
Effect of FY 2011 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.2

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2012 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2013. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2012, Chapter 3.)

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2012, we estimated that outlier payments for capital would equal 6.18 percent of inpatient capital-related payments based on the capital Federal rate in FY 2012. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 6.38 percent for inpatient capital-related payments based on the capital Federal rate in FY 2013. Therefore, we are applying an outlier adjustment factor of 0.9362 in determining the capital Federal rate for FY 2013. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2013 will be somewhat higher than the percentage for FY 2012. This increase in estimated capital outlier payments is primarily due to the decrease in the outlier threshold used to identify outlier cases for both inpatient operating and inpatient capital-related payments, which is discussed in

section II.A. of this Addendum. That is, because the outlier threshold used to identify outlier cases is lower, cases will receive higher outlier payments and more cases will qualify for outlier payments.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2013 outlier adjustment of 0.9362 is a -0.21 percent change from the FY 2012 outlier adjustment of 0.9382. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2013 is 0.9976 (0.9362/0.9382). Thus, the outlier adjustment will decrease the FY 2013 capital Federal rate by 0.21 percent compared to the FY 2012 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we implemented a separate GAF for Puerto Rico, we apply separate budget neutrality adjustments for the national GAF and the Puerto Rico GAF. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier because the GAF for Puerto Rico was implemented in FY 1998.

To determine the factors for FY 2013, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2012 MS-DRG classifications and relative weights and the FY 2012 GAF to estimated

aggregate capital Federal rate payments based on the FY 2012 MS-DRG classifications and relative weights and the FY 2013 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are applying an incremental budget neutrality adjustment factor of 1.0003 for FY 2013 to the previous cumulative FY 2012 adjustment factor of 0.9908, yielding an adjustment factor of 0.9911, through FY 2013. For the Puerto Rico GAFs, we are applying an incremental budget neutrality adjustment factor of 1.0056 for FY 2013 to the previous cumulative FY 2012 adjustment factor of 1.0043, yielding a cumulative adjustment factor of 1.0100 through FY 2013.

We then compared estimated aggregate capital Federal rate payments based on the FY 2012 MS-DRG relative weights and the FY 2013 GAFs to estimate aggregate capital Federal rate payments based on the cumulative effects of the FY 2013 MS-DRG classifications and relative weights and the FY 2013 GAFs. The incremental adjustment factor for DRG classifications and changes in relative weights is 0.9996 both nationally and for Puerto Rico. The cumulative adjustment factors for MS-DRG classifications and changes in relative weights and for changes in the GAFs through FY 2013 are 0.9904 nationally and 1.0095 for Puerto Rico. We note that all the values are calculated with unrounded numbers.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS-DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor (the national capital rate and the Puerto Rico capital rate are

determined separately) for changes in the GAF (including geographic reclassification) and the MS-DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

For FY 2012, we established a GAF/DRG budget neutrality adjustment factor of 1.0004 (76 FR 51803). For FY 2013, we are establishing a GAF/DRG budget neutrality adjustment factor of 0.9998. The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs. The incremental change in the adjustment factor from FY 2012 to FY 2013 is 0.9998. The cumulative change in the capital Federal rate due to this adjustment is 0.9904 (the product of the incremental factors for FYs 1995 through 2012 and the incremental factor of 0.9998 for FY 2013). (For a historical listing of the DRG and GAF budget neutrality adjustment factors, we refer readers to section III. of the Addendum to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51803).)

The factor accounts for the MS-DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2013 geographic reclassification decisions made by the MGCRB compared to FY 2012 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Exceptions Payment Adjustment Factor

Section 412.308(c)(3) of our regulations requires that the capital standard Federal rate be reduced by an adjustment factor equal to the estimated proportion of additional payments for

both regular exceptions and special exceptions under § 412.348 relative to total capital PPS payments.

Since FY 2002, an adjustment for regular exception payments was no longer necessary in determining the capital Federal rate because, in accordance with § 412.348(b), regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991, and before October 1, 2001. Accordingly, in FY 2002 and subsequent fiscal years, no payments are made under the regular exceptions provision (66 FR 39949). Furthermore, as discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51804), there are no longer any remaining hospitals eligible to receive a special exceptions payment under § 412.348(g) because they have reached the limitation on the period for exception payments under § 412.348(g)(7). Therefore, beginning with FY 2012, there is no longer a need for an exceptions payment adjustment factor.

5. Capital Federal Rate for FY 2013

For FY 2012, we established a capital Federal rate of $421.42 (76 FR 51804). We are establishing an update of 1.2 percent in determining the FY 2013 capital Federal rate for all hospitals. (As discussed in greater detail in section V.E. of the preamble of this final rule, at this time we are not adopting our proposal to make an additional -0.8 percent adjustment to the national capital Federal rate in FY 2013 to account for the effect of changes in case-mix resulting from documentation and coding changes that do not reflect real changes in the case-mix in light of the adoption of MS-DRGs. However, the cumulative documentation and coding adjustment factor of 0.9479 applied in determining the FY 2012 capital Federal rate remains applied to that rate. As a result of the 1.2 percent update and other budget neutrality factors discussed above, we are establishing a national capital Federal rate of $425.49 for FY 2013. The national capital Federal rate for FY 2013 was calculated as follows:

- The FY 2013 update factor is 1.0120, that is, the update is 1.2 percent.
- The FY 2013 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS-DRG classifications and relative weights and changes in the GAFs is 0.9998.
- The FY 2013 outlier adjustment factor is 0.9362.

Because the capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not making additional adjustments in the capital Federal rate for these factors, other than the budget neutrality factor for changes in the MS-DRG classifications and relative weights and for changes in the GAFs. (As discussed in section III.A.4. of this Addendum, there is no longer a need for an exceptions payment adjustment factor in determining the capital Federal rate.)

We are providing the following chart that shows how each of the factors and adjustments for FY 2013 affects the computation of the FY 2013 national capital Federal rate in comparison to the FY 2012 national capital Federal rate. The FY 2013 update factor has the effect of increasing the capital Federal rate by 1.2 percent compared to the FY 2012 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.02 percent. The FY 2013 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.21 percent compared to the FY 2012 capital Federal rate. The combined effect of all the changes will increase the national capital Federal rate by 0.97 percent compared to the FY 2012 national capital Federal rate.

**Comparison of Factors and Adjustments:
FY 2012 Capital Federal Rate and
FY 2013 Capital Federal Rate**

	FY 2012	FY 2013	Change	Percent Change
Update Factor[1]	1.0150	1.0120	1.0120	1.20
GAF/DRG Adjustment Factor[1]	1.0040	0.9998	0.9998	-0.02
Outlier Adjustment Factor[2]	0.9382	0.9362	1.0019	-0.21
Capital Federal Rate	$421.42	$425.49	1.0097	0.97

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2012 to FY 2013 resulting from the application of the 0.9998 GAF/DRG budget neutrality adjustment factor for FY 2013 is a net change of 0.9998 (or -0.02 percent).
[2] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2013 outlier adjustment factor is 0.9362/0.9382, or 0.9979 (or -0.21 percent).

In this final rule, we also are providing the following chart that shows how the final FY 2013 capital Federal rate differs from the proposed FY 2013 capital Federal rate as presented in the FY 2013 IPPS/LTCH PPS proposed rule.

**Comparison of Factors and Adjustments:
Proposed FY 2013 Capital Federal Rate and
Final FY 2013 Capital Federal Rate**

	Proposed* FY 2013	Final FY 2013	Change	Percent Change
Update Factor	1.0130	1.0120	0.9990	-0.10
GAF/DRG Adjustment Factor	1.0002	0.9998	0.9997	-0.03
Outlier Adjustment Factor	0.9357	0.9362	1.0005	0.05
MS-DRG Documentation and Coding Adjustment Factor	0.9404	0.9479	1.0080	0.80
Capital Federal Rate	$422.47	$425.49	1.0071	0.71

* The proposed FY 2013 capital Federal rate reflects the correction to the outlier adjustment factor presented in the FY 2013 IPPS/LTCH PPS correction notice (77 FR 34328).

6. Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system for payments made to hospitals located in Puerto Rico under the PPS for acute care hospital inpatient capital-related

costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. Under the broad authority of section 1886(g) of the Act, beginning with discharges occurring on or after October 1, 2004, capital payments made to hospitals located in Puerto Rico are based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate. The Puerto Rico capital rate is derived from the costs of Puerto Rico hospitals only, while the capital Federal rate is derived from the costs of all acute care hospitals participating in the IPPS (including Puerto Rico).

To adjust hospitals' capital payments for geographic variations in capital costs, we apply a GAF to both portions of the blended capital rate. The GAF is calculated using the operating IPPS wage index, and varies depending on the labor market area or rural area in which the hospital is located. We use the Puerto Rico wage index to determine the GAF for the Puerto Rico part of the capital-blended rate and the national wage index to determine the GAF for the national part of the blended capital rate.

Because we implemented a separate GAF for Puerto Rico in FY 1998, we also apply separate budget neutrality adjustment factors for the national GAF and for the Puerto Rico GAF. However, we apply the same budget neutrality adjustment factor for MS-DRG reclassifications and recalibration nationally and for Puerto Rico. The budget neutrality adjustment factors for the national GAF and for the Puerto Rico GAF, and the budget neutrality factor for MS-DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) is discussed above in section III.A.3. of this Addendum.

In computing the payment for a particular Puerto Rico hospital, the Puerto Rico portion of the capital rate (25 percent) is multiplied by the Puerto Rico-specific GAF for the labor market

area in which the hospital is located, and the national portion of the capital rate (75 percent) is multiplied by the national GAF for the labor market area in which the hospital is located (which is computed from national data for all hospitals in the United States and Puerto Rico).

For FY 2012, the special capital rate for hospitals located in Puerto Rico was $203.86 (76 FR 51805). With the changes we are making to the other factors used to determine the capital Federal rate, the FY 2013 special capital rate for hospitals in Puerto Rico is $207.25.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2013

For purposes of calculating payments for each discharge during FY 2013, the capital Federal rate is adjusted as follows: (Standard Federal Rate) x (DRG weight) x (GAF) x (COLA for hospitals located in Alaska and Hawaii) x (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier thresholds for FY 2013 are in section II.A. of this Addendum. For FY 2013, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments is greater than the prospective payment rate for the MS-DRG plus the fixed-loss amount of $21,821.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect--the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021), we rebased and revised the CIPI to a FY 2006 base year to reflect the more current structure of capital costs in hospitals. A complete discussion of this rebasing is provided in section IV. of the preamble of that final rule.

2. Forecast of the CIPI for FY 2013

Based on the latest forecast by IHS Global Insight, Inc. (second quarter of 2012), we are forecasting the FY 2006-based CIPI to increase 1.2 percent in FY 2013. This reflects a projected 1.8 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 1.9 percent increase in other capital expense prices in FY 2013, partially offset by a projected 2.3 percent decline in vintage-weighted interest expenses

in FY 2013. The weighted average of these three factors produces the 1.2 percent increase for the FY 2006-based CIPI as a whole in FY 2013.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages

Historically, hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. An annual per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount for that period was multiplied by the Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to all categories of excluded providers (rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and cancer hospitals).

Payments for services furnished in children's hospitals and cancer hospitals that are excluded from the IPPS continue to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27998), we proposed that the FY 2013 rate-of-increase percentage for updating the target amounts for cancer and children's hospitals and RNHCIs would be the estimated percentage increase in the FY 2013 IPPS operating market basket, in accordance with applicable regulations at § 413.40. In the proposed rule, we estimated the percentage increase in the FY 2013 IPPS operating market basket to be 3.0 percent (that is, the estimate of the market basket rate-of-increase). Based on IHS Global

Insight, Inc.'s 2012 first quarter forecast, with historical data through the 2011 fourth quarter, we estimated the IPPS operating market basket update would be 3.0 percent for FY 2013. However, we proposed that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2013. Therefore, based on IHS Global Insight, Inc.'s 2012 second quarter forecast, with historical data through the 2012 first quarter, we estimate that the final FY 2013 update to the IPPS operating market basket is 2.6 percent. For cancer and children's hospitals and RNHCIs, the final FY 2013 rate-of-increase percentage that will be applied to the FY 2012 target amounts in order to determine the final FY 2013 target amount is 2.6 percent.

IRFs, IPFs, and LTCHs were previously paid under the reasonable cost methodology. However, the statute was amended to provide for the implementation of prospective payment systems for IRFs, IPFs, and LTCHs. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provide transitioning periods of varying lengths of time during which a portion of the prospective payment was based on cost-based reimbursement rules under 42 CFR Part 413 (certain providers do not receive a transition period or may elect to bypass the transition as applicable under 42 CFR Part 412, Subparts N, O, and P.) We note that all of the various transitioning periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble and section V. of the Addendum to this final rule for the update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2013. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Changes to the Payment Rates for the LTCH PPS for FY 2013

A. LTCH PPS Standard Federal Rate for FY 2013

1. Background

In section VII. of the preamble of this final rule, we discuss our changes to the payment rates, factors, and specific policies under the LTCH PPS for FY 2013.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Thus, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior

periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment for the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at §§ 412.523(c)(3)(iv) through (c)(3)(vii). For FY 2012, we updated the standard Federal rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by section 1886(m)(3)(A) of the Act.

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as "the multifactor productivity (MFP) adjustment") as discussed in section VII.D.2.d. of the preamble of this final rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.D.2.d. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the

Affordable Care Act, we use the term “fiscal year” rather than “rate year” for 2011 and subsequent years.)

For FY 2012, consistent with our historical practice, we established an update to the LTCH PPS standard Federal rate based on the full estimated LTCH PPS market basket increase of 2.9 percent and the 1.1 percentage point reductions required by sections 1886(m)(3)(A)(i) and (m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(viii) of the regulations, we established an annual update of 1.8 percent to the standard Federal rate for FY 2012 (76 FR 51769 through 51771 and 51807).

In this final rule, for FY 2013, as discussed in greater detail in section VII.D.2. of the preamble of this final rule, we are establishing an annual update to the LTCH PPS standard Federal rate based on the full estimated increase in the LTCH PPS market basket, less the MFP adjustment consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(C) of the Act. Specifically, in this final rule, based on the best available data, we are establishing an annual update to the standard Federal rate of 1.8 percent, which is based on the full estimated increase in the LTCH PPS market basket of 2.6 percent, less the MFP adjustment of 0.7 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(C) of the Act.

2. Development of the FY 2013 LTCH PPS Standard Federal Rate

We continue to believe that the annual update to the LTCH PPS standard Federal rate should be based on the most recent estimate of the increase in the LTCH PPS market basket, including any statutory adjustments. Consistent with our historical practice, we applied the annual update to the LTCH PPS standard Federal rate from the previous year. In determining the

standard Federal rate for FY 2013, we also made certain regulatory adjustments. Specifically, we made a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3), as discussed in greater detail in section VII.E.4. of the preamble of this final rule (which will not be applicable to payments for discharges occurring prior to December 29, 2012, consistent with the statute. In addition, in determining the FY 2013 standard Federal rate, we applied a budget neutrality adjustment factor for the changes related to the area wage adjustment (that is, changes to the wage data and labor-related share) in accordance with § 412.523(d)(4).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51771 and 51807), we established an annual update to the LTCH PPS standard Federal rate of 1.8 percent for FY 2012 based on the full estimated LTCH PPS market basket increase of 2.9 percent, less the MFP adjustment of 1.0 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(viii), we established an annual update to the standard Federal rate for FY 2012 of 1.8 percent. That is, we applied an update factor of 1.018 to the FY 2011 Federal rate of $39,599.95 to determine the FY 2012 standard Federal rate. Furthermore, for FY 2012, we applied an area wage level budget neutrality factor of 0.99775 to the standard Federal rate to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, we established a standard Federal rate for FY 2012 of $40,222.05 (calculated as $39,599.95 x 1.018 x 0.99775), which is applicable to LTCH PPS discharges occurring on or after October 1, 2011, through September 30, 2012.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28153), we proposed to establish an annual update to the LTCH PPS standard Federal rate of 2.1 percent for FY 2013, based on the full estimated increase in the proposed LTCH PPS market basket of 3.0 percent less the proposed MFP adjustment of 0.8 percentage point, consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act. Therefore, under proposed § 412.523(c)(3)(ix)(A), we proposed to apply a factor of 1.021 to the FY 2012 standard Federal rate of $40,222.05 (as established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51807)) to determine the proposed FY 2013 standard Federal rate. In that same proposed rule, we also proposed that the standard Federal rate for FY 2013 would be further adjusted by the proposed one-time prospective adjustment factor for FY 2013 of 0.98734 under proposed § 412.523(d)(3) (ii)(which would not be applicable to payments for discharges occurring prior to December 29, 2012, consistent with the statute). In addition, for FY 2013, we proposed to apply an area wage level budget neutrality factor of 0.99903 to the standard Federal rate to ensure that any changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, that same proposed rule, we proposed to establish a standard Federal rate for FY 2013 of $40,507.48 (calculated as $40,222.05 × 1.021 × 0.98734 × 0.99903). Furthermore, consistent with the statute, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 would not apply to payments for discharges occurring before December 29, 2012. Therefore, we proposed that payment for discharges occurring on or after October 1, 2012 and on or before December 28, 2012, would not reflect that proposed adjustment and instead would

be paid based on a standard Federal rate of $41,026.88 (calculated as $40,507.48 divided by 0.98734).

Comment: One commenter stated that the proposed update to the standard Federal rate for FY 2013 did not take into account the expected "across the board 2-percent payment cut or sequester" that will be effective in January 2013 under current law. In light of the impending sequester, the commenter recommended that CMS vacate the implementation of the proposed MFP adjustment and the 0.1 percentage point reduction required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act, as well as the proposed one-time prospective adjustment of approximately -1.3 percent. Another commenter requested that CMS provide guidance on how CMS will implement the 2-percent sequestration reduction to Medicare payment to LTCHs that will take effective in January 2013, as required under current law.

Response: Section 1886(m)(3)(A) of the Act specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the "other adjustment" specified in sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as "the multifactor productivity (MFP) adjustment") described in section 1886(b)(3)(B)(xi)(II) of the Act.

Specifically, for FY 2013, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the standard Federal rate be reduced by the productivity adjustment ("the MFP adjustment") described in section 1886(b)(3)(B)(xi)(II) of the Act, and sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act require that any annual update to the standard

Federal rate be reduced by 0.1 percentage point. Therefore, we are not adopting the commenter's suggestion to not apply these statutorily required adjustments in determining the FY 2013 standard Federal rate. In section VII.E.4. of the preamble of this final rule, we discuss and provide responses to the public comments we received on our proposal to apply a one-time prospective adjustment of approximately -1.3 percent in determining the FY 2013 standard Federal rate. For the reasons discussed in that section, we continue to believe it is appropriate to apply a one-time prospective adjustment to the standard Federal rate for FY 2013, and therefore are not adopting the commenter's suggestion to vacate the application of that adjustment.

We are not addressing the implementation of the spending reductions (sequestration order) required by Pub. L.112-25 (the Budget Control Act of 2011) in this final rule as those provisions would impact Medicare payments across settings, and not just affect LTCH PPS payments.

In this final rule, for FY 2013, as noted above and as discussed in greater detail in section VII.D.2. of the preamble of this final rule, consistent with our historical practice, we are establishing an annual update to the LTCH PPS standard Federal rate of 1.8 percent, based on the full estimated increase in the LTCH PPS market basket of 2.6 percent less the MFP adjustment of 0.7 percentage point consistent with section 1886(m)(3)(A)(i) and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act. Furthermore, as discussed in section VII.E.4. of the preamble of this final rule, in determining the standard Federal rate for FY 2013, we are making a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) of approximately -1.3 percent (which will not be applicable to payments for discharges occurring prior to December 29, 2012, consistent with the statute).

In this final rule, under § 412.523(c)(3)(ix)(A), we applied a factor of 1.018 to the FY 2012 standard Federal rate of $40,222.05 (as established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51807)) to determine the FY 2013 standard Federal rate. In addition, as discussed in section VII.E.4. of the preamble of this final rule, the standard Federal rate is further adjusted by the one-time prospective adjustment factor of 0.98734 for FY 2013 under § 412.523(d)(3)(ii). However, consistent with the statute, we specify at § 412.523(c)(3)(ix)(B) that, for payments for discharges occurring on or after October 1, 2012, and before December 29, 2012, payments are based on the standard Federal rate in paragraph (c)(3)(ix)(A) of this section without regard to the one-time prospective adjustment provided for under § 412.523(d)(3)(ii). In addition, as discussed in greater detail in section V.B.5. of this Addendum, for FY 2013, we applied an area wage level budget neutrality factor of 0.999265 to the standard Federal rate to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, in this final rule, under § 412.523(c)(3)(ix)(A), we established a standard Federal rate for FY 2013 of $40,397.96 (calculated as $40,222.05 x 1.018 x 0.98734 x 0.999265). Furthermore, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 will not be applied to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, will not reflect this adjustment and instead will be paid based on a standard Federal rate of $40,915.95 (calculated as $40,397.96 divided by 0.98734).

B. Adjustment for Area Wage Levels under the LTCH PPS for FY 2013

1. Background

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal rate to account for differences in LTCH area wage levels at § 412.525(c). The labor-related share of the LTCH PPS standard Federal rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage index level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH wage index values are the full LTCH PPS wage index values calculated based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Geographic Classifications/Labor Market Area Definitions

As discussed in the August 30, 2002 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 56015 through 56019), in establishing an adjustment for area wage levels, the labor-related portion of a LTCH's Federal prospective payment is adjusted by using an appropriate wage index based on the labor market area in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment at existing

§ 412.525(c) is made on the basis of the location of the LTCH in either an urban area or a rural area as defined in § 412.503. Currently under the LTCH PPS at § 412.503, an "urban area" is defined as a Metropolitan Statistical Area (which would include a metropolitan division, where applicable) as defined by the Executive OMB and a "rural area" is defined as any area outside of an urban area.

In the RY 2006 LTCH PPS final rule (70 FR 24184 through 24185), in regulations at § 412.525(c), we revised the labor market area definitions used under the LTCH PPS effective for discharges occurring on or after July 1, 2005, based on the Executive OMB's CBSA designations, which are based on 2000 Census data. We made this revision because we believe that the CBSA-based labor market area definitions will ensure that the LTCH PPS wage index adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We note that these are the same CBSA-based designations implemented for acute care hospitals under the IPPS at § 412.64(b) (69 FR 49026 through 49034). (For further discussion of the CBSA-based labor market area (geographic classification) definitions currently used under the LTCH PPS, we refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191).) We have updated the LTCH PPS CBSA-based labor market area definitions annually since they were adopted for RY 2006 (73 FR 26812 through 26814, 74 FR 44023 through 44204, and 75 FR 50444 through 50445).

In OMB Bulletin No. 10-2, issued on December 1, 2009, OMB announced that the CBSA changes in that bulletin would be the final update prior to the 2010 Census of Population and Housing. (The OMB bulletin is available on the OMB Web site at http://www.whitehouse.gov/OMB. Go to "Agency Information" and click on "Bulletins".) We

adopted those changes under the LTCH PPS in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444 through 50445), effective beginning October 1, 2010, and adopted their continued use for FY 2012 (76 FR 51808).

In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data. We did not receive any public comments on our proposal. Therefore, in this final rule, consistent with our proposal, for the FY 2013 area wage adjustment, we will continue to use the same labor market areas that we adopted for FY 2012.

3. LTCH PPS Labor-Related Share

Under the adjustment for differences in area wage levels at § 412.525(c), the labor-related share of a LTCH's PPS Federal prospective payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All-Other: Labor-Related Services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket.

For FY 2012, we revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2008-based RPL market basket. Accordingly, the current LTCH PPS labor-related share is based on the relative importance of the labor-related share of operating costs and capital costs of the RPL market basket based on FY 2008 data, as those were the best available data at that time that reflected the cost structure of LTCHs. For FY 2012, we established a labor-related share of 70.199 percent based on the best available data at that time from the FY 2008-based RPL market basket for FY 2012 (76 FR 51766 through 51769 and 51808). (Additional background information on the historical development of the labor-related

share under the LTCH PPS and the development of the RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830).)

As discussed in section VII.C. of the preamble of this final rule, we are revising and rebasing the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. As we proposed, in this final rule, we determined the labor-related share for FY 2013 as the sum of the FY 2013 relative importance of each labor-related cost category of the FY 2009-based LTCH-specific market basket. Consistent with the current labor-related share determined from the relative importance of each labor-related cost category of the FY 2008-based RPL market basket, we determined the LTCH PPS labor-related share for FY 2013 based on the relative importance of the labor-related share of operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-Related Services) and the labor-related share of capital costs of the LTCH-specific market basket based on FY 2009 data, as we believe these are currently the best data available to reflect the cost structure of LTCHs.

In this final rule, consistent with our proposal to use the most recent available data to determine the labor-related share for FY 2013, we are establishing a labor-related share under the LTCH PPS for FY 2013 based on IGI's second quarter 2012 forecast of the FY 2009-based LTCH-specific market basket for FY 2013, as these are the most recent available data at this time that reflect the cost structure of LTCHs. As discussed in greater detail in section VII.D.3.f. of this preamble, the sum of the relative importance for FY 2013 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All-Other: Labor-related Services) is 58.843 percent and the labor-related share of capital costs is 4.253 percent. Therefore, in this final rule, under the authority set forth

in section 123 of the BBRA as amended by section 307(b) of the BIPA, we are establishing a labor-related share of 63.096 percent (58.843 percent plus 4.253 percent) under the LTCH PPS for FY 2013, which will be effective for discharges occurring on or after October 1, 2012, and through September 30, 2013. (For additional details on the development of the LTCH PPS labor-related share for FY 2013, we refer readers to section VII.D.3.f. of the preamble of this final rule.)

4. LTCH PPS Wage Index for FY 2013

Historically, under the LTCH PPS, we have established LTCH PPS wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on a LTCH's actual location without regard to the urban or rural designation of any related or affiliated provider.

In the FY 2012 LTCH PPS final rule (76 FR 51808 through 51809), we calculated the FY 2012 LTCH PPS wage index values using the same data used for the FY 2012 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2008), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2012 LTCH PPS wage index values consistent with the urban and rural geographic classifications (labor market areas) and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located (as

discussed in section III.D. of the preamble of this final rule). We also continued to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable wage index values under the LTCH PPS for FY 2013, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, as we proposed, we used wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2009, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We used FY 2009 data because these data are the most recent complete data available. These are the same data used to compute the FY 2013 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule. (For our rationale for using IPPS hospital wage data as a proxy for determining the wage index values used under the LTCH PPS, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44024 through 44025).)

As we proposed, the FY 2013 LTCH PPS wage index values we are presenting in this final rule are computed consistent with the urban and rural geographic classifications (labor market areas) discussed above in section V.B.2. of the Addendum to this final rule and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus or campuses are located (as discussed in section III.G. of the preamble of this final rule). Furthermore, in determining the FY 2013 LTCH PPS

wage index values in this final rule, as we proposed, we continued to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

As discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28154), we established a methodology for determining LTCH PPS wage index values for areas that have no IPPS wage data in the RY 2009 LTCH PPS final rule, and as we proposed, we are continuing to use this methodology for FY 2013. (We refer readers to the RY 2009 LTCH PPS final rule (73 FR 26817 through 26818) for an explanation of and rationale for our policy for determining LTCH PPS wage index values for areas that have no IPPS wage data.)

There are currently no LTCHs located in labor areas without IPPS hospital wage data (or IPPS hospitals) for FY 2013. However, we calculate LTCH PPS wage index values for these areas using our established methodology in the event that, in the future, a LTCH should open in one of those areas. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2009 IPPS wage data that we used to determine the FY 2013 LTCH PPS wage index values in this final rule, there are no IPPS wage data for the urban area Hinesville-Fort Stewart, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the FY 2013 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this final rule and

available via the Internet on the CMS Web site). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on FY 2009 IPPS wage data that we used to determine the FY 2013 LTCH PPS wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data for FY 2013. We note that, as IPPS wage data are dynamic, it is possible that rural areas without IPPS wage data will vary in the future.

The FY 2013 LTCH wage index values that will be applicable for LTCH discharges occurring on or after October 1, 2012, through September 30, 2013, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site.

5. Budget Neutrality Adjustment for Changes to the Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809), under § 412.525(c)(2), we established that any changes to the wage index values or labor-related share will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that will be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment are budget neutral such that any changes to the wage index values or labor-related share will not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we established that we will apply an area

wage level adjustment budget neutrality factor in determining the standard Federal rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor.

For FY 2013, in accordance with § 412.523(d)(4), we applied an area wage level adjustment budget neutrality factor to adjust the standard Federal rate to account for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, as we proposed, we determined an area wage level adjustment budget neutrality factor that will be applied to the standard Federal rate under at § 412.523(d)(4) for FY 2013 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS payments using the FY 2012 wage index values (as established in Tables 12A and 12B listed in the Addendum to the FY 2012 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site) and the FY 2012 labor-related share of 70.199 percent (as established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51767 and 51808).

Step 2—We simulated estimated aggregate LTCH PPS payments using the FY 2013 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this final rule and available via the Internet on the CMS Web site) and the FY 2013 labor related share of 63.096 percent (based on the latest available data as discussed in section VII.C.3.f. of this preamble).

Step 3—We calculated the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2012 area wage level adjustments

(calculated in Step 1) by the estimated total LTCH PPS payments using the FY 2013 area wage level adjustments (calculated in Step 2) to determine the area wage level adjustment budget neutrality factor for FY 2013.

Step 4—We then applied the FY 2013 area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2013 LTCH PPS standard Federal rate after the application of the FY 2013 annual update (discussed in section V.A.2. of the Addendum to this final rule). For this final rule, using the steps in the methodology described above, we determined a FY 2013 area wage level adjustment budget neutrality factor of 0.999265. Accordingly, in section V.A.2. of the Addendum to this final rule, to determine the FY 2013 LTCH PPS standard Federal rate, we applied an area wage level adjustment budget neutrality factor of 0.099265, in accordance with § 412.523(d)(4). The FY 2013 LTCH PPS standard Federal rate shown in Table 1E of the Addendum to this final rule reflects this adjustment factor.

C. LTCH PPS Cost-of-Living Adjustment for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels described above.

Historically, we used the most recent updated COLA factors obtained from the U.S. Office of Personnel Management (OPM) Web site at http://www.opm.gov/oca/cola/rates.asp to adjust the LTCH PPS payments for LTCHs in Alaska and Hawaii. Recent statutory changes transition the Alaska and Hawaii COLAs to locality pay (phased in over a 3-year period

beginning in January 2010, with COLA rates being frozen as of October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay). As stated previously, we do not believe it is appropriate to use either the 2010 or 2011 reduced COLA factors to adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii for Medicare payment purposes. Therefore, for FY 2012, we continued to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii.

As we discuss in section VII.D.4. of the preamble of this final rule, we believe it was appropriate to use "frozen" COLA factors to adjust payments in FY 2012, while we explored alternatives for updating the COLA factors in the future. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28019 through 28020 and 28155), we proposed to continue to use the same "frozen" COLA factors used in FY 2012 to adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii in FY 2013 under § 412.525(b). In that same proposed rule, we also proposed a methodology to update the COLA factors for Alaska and Hawaii, beginning in FY 2014, based on a comparison of the growth in the CPIs for Anchorage, Alaska and Honolulu, Hawaii relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). As discussed in section VII.D.4. of the preamble of this final rule, we did not receive any public comments on these proposals and we are adopting them as final, without modification, in this final rule. As explained previously, we believe using these COLA factors will appropriately adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii. (For additional details on the methodology we are adopting in this final rule to update the COLA factors for Alaska and

Hawaii beginning in FY 2014, we refer readers to section VII.D.4. of the preamble of this final rule.)

In this final rule, for FY 2013, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, consistent with our current policy, we are applying a COLA to the LTCH PPS payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the factors listed in the chart below. These factors are the same COLA factors used to adjust payments in FY 2012 (which are based on OPM's 2009 COLA factors). As stated above, we believe using these COLA factors will appropriately adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii under § 412.525(b).

Cost-of-Living Adjustment Factors for Alaska and Hawaii Hospitals for the LTCH PPS for FY 2013

Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
All other areas of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: http://www.opm.gov/oca/cola/rates.asp.)

D. Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. Background

Under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in the regulations at § 412.525(a), we established an adjustment for additional payments for outlier cases that have extraordinarily high costs relative to the costs of most discharges. We refer to these cases as high cost outliers (HCOs). Providing additional payments for outliers strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. These additional payments reduce the financial losses that would otherwise be incurred when treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. We set the outlier threshold before the beginning of the applicable rate year so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS.

Under § 412.525(a) in the regulations (in conjunction with § 412.503), we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted LTCH PPS payment for the MS-LTC-DRG plus a fixed-loss amount. Specifically, in accordance with

§ 412.525(a)(3) (in conjunction with § 412.503), we make an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the patient case and the outlier threshold, which is the sum of the adjusted Federal prospective payment for the MS-LTC-DRG and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital will incur under the outlier policy for a case with unusually high costs. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the LTCH PPS HCO policy, the LTCH's loss is limited to the fixed-loss amount and a fixed percentage of costs above the outlier threshold (adjusted MS-LTC-DRG payment plus the fixed-loss amount). The fixed percentage of costs is called the marginal cost factor. We calculate the estimated cost of a case by multiplying the Medicare allowable covered charge by the hospital's overall hospital cost-to-charge ratio (CCR).

Under the LTCH PPS HCO policy at § 412.525(a), we determine a fixed-loss amount, that is, the maximum loss that a LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by estimating aggregate payments with and without an outlier policy. The fixed-loss amount results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments. Currently, MedPAR claims data and CCRs based on data from the most recent Provider-Specific File (PSF) (or from the applicable statewide average CCR if a LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

2. Determining LTCH CCRs under the LTCH PPS

a. Background

The following is a discussion of CCRs that are used in determining payments for HCO and SSO cases under the LTCH PPS, at § 412.525(a) and § 412.529, respectively. Although this section is specific to HCO cases, because CCRs and the policies and methodologies pertaining to them are used in determining payments for both HCO and SSO cases (to determine the estimated cost of the case at § 412.529(d)(2)), we are discussing the determination of CCRs under the LTCH PPS for both of these types of cases simultaneously.

In determining both HCO payments (at § 412.525(a)) and SSO payments (at § 412.529), we calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. In general, we use the LTCH's overall CCR, which is computed based on either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period, in accordance with § 412.525(a)(4)(iv)(B) and § 412.529(f)(4)(ii) for HCOs and SSOs, respectively. (We note that, in some instances, we use an alternative CCR, such as the statewide average CCR in accordance with the regulations at § 412.525(a)(4)(iv)(C) and § 412.529(f)(4)(iii), or a CCR that is specified by CMS or that is requested by the hospital under the provisions of the regulations at § 412.525(a)(4)(iv)(A) and § 412.529(f)(4)(i).) Under the LTCH PPS, a single prospective payment per discharge is made for both inpatient operating and capital-related costs. Therefore, we compute a single "overall" or "total" LTCH-specific CCR based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100-4)) as compared to total charges. Specifically, a LTCH's CCR is calculated by dividing a LTCH's total Medicare costs (that is, the sum of its operating and capital inpatient routine and ancillary costs) by its total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges).

b. LTCH Total CCR Ceiling

Generally, a LTCH is assigned the applicable statewide average CCR if, among other things, a LTCH's CCR is found to be in excess of the applicable maximum CCR threshold (that is, the LTCH CCR ceiling). This is because CCRs above this threshold are most likely due to faulty data reporting or entry, and, therefore, CCRs based on erroneous data should not be used to identify and make payments for outlier cases. Thus, under our established policy, generally, if a LTCH's calculated CCR is above the applicable ceiling, the applicable LTCH PPS statewide average CCR is assigned to the LTCH instead of the CCR computed from its most recent (settled or tentatively settled) cost report data.

In accordance with § 412.525(a)(4)(iv)(C)(2) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs, in the proposed rule, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the December 2011 update of the PSF, we proposed to establish a total CCR ceiling of 1.210 under the LTCH PPS that would be effective for discharges occurring on or after October 1, 2012, through September 30, 2013. Consistent with our historical policy of using the best available data, we also proposed that if more recent data became available, we would use such data to establish a total CCR ceiling for FY 2013 in the final rule. We did not receive any public comments on our proposals related to determining the LTCH total CCR ceiling for FY 2013, and are adopting them as final, without modification, in this final rule.

In accordance with § 412.525(a)(4)(iv)(C)(2) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs, in this final rule, as we proposed, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the latest available data (that is, the March 2012 update of the PSF), we are establishing a total CCR

ceiling of 1.212 under the LTCH PPS that will be effective for discharges occurring on or after October 1, 2012, through September 30, 2013.

c. LTCH Statewide Average CCRs

Our general methodology established for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling (described above) because it is based on "total" IPPS CCR data. Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C) and the SSO policy at § 412.529(f)(4)(iii), the fiscal intermediary or MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for a LTCH in one of the following circumstances: (1) new LTCHs that have not yet submitted their first Medicare cost report (for this purpose, consistent with current policy, a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose CCR is in excess of the LTCH CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the fiscal intermediary or MAC may consider in determining a LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as a LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

In the proposed rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS total CCR data from the December 2011 update of the PSF, we proposed LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1,

2012, through September 30, 2013, in Table 8C listed in section VI. of the Addendum to that proposed rule and available via the Internet. We did not receive any public comments on our proposals related to determining the LTCH PPS statewide average CCRs for FY 2013, and are adopting them as final, without modification, in this final rule.

Consistent with our historical practice of using the best available data, in this final rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS "total CCR" data from the March 2012 update of the PSF, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2012, through September 20, 2013, in Table 8C listed in section VI. of the Addendum to this final rule (and available via the Internet).

All areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS.

In addition, as we proposed, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, in this final rule, we continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We use this proxy because we believe that the CCR data on the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of LTCH HCO and SSO Payments

We note that under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(D) and the LTCH PPS SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO cases, respectively, are subject to reconciliation. Specifically, any reconciliation of outlier payments is based on the CCR that is calculated based on a ratio of cost-to-charge data computed from the relevant cost report determined at the time the cost report coinciding with the discharge is settled. For additional information, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100-4) as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Establishment of the LTCH PPS Fixed-Loss Amount for FY 2013

When we implemented the LTCH PPS, as discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56026), under the broad authority of section 123 of the BBRA as amended by section 307(b) of BIPA, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS. To determine the fixed-loss amount, we estimate outlier payments and total LTCH PPS payments for each case using claims data from the MedPAR files. Specifically, to determine the outlier payment for each case, we estimate the cost of the case by multiplying the Medicare covered charges from the claim by the LTCH's CCR. Under § 412.525(a)(3) (in conjunction with § 412.503), if the estimated cost of the case exceeds the outlier threshold, we make an outlier payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (that is, the sum of the adjusted Federal prospective payment for the MS-LTC-DRG and the fixed-loss amount).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28175), we presented our proposals regarding the methodology and data we would use to calculate the fixed-loss amount for FY 2013. In general, we proposed to continue to use our existing methodology to calculate a fixed-loss amount for FY 2013 using the best available data that would maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments (based on the rates and policies presented in that proposed rule). (For additional detail on the rationale for setting the HCO payment "target" at 8 percent of total estimated LTCH PPS payments, we refer readers to the to the FY 2003 LTCH PPS final rule (67 FR 56022 through 56024).) Using our existing methodology, we proposed a fixed-loss amount of $15,728 for FY 2013. (We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule for additional details on our proposals related to the development of the fixed-loss amount for FY 2013 (77 FR 28157).)

Comment: A few commenters expressed support for the proposed fixed-loss amount for FY 2013, stating that the lower fixed-loss amount calculated using our proposed methodology would maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments, consistent with current policy.

Response: We appreciate the commenters' support for our proposed methodology.

In this final rule, we are adopting our proposal as final without modification. However, consistent with our historical practice of using the best available data, and our proposal to use more recent data if they become available, we used the most recent available LTCH claims data and CCR data at this time to calculate the fixed-loss amount for FY 2013 for this final rule.

In this final rule, we continued to use our existing methodology to calculate the fixed-loss amount for FY 2013 (based on the data and the rates and policies presented in this final rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH

PPS payments. Consistent with our historical practice of using the best data available, in determining the fixed-loss amount for FY 2013, we used the most recent available LTCH claims data and CCR data at this time. Specifically, for this final rule, we used LTCH claims data from the March 2012 update of the FY 2011 MedPAR file and CCRs from the March 2012 update of the PSF to determine a fixed-loss amount that would result in estimated outlier payments projected to be equal to 8 percent of total estimated payments in FY 2013 because these data are the most recent complete LTCH data available at this time.

Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we established a fixed-loss amount of $17,931 for FY 2012. For this final rule, we are establishing a fixed-loss amount of $15,408 for FY 2013. Thus, we will make an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal LTCH payment for the MS-LTC-DRG and the fixed-loss amount of $15,408). We also note that the fixed-loss amount of $15,408 for FY 2013 is lower than the FY 2012 fixed-loss amount of $17,931 and slightly lower than the proposed FY 2013 fixed-loss amount of $15,728. Based on our payment simulations using the most recent available data at this time, the decrease in the fixed-loss amount for FY 2013 is necessary to maintain the existing requirement that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments. (For further information on the existing 8 percent HCO "target" requirement, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024). Maintaining the fixed-loss amount at the current level would result in HCO payments that are less than the current regulatory 8-percent requirement because a higher fixed-loss amount would result in fewer cases qualifying as outlier cases. In addition, maintaining the higher fixed-loss amount would result in

a decrease in the amount of the additional payment for an HCO case because the maximum loss that a LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be larger. For these reasons, we believe that lowering the fixed-loss amount is appropriate and necessary to maintain that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments as required under § 412.525(a).

4. Application of Outlier Policy to SSO Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026), under some rare circumstances, a LTCH discharge could qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case. In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS-LTC-DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the fixed-loss amount), the discharge is eligible for payment as an HCO. Thus, for an SSO case in FY 2013, the HCO payment would be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the fixed-loss amount of $15,408 and the amount paid under the SSO policy as specified in § 412.529).

E. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2013

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal rate. Under § 412.525(c), the standard Federal rate is adjusted to account for differences in area wages by multiplying the labor-related share of the standard Federal rate by the applicable LTCH PPS wage index (FY 2013 values shown in Tables 12A and 12B listed in section VI. of the Addendum of this final rule and available via the Internet). The standard Federal rate is also adjusted to account for the higher costs of hospitals in Alaska and Hawaii by multiplying the

nonlabor-related portion of the standard Federal rate by the applicable cost-of-living factor (FY 2013 factors shown in the chart in section V.C. of the Addendum of this final rule) in accordance with § 412.525(b). In this final rule, we are establishing a standard Federal rate for FY 2013 of $40,397.96 (however, payment for discharges occurring on or after October 1, 2012, and before December 29, 2012 will not reflect that adjustment consistent with the statute, and instead will be paid based on a standard Federal rate of $40,915.95), as discussed above in section V.A.2. of the Addendum of this final rule. We illustrate the methodology to adjust the LTCH PPS Federal standard rate for FY 2013 in the following example:

Example:

During FY 2013, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974) and discharged on January 1, 2013. The FY 2013 LTCH PPS wage index value for CBSA 16974 is 1.0600 (obtained from Table 12A listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site). The Medicare patient is classified into MS-LTC-DRG 28 (Spinal Procedures with MCC), which has a relative weight for FY 2013 of 1.1124 (obtained from Table 11 listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site).

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient in FY 2013, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2013 standard Federal rate ($40,397.96) by the labor-related share (63.096 percent) and the wage index value (1.0600). This wage-adjusted amount is then added to the nonlabor-related portion of the unadjusted standard Federal rate (36.904 percent; adjusted for cost of living, if applicable) to determine the adjusted Federal rate, which is then multiplied by the MS-LTC-DRG relative weight (1.1124) to calculate the total adjusted Federal LTCH PPS

prospective payment for FY 2013 ($46,693.95). The table below illustrates the components of the calculations in this example.

Unadjusted Standard Federal Prospective Payment Rate	$40,397.96
Labor-Related Share	x 0.63096
Labor-Related Portion of the Federal Rate	= $25,489.49
Wage Index (CBSA 16974)	x 1.0600
Wage-Adjusted Labor Share of Federal Rate	= $27,018.6
Nonlabor-Related Portion of the Federal Rate ($40,397.96 x 0.36904)	+ $14,908.46
Adjusted Federal Rate Amount	= $41,927.32
MS-LTC-DRG 28 Relative Weight	x 1.1124
Total Adjusted Federal Prospective Payment	= $46,639.95

VI. Tables Referenced in this Final Rule and Available Only through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this final rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FY 2012, for the FY 2013 rulemaking cycle, the IPPS and LTCH tables will not be published as part of the annual IPPS/LTCH PPS proposed and final rulemakings and will be available only through the Internet. Specifically, IPPS Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 5, 6A, 6B, 6C, 6D, 6E, 6F, 6G, 6I, 6I.1, 6.I.2, 6J, 6J.1, 6K, 7A, 7B, 8A, 8B, 9A, 9C, 10 and new Tables 15 and 16 and LTCH PPS Tables 8C, 11, 12A, 12B, 13A, and 13B will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS table 1E, displayed at the end of this section, will continue to be published in the **Federal Register** as part of the annual proposed and final rules. As discussed in section II.G.9. of the preamble of this final rule, for FY 2013, there will be one change to the ICD-9-CM coding system, effective October 1, 2012. We are creating new procedure code 00.95 (Injection or infusion of glucarpidase). The new procedure code is listed in Table 6B (New Procedure Codes) for this final rule, which is available via the Internet. There are no new, revised, or deleted diagnosis codes and no revised or deleted procedure codes effective October 1, 2012, that are usually announced in Tables 6A (New Diagnosis Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles), and 6F (Revised Procedure Codes). Therefore, IPPS Tables 6A, 6C, 6D, 6E and 6F are not being published as part of this FY 2013 rulemaking cycle. As discussed in section IV.E. of the preamble of this final rule, effective FY 2013 and forward, the low-volume hospital definition and payment adjustment methodology under section 1886(d)(12) of the Act returns to the pre-

Affordable Care Act definition and payment adjustment methodology (we refer readers to section IV.E. for complete details on the low-volume hospital payment adjustment). Therefore, we are no longer including a table (previously Table 14) in this final rule that lists the low-volume payment adjustments.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified below should contact Michael Treitel at (410) 786-4552.

The following IPPS tables for this FY 2013 final rule are available only through the Internet on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. Click on the link on the left side of the screen titled, "FY 2013 IPPS Final Rule Home Page" or "Acute Inpatient – Files for Download".

Table 2.—Acute Care Hospitals Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2011; Hospital Wage Indexes for Federal Fiscal Year 2013; Hospital Average Hourly Wages for Federal Fiscal Years 2011 (2007 Wage Data), 2012(2008 Wage Data), and 2013 (2009 Wage Data); and 3-Year Average of Hospital Average Hourly Wages

Table 3A.—FY 2013 and 3-Year* Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA

Table 3B.—FY 2013 and 3-Year* Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA

Table 4A.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State--FY 2013

Table 4B.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State--FY 2013

Table 4C.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State--FY 2013

Table 4D.—States Designated as Frontier, with Acute Care Hospitals Receiving at a Minimum the Frontier State Floor Wage Index[1]; Urban Areas with Acute Care Hospitals Receiving the Statewide Rural Floor or Imputed Floor Wage Index—FY 2013

Table 4E.—Urban CBSAs and Constituent Counties for Acute Care Hospitals--FY 2013

Table 4F.—Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA--FY 2013

Table 4J.—Out-Migration Adjustment for Acute Care Hospitals—FY 2013

Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS-DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay--FY 2013

Table 6B.—New Procedure Codes – FY 2013

Table 6G.—Additions to the CC Exclusions List-FY 2013

Table 6I.—MajorCC List—FY 2013

Table 6I.2.—Summary of Deletions from the MS-DRG MCC List—FY 2013

Table 6J.—Complete CC List—FY 2013

Table 6J.1.—Summary of Additions to the MS-DRG CC List—FY 2013

Table 6K.—Complete List of CC Exclusions—FY 2013

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2011 MedPAR Update—March 2012 GROUPER V29.0 MS-DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2011 MedPAR Update—March 2012 GROUPER V30.0 MS-DRGs

Table 8A.—FY 2013 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—FY 2013 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A.—Hospital Reclassifications and Redesignations--FY 2013

Table 9C.—Hospitals Redesignated as Rural under Section 1886(d)(8)(E) of the Act--FY 2013

Table 10.—New Technology Add-On Payment Thresholds for Applications for FY 2014

Table 15.—FY 2013 Final Readmissions Adjustment Factors

Table 16.—Proxy Hospital Inpatient Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2013

The following LTCH PPS tables for this FY 2013 final rule are available only through the Internet on the CMS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html under the list item for Regulation Number CMS-1588-F.

Table 8C.—FY 2013 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—MS-LTC-DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for Discharges Occurring from October 1, 2012 through September 30, 2013 under the LTCH PPS

Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2012 through September 30, 2013

Table 12B.—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2012 through September 30, 2013

Table 13A.—Composition of Low-Volume Quintiles for MS-LTC-DRGs—FY 2013

Table 13B.—No-Volume MS-LTC-DRG Crosswalk for FY 2013

TABLE 1A.—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.8 PERCENT LABOR SHARE/31.2 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2013

Full Update (1.8 Percent)		Reduced Update (-0.2 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,679.95	$1,668.81	$3,607.65	$1,636.02

TABLE 1B.—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)--FY 2013

Full Update (1.8 Percent)		Reduced Update (-0.2 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,316.23	$2,032.53	$3,251.08	$1,992.59

TABLE 1C.—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR--FY 2013

	Rates if Wage Index is Greater Than 1		Rates if Wage Index is Less Than or Equal to 1	
	Labor	**Nonlabor**	**Labor**	**Nonlabor**
National	$3,679.95	$1,668.81	$3,316.23	$2,032.53
Puerto Rico	$1,564.17	$954.62	$1,561.65	$957.14

TABLE 1D.—CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2013

	Rate
National	$425.49
Puerto Rico	$207.25

TABLE 1E.—LTCH STANDARD FEDERAL PROSPECTIVE PAYMENT RATE--FY 2013

	Rate
Standard Federal Rate*	$40,397.96

* Consistent with section 114(c)(4) of the MMSEA as amended by sections 3106(a) and 10312 of the Affordable Care Act, the one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 is not applied to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, does not reflect that adjustment and instead such discharges are paid based on a standard Federal rate of $40,915.95 (calculated as $40,397.96 divided by 0.98734).

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this final rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the changes for FY 2013 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $2.45 billion increase in FY 2013 operating payments (or 2.3 percent change) and an estimated $154 million increase in FY 2013 capital payments (or 1.8 percent change). These changes are relative to payments made in FY2012. The impact

analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by $92 million in FY 2013 relative to FY 2012.

Our operating impact estimate includes the 1.0 percent documentation and coding adjustment applied to the IPPS standardized amounts (which accounts for the -1.9 percent documentation and coding adjustment and +2.9 percent adjustment to restore the one-time recoupment adjustment made to the national standardized amount for FY 2012). In addition, our operating impact estimate includes the 1.8 percent hospital update to the standardized amount (which includes the 2.6 percent market basket update less 0.7 percentage point for the multifactor productivity adjustment and less 0.1 percentage point required under the Affordable Care Act). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule will affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant.

B. Need

This final rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS payment system.

C. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2013, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix.

E. Hospitals Included in and Excluded from the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 32 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the

prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, only the 45 such hospitals in Maryland remain excluded from the IPPS pursuant to the waiver under section 1814(b)(3) of the Act.

As of July 2012, there are 3,423 IPPS acute care hospitals included in our analysis. This represents about 67 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,328 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. There are also 1,268 IPPS-excluded hospitals and 2,063 IPPS-excluded hospital units. These IPPS-excluded hospitals and units include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, and cancer hospitals, which are paid under separate payment systems. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2013 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2012, there were 3,331 hospitals and hospital units excluded from the IPPS. Of these, 94 children's hospitals, 11 cancer hospitals, and 18 RNHCIs are being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. The remaining providers, 231 rehabilitation hospitals and 908 rehabilitation units, and 442 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 472 psychiatric hospitals and 1,155 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated above, IRFs and IPFs are not affected by the rate updates discussed in

this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix.

In the past, certain hospitals and units excluded from the IPPS have been paid based on their reasonable costs subject to limits as established by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Cancer and children's hospitals continue to be paid on a reasonable cost basis subject to TEFRA limits for FY 2013. For these hospitals (cancer and children's hospitals), consistent with the authority provided in section 1886(b)(3)(B)(ii) of the Act, the update is the estimated FY 2013 percentage increase in the IPPS operating market basket. In compliance with section 404 of the MMA, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43930), we replaced the FY 2002-based IPPS operating and capital market baskets with the revised and rebased FY 2006-based IPPS operating and capital market baskets. Therefore, consistent with current law, based on IHS Global Insight, Inc.'s 2012 second quarter forecast, with historical data through the 2012 first quarter, we are estimating that the FY 2013 update based on the IPPS operating market basket is 2.6 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently 0.7 percentage point) and a 0.1 percentage point reduction to the market basket update resulting in a 1.8 percent applicable percentage increase for IPPS hospitals subject to a reduction of 2.0 percentage points if the hospital fails to submit quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act. RNCHIs, children's hospitals and cancer hospitals are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40. Therefore, for RNHCIs, the update is the same as for children's and cancer hospitals, which is the percentage increase in the FY 2013 IPPS

operating market basket, estimated at 2.6 percent, without the reductions required under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that will not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of 50 percent of its reasonable costs in excess of 110 percent of the limit, or 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, cancer and children's hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2013 for operating costs of acute care hospitals. The FY 2013 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2013 operating payments will increase by 2.3 percent compared to FY 2012. In addition to the applicable percentage increase, this amount

reflects the FY 2013 adjustments for documentation and coding described in section II.D. of the preamble of this final rule: 1.0 percent for the IPPS national standardized amounts and -0.5 percent for the IPPS hospital-specific rates. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain changes in this final rule. However, there are other changes for which we do not have data available that will allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented below are taken from the FY 2011 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables

with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2011 MedPAR file, we simulated payments under the operating IPPS given various combinations of payment parameters. As described above, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, or the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2013 are discussed in section I.I. of this Appendix.

We discuss the following changes below:

- The effects of the application of the documentation and coding adjustment and applicable percentage increase (including the market basket update, the multifactor productivity adjustment and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.

- The effects of the annual reclassification of diagnoses and procedures, full implementation of the MS-DRG system and 100 percent cost-based MS-DRG relative weights.

- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2009, compared to the FY 2008 wage data.

- The effects of the recalibration of the MS-DRG relative weights as required by section 1886(d)(4)(C) of the Act, including the wage and recalibration budget neutrality factors.

- The effects of the geographic reclassifications by the MGCRB that will be effective in FY 2013.

● The effects of the rural floor and imputed floor with the application of the national budget neutrality factor applied to the wage index, as required by the Affordable Care Act.

● The effects of the frontier State wage index provision that requires that hospitals located in States that qualify as frontier States cannot have a wage index less than 1.0. This provision is not budget neutral.

● The effects of the implementation of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

● The effects of the policies for implementation of the Hospital Readmissions Reduction Program under section 3025 of the Affordable Care Act, that adjusts hospital's base operating DRG amount by an adjustment factor to account for a hospital's excess readmissions.

● The effects of the expiration of the special payment status for MDHs under section 3124 of the Affordable Care Act under which MDHs that currently receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital-specific rate will be paid based on the Federal standardized amount starting in FY 2013.

● The total estimated change in payments based on the FY 2013 policies relative to payments based on FY 2012 policies that include the applicable percentage increase of 1.8 percent (or 2.6 percent market basket update with a reduction of 0.7 percentage point for the multifactor productivity adjustment, and a 0.1 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the FY 2013 changes, our analysis begins with a FY 2012 baseline simulation model using: the FY 2013 applicable percentage increase of 1.8 percent and the documentation and coding adjustment of 1.0 percent to the Federal standardized amount and the -0.5 percent documentation and coding adjustment to the hospital-specific rate; the FY 2012 MS-DRG GROUPER (Version 29.0); the most current CBSA designations for hospitals based on OMB's MSA definitions; the FY 2012 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS-DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Pub. L. 109-171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111-5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111-148), provides that, for FY 2007 and each subsequent year, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner and at a time specified by the Secretary. (Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act.) At the time that this impact was prepared, 52 hospitals did not receive the full market basket rate-of-increase for FY 2012 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the payment changes for FY 2013 using a reduced update for these 52 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2013.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2013 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our final comparison illustrates the percent change in payments per case from FY 2012 to FY 2013. Three factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2013 using an applicable percentage increase of 1.8 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.6 percent with a reduction of 0.7 percentage point for the multifactor productivity adjustment and a 0.1 percentage point reduction as required under the Affordable Care Act. (Hospitals that fail to comply with the quality data submission requirements will receive an update of -0.2 percent (this update includes the 2.0 percentage point reduction for failure to submit these data)). Under section 1886(b)(3)(B)(iv) of the Act, the updates to the hospital-specific amounts for SCHs are also equal to the applicable percentage increase, or 1.8 percent. In addition, we are updating the Puerto Rico-specific amount by an applicable percentage increase of 1.8 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2012 to FY 2013 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2012 that are no longer reclassified in FY 2013. Conversely, payments may increase for hospitals not reclassified in FY 2012 that are reclassified in FY 2013.

A third significant factor is that we currently estimate that actual outlier payments during FY 2012 will be 5.0 percent of total MS-DRG payments. Our updated FY 2012 outlier estimate

accounts for changes to the FY 2012 IPPS payments required under the Affordable Care Act. When the FY 2012 final rule was published, we projected FY 2012 outlier payments would be 5.1 percent of total MS-DRG plus outlier payments; the average standardized amounts were offset correspondingly. The effects of the lower than expected outlier payments during FY 2012 (as discussed in the Addendum to this final rule) are reflected in the analyses below comparing our current estimates of FY 2012 payments per case to estimated FY 2013 payments per case (with outlier payments projected to equal 5.1 percent of total MS-DRG payments).

Comment: Some commenters stated that CMS' FY 2013 IPPS/LTCH PPS proposed rule showed an increase in operating payments of 0.9 percent or $904 million by 2013, but that the estimated 0.9 percent increase failed to account for a decrease in IME payments which will be the consequence of changes CMS makes in calculating the number of beds to be included in its bed-to-resident ratio, as well as the expiration of temporary increases arising from the Affordable Care Act.

Response: Section H of the Addendum provides the impacts of other policy changes that we are not able to model in the IPPS payment simulation model in the IPPS Operating Impact statement. Finally, all estimates due to policy changes in the FY 2013 IPPS/LTCH PPS final rule are included in the Accounting Statement.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2013. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,423 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: all urban, which is further divided into large urban and other urban; and rural. There are 2,497 hospitals located in urban areas included in our analysis. Among these, there are 1,373 hospitals located in large urban areas (populations over 1 million), and 1,124 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 926 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2012 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,512; 1,383; 1,129; and 911, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive DSH payments, or some combination of these two adjustments. There are 2,392 nonteaching hospitals in our analysis, 789 teaching hospitals with fewer than 100 residents, and 242 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next five rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 203 RRCs, 326 SCHs, 195 former MDHs, and 118 hospitals that are both SCHs and RRCs, and 18 hospitals that were former MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2009 or FY 2008 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2013. The second grouping shows the MGCRB rural reclassifications. The final category shows the impact of the policy changes on the 19 cardiac hospitals.

TABLE I.— IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2013

	No. of Hospitals[1] (1)	Hospital Rate Update and Documenta-tion and Coding Adjust-ment [2] (2)	FY 2013 Weights and DRG Changes with Appli-cation of Recali-bration Budget Neu-trality[3] (3)	FY 2013 Wage Data with Appli-cation of Wage Budget Neu-trality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recali-bration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassi-fications[6] (6)	Rural Floor and Imputed Floor with Applica-tion of National Rural Floor Budget Neu-trality[7] (7)	Appli-cation of the Frontier Wage Index[8] (8)	FY 2013 Out-Migra-tion Adjust-ment[9] (9)	Expi-ration of MDH Status[10] (10)	Hospital Read-missions Reduc-tion Pro-gram[11] (11)	All FY 2013 Changes[12] (12)
All Hospitals	3,423	2.7	0	0	0	0	0	0.1	0	-0.2	-0.3	2.3
By Geographic Location:												
Urban hospitals	2,497	2.7	0	0	0.1	-0.2	0	0.1	0	0	-0.3	2.5
Large urban areas	1,373	2.7	0	0.2	0.2	-0.3	0	0	0.1	0	-0.3	2.6
Other urban areas	1,124	2.7	0	-0.2	-0.1	-0.1	0.2	0.2	0	-0.1	-0.2	2.4
Rural hospitals	926	2.3	-0.1	-0.3	-0.3	2.1	-0.3	0.1	0.1	-1.4	-0.3	0.3
Bed Size (Urban):												
0-99 beds	633	2.7	0	0.2	0.2	-0.6	0.2	0.2	0	-0.4	-0.2	2.5
100-199 beds	780	2.8	0	0.1	0.2	-0.1	0.3	0.1	0.1	-0.1	-0.3	2.5
200-299 beds	448	2.7	0	0.1	0.1	-0.2	0	0.1	0.1	0	-0.3	2.6
300-499 beds	430	2.7	0	0	0	-0.2	0.1	0.1	0	0	-0.2	2.6
500 or more beds	206	2.7	0	-0.1	0	-0.3	-0.1	0	0	0	-0.3	2.3
Bed Size (Rural):												
0-49 beds	321	2.3	-0.1	-0.4	-0.4	0.8	-0.3	0.1	0.2	-2.6	-0.3	-1.1
50-99 beds	347	2.2	-0.1	-0.3	-0.4	1.3	-0.3	0.1	0.2	-3.3	-0.2	-1.7
100-149 beds	153	2.3	-0.1	-0.3	-0.4	2.6	-0.3	0	0	-0.7	-0.3	1
150-199 beds	58	2.3	-0.1	-0.2	-0.3	2.3	-0.3	0.2	0	-0.2	-0.2	1.5
200 or more beds	47	2.2	0	-0.2	-0.2	3	-0.3	0	0	0	-0.2	2

CMS-1588-F

	No. of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassifications[6] (6)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Application of the Frontier Wage Index[8] (8)	FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status[10] (10)	Hospital Readmissions Reduction Program[11] (11)	All FY 2013 Changes[12] (12)
Urban by Region:												
New England	120	2.7	0	0.9	0.9	0.7	3.6	0	0.3	0	-0.3	1.5
Middle Atlantic	318	2.8	0	-0.1	0	0.1	-0.3	0	0.1	0	-0.4	1.7
South Atlantic	380	2.7	0	-0.4	-0.4	-0.4	-0.4	0	0	0	-0.2	2.3
East North Central	399	2.7	0	0.2	0.2	-0.2	-0.4	0	0	0	-0.3	2.6
East South Central	151	2.7	0	-1	-0.8	-0.3	-0.4	0	0	0	-0.3	1.8
West North Central	165	2.6	0	0.4	0.4	-0.7	-0.4	0.8	0	-0.1	-0.2	3
West South Central	372	2.7	0	-0.3	-0.3	-0.6	-0.4	0	0	-0.1	-0.1	2.4
Mountain	159	2.6	0	-0.3	-0.3	-0.3	0.6	0.2	0	0	-0.1	3.2
Pacific	382	2.7	-0.1	0.8	0.7	-0.2	0.6	0	0	0	-0.1	4
Puerto Rico	51	2.6	0	0.2	0.2	-0.8	0.1	0	0	0	0	2.6
Rural by Region:												
New England	23	2.4	-0.1	-0.3	-0.4	2.7	-0.4	0	0	-3.4	0	-0.8
Middle Atlantic	69	2.1	-0.1	-0.3	-0.4	1.8	-0.3	0	0	-1.6	-0.3	-0.1
South Atlantic	166	2.4	-0.1	-0.5	-0.6	2.7	-0.4	0	0.1	-1.2	-0.3	0.6
East North Central	120	2	-0.1	0	-0.1	1.4	-0.2	0	0.1	-1.6	-0.2	-0.1
East South Central	173	2.7	-0.1	-0.5	-0.5	2.9	-0.4	0	0.1	-1.3	-0.4	0.7
West North Central	98	1.7	-0.1	-0.2	-0.3	1.3	-0.2	0.2	0.1	-1.2	-0.1	0.2
West South Central	181	2.5	-0.1	-0.1	-0.1	2.3	-0.4	0	0.1	-1.7	-0.4	0.1

CMS-1588-F

	No. of Hospitals[1] (1)	Hospital Rate Update and Documenta-tion and Coding Adjust-ment [2] (2)	FY 2013 Weights and DRG Changes with Appli-cation of Recali-bration Budget Neu-trality[3] (3)	FY 2013 Wage Data with Appli-cation of Wage Budget Neu-trality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recali-bration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassi-fications[6] (6)	Rural Floor and Imputed Floor with Applica-tion of National Rural Floor Budget Neu-trality[7] (7)	Appli-cation of the Frontier Wage Index[8] (8)	FY 2013 Out-Migra-tion Adjust-ment[9] (9)	Expi-ration of MDH Status[10] (10)	Hospital Read-missions Reduc-tion Pro-gram[11] (11)	All FY 2013 Changes[12] (12)
Mountain	65	1.6	-0.1	0	-0.1	0.4	-0.2	0.8	0	-0.5	-0.1	1.1
Pacific	30	1.8	-0.2	-0.1	-0.2	1.2	-0.2	0	0	-0.3	-0.1	0.9
Puerto Rico	1	2.6	0	0.7	0.6	-0.9	-0.4	0	0	0	0	2.9
By Payment Classification:												
Urban hospitals	2,512	2.7	0	0	0.1	-0.2	0	0.1	0	0	-0.3	2.5
Large urban areas	1,383	2.7	0	0.2	0.2	-0.3	0	0	0.1	0	-0.3	2.6
Other urban areas	1,129	2.7	0	-0.2	-0.1	0	0.2	0.2	0	0	-0.2	2.4
Rural areas	911	2.2	-0.1	-0.2	-0.3	1.8	-0.3	0.1	0.1	-1.5	-0.2	0.4
Teaching Status:												
Nonteaching	2,392	2.7	0	-0.1	-0.1	0.3	0.1	0	0.1	-0.4	-0.3	2
Fewer than 100 residents	789	2.7	0	0.1	0.1	-0.1	-0.1	0.1	0	0	-0.2	2.5
100 or more residents	242	2.7	0	0.1	0.1	-0.2	0	0	0	0	-0.3	2.3
Urban DSH:												
Non-DSH	700	2.7	-0.1	0.2	0.1	-0.2	0.1	0.1	0.1	-0.3	-0.3	2.1
100 or more beds	1,558	2.7	0	0	0	-0.2	0	0.1	0	0	-0.3	2.5
Less than 100 beds	345	2.7	0	0.2	0.2	-0.1	0.2	0.1	0	-0.4	-0.2	2.5
Rural DSH:												
SCH	258	1.6	-0.2	-0.1	-0.3	0.4	-0.1	0	0	-1.8	-0.2	-0.5
RRC	232	2.3	-0.1	-0.2	-0.2	2.6	-0.3	0.1	0	-0.5	-0.2	1.6
100 or more beds	34	2.8	-0.1	-0.3	-0.4	2.3	-0.5	0	0.1	-0.9	-0.4	0.7

CMS-1588-F

	No. of Hospitals[1] (1)	Hospital Rate Update and Documenta-tion and Coding Adjust-ment [2] (2)	FY 2013 Weights and DRG Changes with Appli-cation of Recali-bration Budget Neu-trality[3] (3)	FY 2013 Wage Data with Appli-cation of Wage Budget Neu-trality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recali-bration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassi-fications[6] (6)	Rural Floor and Imputed Floor with Applica-tion of National Rural Floor Budget Neu-trality[7] (7)	Appli-cation of the Frontier Wage Index[8] (8)	FY 2013 Out-Migra-tion Adjust-ment[9] (9)	Expi-ration of MDH Status[10] (10)	Hospital Read-missions Reduc-tion Pro-gram[11] (11)	All FY 2013 Changes[12] (12)
Less than 100 beds	296	2.8	-0.1	-0.6	-0.6	1	-0.4	0	0.4	-3.7	-0.4	-1.9
Urban teaching and DSH:												
Both teaching and DSH	825	2.7	0	0	0.1	-0.3	-0.1	0.1	0	0	-0.3	2.5
Teaching and no DSH	139	2.7	-0.1	0.4	0.3	-0.1	0.2	0	0.2	0	-0.3	2.3
No teaching and DSH	1,078	2.7	0	-0.1	-0.1	0	0.3	0	0	0	-0.3	2.6
No teaching and no DSH	470	2.8	0	0	0	-0.4	0	0.1	0.1	-0.1	-0.3	2.4
Special Hospital Types:												
RRC	203	2.8	0	-0.1	-0.1	3	-0.4	0.4	0	-0.7	-0.2	2.1
SCH	326	1.6	-0.2	-0.1	-0.3	0.1	-0.1	0.1	0.1	0	-0.2	0.1
Former MDH	195	2.8	-0.1	-0.4	-0.4	0.6	-0.2	0	0.3	-7.8	-0.4	-6.4
SCH and RRC	118	1.6	-0.1	0	-0.2	1.1	-0.1	0.1	0	0	-0.2	1.4
Former MDH and RRC	18	2.8	0.1	0	0.1	2	-0.5	0	0.1	-13.7	-0.3	-12.5
Type of Ownership:												
Voluntary	1,971	2.7	0	0.1	0.1	0	0	0.1	0.1	-0.1	-0.3	2.3
Proprietary	868	2.7	0.1	-0.3	-0.3	0	-0.1	0	0.1	-0.3	-0.3	2.4
Government	563	2.6	0	-0.2	-0.2	0	-0.1	0	0	-0.2	-0.2	2.3
Medicare Utilization as a Percent of Inpatient Days:												
0-25	376	2.7	0.1	0.1	0.2	-0.3	0.1	0	0	0	-0.2	3.4

CMS-1588-F

	No. of Hospitals[1] (1)	Hospital Rate Update and Documenta-tion and Coding Adjust-ment [2] (2)	FY 2013 Weights and DRG Changes with Appli-cation of Recali-bration Budget Neu-trality[3] (3)	FY 2013 Wage Data with Appli-cation of Wage Budget Neu-trality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recali-bration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassi-fications[6] (6)	Rural Floor and Imputed Floor with Applica-tion of National Rural Floor Budget Neu-trality[7] (7)	Appli-cation of the Frontier Wage Index[8] (8)	FY 2013 Out-Migra-tion Adjust-ment[9] (9)	Expi-ration of MDH Status[10] (10)	Hospital Read-missions Reduc-tion Pro-gram[11] (11)	All FY 2013 Changes[12] (12)
25-50	1,834	2.7	0	0	0	-0.2	0	0.1	0	0	-0.2	2.4
50-65	974	2.6	0	0	0	0.7	0	0	0.1	-0.5	-0.3	1.5
Over 65	166	2.5	-0.1	-0.4	-0.4	0.3	0	0.1	0.1	-1.3	-0.4	0.4
FY 2013 Reclassifications by the Medicare Geographic Classification Review Board:												
All Reclassified Hospitals	654	2.6	0	0	0	2.9	0.1	0.1	0	-0.2	-0.3	2.1
Non-Reclassified Hospitals	2,769	2.7	0	0	0	-0.7	0	0.1	0.1	-0.1	-0.2	2.3
Urban Hospitals Reclassified	320	2.7	0	0.1	0.1	2.8	0.3	0.1	0	0	-0.3	2.6
Urban Nonreclassified Hospitals, FY 2013:	2,137	2.7	0	0	0	-0.7	0	0.1	0.1	0	-0.2	2.5
All Rural Hospitals Reclassified FY 2013:	334	2.3	-0.1	-0.3	-0.3	3.1	-0.3	0	0	-0.8	-0.3	1.1
Rural Nonreclassified Hospitals FY 2013:	531	2.2	-0.1	-0.3	-0.4	-0.1	-0.3	0.1	0.3	-2.5	-0.3	-1.1
All Section 401 Reclassified Hospitals:	46	2	-0.1	0.2	0.1	0.3	0	0	0.1	-2.5	-0.2	0.5

CMS-1588-F

	No. of Hospitals[1] (1)	Hospital Rate Update and Documenta-tion and Coding Adjust-ment [2] (2)	FY 2013 Weights and DRG Changes with Appli-cation of Recali-bration Budget Neu-trality[3] (3)	FY 2013 Wage Data with Appli-cation of Wage Budget Neu-trality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recali-bration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassi-fications[6] (6)	Rural Floor and Imputed Floor with Applica-tion of National Rural Floor Budget Neu-trality[7] (7)	Appli-cation of the Frontier Wage Index[8] (8)	FY 2013 Out-Migra-tion Adjust-ment[9] (9)	Expi-ration of MDH Status[10] (10)	Hospital Read-missions Reduc-tion Pro-gram[11] (11)	All FY 2013 Changes[12] (12)
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	2.5	-0.1	-0.2	-0.2	2.8	-0.4	0	0.1	-3.3	-0.2	-2
Specialty Hospitals												
Cardiac specialty Hospitals	19	2.8	0.1	-0.2	-0.2	-0.8	0.1	0.6	0	0	-0.1	3.9

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2011, and hospital cost report data are from reporting periods beginning in FY 2009 and FY 2008.

[2] This column displays the payment impact of the hospital rate update and documentation and coding adjustment including the 1.8 percent adjustment to the national standardized amount (the 2.6 percent market basket update reduced by the 0.7 percentage point for the multifactor productivity adjustment and the 0.1 percentage point reduction under the Affordable Care Act) and the 1.0 percent documentation and coding adjustment to the national standardized amount (-1.9 documentation and coding adjustment and 2.9 percent return to the rate to account for the one-time documentation and coding recoupment from FY 2012). In addition, it displays the payment impact of the hospital rate update of 1.8 percent and the documentation and coding adjustment of -0.5 percent to the hospital-specific rate.

[3] This column displays the payment impact of the changes to the Version 30.0 GROUPER and the recalibration of the MS-DRG weights based on FY 2011 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.998431 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2009 cost report data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000331.

[5] This column displays the combined payment impact of the changes in Columns 3 through 4 and the cumulative budget neutrality factor for MS-DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The cumulative wage and recalibration budget neutrality factor of 0.998761 is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.

[6] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2013 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2013. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.991276.

[7] This column displays the effects of the rural floor and imputed floor, including the Affordable Care Act requirement that the floor budget neutrality is at a 100 percent national level adjustment. This column does not reflect the alternative temporary methodology beginning in FY 2013; we note that the impact of that methodology is discussed separately and will have a negligible impact on budget neutrality. The rural floor and imputed floor budget neutrality factor is 0.991340.

[8] This column shows the impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0.

[9] This column displays the impact of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

[10] This column displays the impact of the expiration of MDH status, under section 3124 of the Affordable Care Act, a non-budget neutral payment provision.

[11] This column displays the impact of the implementation of the Hospital Readmissions Reduction Program, section 3025 of the Affordable Care Act, a non-budget neutral provision that adjusts a hospital's payment for excess readmissions.

[12] This column shows the changes in payments from FY 2012 to FY 2013. It reflects the impact of the FY 2013 hospital update, the adjustments due to the documentation and coding. It also reflects changes in hospitals' reclassification status in FY 2013 compared to FY 2012. It incorporates all of the changes displayed in Columns 2, 5, 6, 7, 8, 9, 10 and 11 (the changes displayed in Columns 3 and 4 are included in Column 5). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

a. Effects of the Hospital Update and Documentation and Coding Adjustment (Column 2)

As discussed in section II.D. of the preamble of this final rule, this column includes the hospital update, including the 2.6 percent market basket update, the reduction of 0.7 percentage point for the multifactor productivity adjustment, and the 0.1 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the FY 2013 documentation and coding adjustment of 1.0 percent on the national standardized amount, which includes the -1.9 percent prospective adjustment for documentation and coding and a 2.9 percent adjustment to restore the one-time recoupment adjustment made to the national standardized amount for FY 2012. As a result, we are making a 2.8 percent update to the national standardized amount.

This column also includes the 1.3 percent update to the hospital-specific rates, which includes the 1.8 percent for the hospital update and -0.5 percent documentation and coding adjustment.

Overall, hospitals will experience a 2.7 percent increase in payments primarily due to the effects of the hospital update and documentation and coding adjustment on the national standardized amount. Hospitals that are paid under the hospital-specific rate, namely SCHs, will see a 1.3 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate will see increases in payments less than 2.8 percent.

b. Effects of the Changes to the MS-DRG Reclassifications and Relative Cost-Based Weights with Recalibration Budget Neutrality (Column 3)

Column 3 shows the effects of the changes to the MS-DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS-DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this final rule, the FY 2013 MS-DRG relative weights will be 100 percent cost-based and 100 percent MS-DRGs. For FY 2013, the MS-DRGs are calculated using the FY 2011 MedPAR data grouped to the Version 30.0 (FY 2013) MS-DRGs. The methods of calculating the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.H. of the preamble of this final rule.

The "All Hospitals" line in Column 3 indicates that changes due to the MS-DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.998431 on to the standardized amount. Due to the changes to the MS-DRG GROUPER in this final rule, there were some shifts in payments due to changes in the relative weights with rural hospitals experiencing a 0.1 percent decrease in payments.

c. Effects of the Wage Index Changes (Column 4)

Column 4 shows the impact of updated wage data with the application of the wage budget neutrality factor. Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2013 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2008 and before October 1, 2009. The estimated impact of the updated wage data and labor share on hospital payments is isolated in Column 4 by holding the other payment parameters constant in this simulation. That is, Column 4 shows the percentage change in payments when going from a model using the FY 2012 wage index, based on FY 2008 wage data, the current labor-related share and having a 100-percent occupational mix adjustment applied, to a model using the FY 2013 pre-reclassification wage index with the labor-related share, also having a 100-percent occupational mix adjustment applied, based on FY 2009 wage data (while holding other payment parameters such as use of the Version 30.0 MS-DRG GROUPER constant). The occupational mix adjustment is based on the 2010 occupational mix survey.

In addition, the column shows the impact of the application of wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the

Act. Therefore, for FY 2013, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The wage budget neutrality factor is 1.000331, and the overall payment change is 0 percent.

Column 4 shows the impacts of updating the wage data using FY 2009 cost reports. Overall, the new wage data will lead to a 0.0 percent change for all hospitals before being combined with the wage budget neutrality adjustment shown in Column 4. Among the regions, the largest increase is in the urban New England region, which experiences a 0.9 percent increase. The largest decline from updating the wage data is seen in the rural East South Central region (-0.5 percent decrease).

In looking at the wage data itself, the national average hourly wage increased 3.3 percent compared to FY 2012. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 3.3 percent increase in average hourly wage. Of the 3,409 hospitals with wage data for both FYs 2012 and 2013, 1,529, or 44.9 percent, experienced an average hourly wage increase of 3.3 percent or more.

The following chart compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2013 relative to FY 2012. Among urban hospitals, none will experience an increase of more than 5 percent and less than 10

percent and none will experience an increase of more than 10 percent. Among rural hospitals, none will experience an increase of more than 5 percent and less than 10 percent, and none will experience an increase of more than 10 percent. However, 926 rural hospitals will experience increases or decreases of less than 5 percent, while 2,483 urban hospitals will experience increases or decreases of less than 5 percent. No urban hospitals will experience decreases in their wage index values of more than 5 percent and less than 10 percent. No urban hospitals will experience decreases in their wage index values of more than 10 percent. No rural hospitals will experience a decrease of more than 10 percent. No rural hospitals will experience decreases in their wage index values of greater than 5 percent but less than 10 percent. These figures reflect changes in the "pre-reclassified, occupational mix-adjusted wage index," that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. (We refer readers to sections III.G.2. through III.I. of the preamble of this final rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the "post-reclassified wage index" or "payment wage index," the final wage index that includes all such exceptions and adjustments (as reflected in Tables 2, 4A, 4B, 4C, and 4F of the Addendum to this final rule, which are available via the Internet on the CMS Web site) is used to adjust the labor-related share of a hospital's standardized amount, either 68.8 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the pre-reclassified wage index figures in the

chart below may illustrate a somewhat larger or smaller change than will occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the average hourly wage data for urban and rural hospitals.

Percentage Change in Area Wage Index Values	**Number of Hospitals**	
	Urban	Rural
Increase more than 10 percent	0	0
Increase more than 5 percent and less than 10 percent	0	0
Increase or decrease less than 5 percent	2,483	926
Decrease more than 5 percent and less than 10 percent	0	0
Decrease more than 10 percent	0	0

d. Combined Effects of the MS-DRG and Wage Index Changes (Column 5)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS-DRG reclassifications and the relative weights cannot increase or decrease aggregate payments. In addition, section 1886(d)(3)(E) of the Act specifies that any updates or adjustments to the wage index are to be budget neutral. We computed a wage budget neutrality factor of 1.000331, and a recalibration budget neutrality factor of 0.998431 (which is applied to the Puerto Rico-specific standardized amount and the hospital-specific rates). The product of the two budget neutrality factors is the cumulative wage and recalibration budget neutrality factor. The cumulative wage and recalibration budget neutrality adjustment is 0.998761, or approximately -0.1 percent, which is applied to the national standardized amounts. Because the wage budget neutrality and the recalibration budget neutrality are calculated under different methodologies according to the statute, when the two budget neutralities are combined and applied to the standardized amount, the overall

payment impact is not necessarily budget neutral. However, in this final rule, we are estimating that the changes in the MS-DRG relative weights and updated wage data with wage and budget neutrality applied will result in a 0.0 change in payments.

We estimate that the combined impact of the changes to the relative weights and MS-DRGs and the updated wage data with budget neutrality applied will result in 0.1 percent increase in payments for urban hospitals and 0.3 percent decrease in payments for rural hospitals. Urban New England hospitals will experience a 0.9 percent increase in payments due to increases in their wages compared to the national average, while the urban East South Central area will experience a 0.8 decrease in payments and rural South Atlantic will experience a 0.6 decrease in payments because of below average increases in wages.

e. Effects of MGCRB Reclassifications (Column 6)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on other bases than where they are geographically located). The changes in Column 6 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2013 which affect hospitals' wage index area assignments.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital’s reclassification request for the purpose of using another area’s wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS

Administrator. Further, hospitals have 45 days from publication of the IPPS rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, we are applying an adjustment of 0.991276 to ensure that the effects of the reclassifications under section 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification will increase payments to rural hospitals by an average of 2.1 percent. By region, all the rural hospital categories, with the exception of one rural Puerto Rico hospital, will experience increases in payments due to MGCRB reclassification. Rural hospitals in the East South Central region will experience a 2.9 percent increase in payments and rural hospitals in the Mountain region will experience a 0.4 percent increase in payments. Urban hospitals in New England and the Middle Atlantic will experience an increase in payments of 0.7 percent and 0.1 percent, respectively, largely due to reclassifications of hospitals in Connecticut and New Jersey.

Table 9A listed in section VI. of the Addendum to this final rule and available via the Internet reflects the reclassifications for FY 2013.

f. Effects of the Rural and Imputed Floor, Including Application of National Budget Neutrality (Column 7)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FY 2011 IPPS/LTCH PPS final rule

and this final rule, section 4410 of Pub. L. 105-33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We apply a uniform budget neutrality adjustment to the wage index. In addition, the imputed floor, which is budget neutral, was extended in FY 2012 for 2 additional years. In the past only urban hospitals in New Jersey had been receiving the imputed floor. As discussed earlier in this final rule, we are finalizing the proposal in the FY 2013 IPPS/LTCH PPS proposed rule to establish an alternative temporary methodology for the imputed floor, which will result in an imputed floor for Rhode Island for FY 2013.

The imputed floor for Rhode Island is also accounted for in the calculation of the rural floor and imputed rural floor budget neutrality factor. The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and the imputed floor is part of the rural floor budget neutrality factor applied to the wage index nationally. The FY 2013 rural floor budget neutrality factor applied to the wage index is 0.991340, which will reduce wage indexes by -0.87 percent.

Column 7 shows the projected impact of the rural floor and imputed floor with the national rural floor budget neutrality factor applied to the wage index. The column compares the post-reclassification FY 2013 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2013 wage index of providers with the rural floor and imputed floor adjustment. Only urban hospitals can benefit from the rural floor provision. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is

not made) experience a decrease in payments due to the budget neutrality adjustment applied nationally to their wage index.

We project that, in aggregate, rural hospitals will experience a 0.3 percent decrease in payments as a result of the application of rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in other urban areas (populations of 1 million or fewer) will experience a 0.2 percent increase in payments because those providers benefit from the rural floor. Urban hospitals in the New England region can expect a 3.6 percent increase in payments primarily due to the application of the rural floor in Massachusetts and the application of national rural floor budget neutrality as required by the Affordable Care Act. All 60 urban providers in Massachusetts are expected to receive the rural floor wage index value, including rural floor budget neutrality, of 1.3047. During most past years, there have been no IPPS hospitals located in rural areas in Massachusetts. There was one urban IPPS hospital that was reclassified to rural Massachusetts (under section 1886(d)(8)(E) of the Act) which established the Massachusetts rural floor, but the wage index resulting from that hospital's data was not high enough for any urban hospital to benefit from the rural floor policy. However, beginning with the FY 2012 wage index, the rural floor for the State is established by the conversion of a CAH to an IPPS hospital that is geographically located in rural Massachusetts. We estimate that Massachusetts hospitals will receive approximately a 5.7 percent increase in IPPS payments due to the application of rural floor.

Urban Mountain hospitals are estimated to receive a 0.6 percent increase in payments due to an increase in the rural floor for Arizona hospitals, as compared to our estimates published in the FY 2013 IPPS/LTCH PPS proposed rule. The Arizona rural floor wage index increased significantly from 0.9243 to 1.0661, attributable to one urban hospital that reclassified to rural Arizona under § 412.103 of the Medicare regulations. As a result, 46 out of the 53 urban hospitals in Arizona will benefit from the rural floor of 1.0661. Urban Arizona hospitals will experience a 2.2 percent increase in payments (approximately $33 million) due to the increase in the rural floor.

Urban Puerto Rico hospitals are expected to experience a 0.1 percent increase in payments as a result of the application of a Puerto Rico rural floor. Urban Puerto Rico hospitals will receive a rural floor as a result of a one IPPS hospital located in rural Puerto Rico setting a rural floor. We are applying a rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.987620 or -1.2 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals.

There are 29 hospitals in New Jersey that benefit from the extension of the imputed floor and will receive the imputed floor wage index value, including rural floor budget neutrality of 1.0994, which we estimate will increase their payments by approximately $29 million. Urban Middle Atlantic hospitals will experience a 0.3 percent decrease in payments, which reflects the increase in payments for New Jersey hospitals receiving the imputed floor and a decrease for all other urban hospitals in the in

the Middle Atlantic region. Four Rhode Island hospitals benefit from the newly established imputed rural floor and will receive an additional $2.5 million.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the rural floor and imputed floor with budget neutrality at the State level. Column 1 of the table below displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that will receive the rural floor or imputed floor wage index for FY 2013. Column 3 displays the percentage of total payments each State will receive or contribute to fund the rural floor and imputed floor with national budget neutrality. The column compares the post-reclassification FY 2013 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2013 wage index of providers with the rural floor and imputed floor adjustment. Column 4 displays the estimated payment amount that each State will gain or lose due to the application of the rural floor and imputed floor with national budget neutrality.

FY 2013 IPPS Estimated Payments Due to Rural Floor and Imputed Floor with National Budget Neutrality

State	Number of Hospitals (1)	Number of Hospitals Receiving Rural Floor or Imputed Floor (2)	Percent Change in Payments due to Application of Rural Floor and Imputed Floor with Budget Neutrality (3)	Difference (in millions) (4)
Alabama	96	3	-0.4	-$8.2
Alaska	6	4	1.5	$2.3
Arizona	58	45	1.7	$31.4
Arkansas	45	0	-0.5	-$5.2
California	311	180	0.9	$98.5
Colorado	46	7	0.5	$5.8

FY 2013 IPPS Estimated Payments Due to Rural Floor and Imputed Floor with National Budget Neutrality				
State	Number of Hospitals (1)	Number of Hospitals Receiving Rural Floor or Imputed Floor (2)	Percent Change in Payments due to Application of Rural Floor and Imputed Floor with Budget Neutrality (3)	Difference (in millions) (4)
Connecticut	32	11	1	$16.7
Delaware	6	0	-0.5	-$2.1
Florida	169	8	-0.4	-$28.3
Georgia	108	0	-0.4	-$12.7
Hawaii	14	0	-0.4	-$1.1
Idaho	14	0	-0.3	-$1.0
Illinois	130	8	-0.5	-$26.2
Indiana	89	0	-0.5	-$11.7
Iowa	34	0	-0.4	-$4.4
Kansas	55	0	-0.4	-$3.5
Kentucky	65	0	-0.4	-$8.4
Louisiana	98	7	-0.4	-$7.1
Maine	20	0	-0.5	-$2.4
Massachusetts	61	60	5.7	$188.0
Michigan	96	0	-0.5	-$21.2
Minnesota	51	0	-0.5	-$8.6
Mississippi	66	0	-0.4	-$5.5
Missouri	76	2	-0.4	-$10.9
Montana	12	1	-0.3	-$0.7
Nebraska	23	0	-0.4	-$2.5
Nevada	24	4	-0.4	-$3.2
New Hampshire	13	9	2.1	$10.0
New Jersey	65	29	0.4	$14.4
New Mexico	27	0	-0.3	-$1.5
New York	168	0	-0.5	-$46.8
North Carolina	88	0	-0.4	-$16.4
North Dakota	6	4	-0.2	-$0.6
Ohio	139	8	-0.4	-$15.0
Oklahoma	85	0	-0.4	-$5.7
Oregon	33	0	-0.5	-$4.1
Pennsylvania	154	14	-0.4	-$17.5
Puerto Rico	52	13	0.1	$0.1
Rhode Island	11	4	0.5	$2.1
South Carolina	56	5	-0.3	-$5.9
South Dakota	18	0	-0.3	-$0.8
Tennessee	97	10	-0.3	-$7.4

FY 2013 IPPS Estimated Payments Due to Rural Floor and Imputed Floor with National Budget Neutrality				
State	Number of Hospitals (1)	Number of Hospitals Receiving Rural Floor or Imputed Floor (2)	Percent Change in Payments due to Application of Rural Floor and Imputed Floor with Budget Neutrality (3)	Difference (in millions) (4)
Texas	325	2	-0.4	-$33.0
Utah	32	0	-0.4	-$1.8
Vermont	6	0	-0.3	-$0.7
Virginia	79	1	-0.4	-$10.1
Washington	48	5	-0.3	-$6.3
Washington, D.C.	7	0	-0.5	-$2.5
West Virginia	33	2	-0.3	-$2.9
Wisconsin	65	8	-0.3	-$5.0
Wyoming	11	0	-0.1	-$0.2

g. Effects of the Application of the Frontier State Wage Index (Column 8)

Section 10324(a) of Affordable Care Act requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in "frontier States." The term "frontier States" is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, four States (Montana, North Dakota, South Dakota, and Wyoming) are considered frontier States and 45 hospitals located in those States will receive a frontier wage index of 1.0. Although Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, its FY 2013 rural floor value of 1.0256 is greater and, therefore, is the State's minimum wage index for FY 2013. As a result, hospitals located in Nevada will not experience a change in payment as a result of

this provision. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $69 million.

Urban hospitals located in the West North Central region and urban hospitals located in the Mountain region will receive an increase in payments by 0.8 percent and 0.2 percent, respectively because many of the hospitals located in this region are frontier hospitals. Similarly, rural hospitals located in the Mountain region and rural hospitals in the West North Central region will experience an increase in payments by 0.8 percent and 0.2 percent, respectively.

h. Effects of the Wage Index Adjustment for Out-Migration (Column 9)

Section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. Overall, rural hospitals will experience a 0.1 percent increase in payments as a result of the out-migration wage adjustment. Rural DSH providers with less than 100 beds will experience a 0.4 percent increase in payments. Urban New England hospitals will experience a 0.3 percent increase in payments due to increases in their out-migration wage adjustment attributable to the hospitals located in counties neighboring

Massachusetts that has a higher wage index due to the Massachusetts rural floor. There are 287 providers that will receive the out-migration wage adjustment in FY 2013. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase to be approximately $53 million.

i. Effects of the Expiration of MDH Special Payment Status (Column 10)

Column 10 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision, under section 3124 of the Affordable Care Act. Hospitals that qualified to be MDHs receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital-specific rate (a hospital-specific cost-based rate). Because this provision was not budget neutral, the expiration of this payment provision results in a 0.2 percent decrease in payments overall. There are currently 213 MDHs, of which 98 were estimated to be paid under the blended payment of the federal standardized amount and hospital-specific rate. Because those 98 MDHs will no longer receive the blended payment and will be paid only under the Federal standardized amount in FY 2013, it is estimated that those hospitals will experience an overall decrease in payments of approximately $183 million.

MDHs were generally rural hospitals, so the expiration of the MDH program will result in an overall decrease in payments to rural hospitals of 1.4 percent. Rural New England hospitals can expect a decrease in payments of 3.4 percent because 8 out of the 23 rural New England hospitals are MDHs that will lose this special payment status under

the expiration of the program at the end of FY 2012. MDHs can expect a decrease in payments of 7.8 percent.

j. Effects of the Hospital Readmissions Reduction Program (Column 11)

Column 11 shows our estimates of effects of the policies for implementation of the Hospital Readmissions Reduction Program, which was established under section 3025 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions, which is based on a hospital's risk-adjusted readmission rate during a 3-year period for three applicable conditions: Acute Myocardial Infarction, Heart Failure, and Pneumonia. This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in statute as 0.99 (or a 1-percent reduction) for FY 2013. A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section IV.A. of the preamble of this final rule) is the portion of the IPPS payment subject to the readmissions payment adjustment (DSH, IME, outliers and low-volume add-on payments are not subject to the readmissions adjustment). In this final rule, we estimate that 2,206 hospitals will have their base operating DRG payments reduced by the readmissions adjustment, resulting in a 0.3 percent decrease in payments to hospitals overall.

Urban hospitals in the Middle Atlantic, rural hospitals in the East South Central region, West South Central region, rural DSH hospitals and hospitals with Medicare

utilization of over 65 percent will experience the highest decreases of 0.4 percent among the different hospital categories. Urban hospitals in the West South Central region, Mountain region and Pacific region will experience the smallest decreases of 0.1 percent in payments. Puerto Rico hospitals show a 0 percent change in payments because they are exempt from the provision.

k. Effects of All FY 2013 Changes (Column 12)

Column 12 shows our estimate of the changes in payments per discharge from FY 2012 and FY 2013, resulting from all changes reflected in this final rule for FY 2013. It includes combined effects of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 2.3 percent for FY 2013 relative to FY 2012. As discussed in section II.D. of the preamble of this final rule, this column includes the FY 2013 documentation and coding adjustment of 1.0 percent on the national standardized amount (the -1.9 percent documentation and coding adjustment and the 2.9 percent adjustment to restore the one-time recoupment adjustment made to national standardized amount) and the -0.5 percent documentation and coding adjustment on the hospital-specific rates. In addition, this column includes the annual hospital update of 1.8 percent to the national standardized amount. This annual hospital update includes the 2.6 percent market basket update, the reduction of 0.7 percentage point for the multifactor productivity adjustment, and the 0.1 percentage point reduction under section 3401 of the Affordable Care Act. As described in Column 2, the annual hospital update, combined with the documentation and coding adjustment, results in a 2.7 percent increase in payments in FY 2013 relative to FY 2012.

In addition, Column 8 describes an estimated 0.1 percent increase in payments due to the frontier State wage index. Column 10 describes the estimated 0.2 percent decrease in payments due to the expiration of the MDH status under section 3124 of the Affordable Care Act. Column 11 shows the estimated 0.3 percent decrease in payments due to the establishment of the Hospital Readmissions Reduction Program, which reduces a hospital's base operating DRG payments by a readmission adjustment factor based on a hospital's performance on readmissions for specified conditions. In addition, although not shown in the impacts table, payments are estimated to decrease by 0.1 due to the expiration of section 508 reclassifications that had been extended for 6 months of FY 2012 under section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112-78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96). Section 508 was not a budget-neutral provision. The impact of moving from our estimate of FY 2012 outlier payments, 5.0 percent, to the estimate of FY 2013 outlier payments, 5.1 percent, results in an increase of 0.1 percent in FY 2013 payments relative to FY 2012. There might also be interactive effects among the various factors comprising the payment system that we are not able to isolate. For these reasons, the values in Column 12 may not equal the sum of the percentage changes described above.

The overall change in payments per discharge for hospitals paid under the IPPS in FY 2013 is estimated to increase by 2.3 percent. The payment increase among the hospital categories is largely attributed to the updates to the rate including the hospital update. Hospitals in urban areas will experience an estimated 2.5 percent increase in

payments per discharge in FY 2013 compared to FY 2012. Hospital payments per discharge in rural areas are estimated to increase by 0.3 percent in FY 2013 as compared to FY 2012 due to the expiration of MDH status.

Among urban census divisions, the Urban New England hospitals will experience an estimated 1.5 percent increase in payments, less than the national average, because many of the urban providers in this region had benefited from section 508 reclassifications in FY 2012 that will expire for FY 2013. Urban hospitals in the Pacific will see the largest payment increases (4.0 percent) because the hospitals are benefitting from the rural floors in their States.

Among the rural regions, the hospitals in the New England Region will experience the estimated decreases in payments of 0.8 percent, due to the expiration of MDH status. Rural hospitals in the Mountain Region are estimated to experience a 1.1 percent increase because the rural providers in this region benefit from MGCRB reclassification and the application of the Frontier wage index, which offsets decreases due to the rural floor and the expiration of MDH status.

Among special categories of hospitals, former MDHs will receive an estimated payment decrease of 6.4 percent due to the expiration of the MDH status. SCHs are paid the higher of their Federal rate and the hospital-specific rate. Overall, SCHs are estimated to experience a payment increase of 0.1 percent due to the application of the rural floor budget neutrality and the implementation of the Hospital Readmissions Reduction Program.

Rural hospitals reclassified for FY 2013 will receive an estimated 1.1 percent payment increase. Rural hospitals that are not reclassifying are estimated to receive a payment decrease of 1.1 percent due to lower wage data, the application of rural floor budget neutrality and expiration of MDH status. Urban reclassified hospitals will experience an estimated payment increase at 2.6 percent due to the benefits under MGCRB reclassification and the rural floor. Urban nonreclassified hospitals will experience an estimated payment increase of 2.5 percent.

Cardiac hospitals are expected to experience a payment increase 3.9 percent in FY 2013 relative to FY 2012 primarily due to benefits to the changes in the relative weights and the application of the Frontier wage index.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2013 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2012 with the average payments per discharge for FY 2013, as calculated under our models. Thus, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 12 of Table I.

TABLE II.--IMPACT ANALYSIS OF CHANGES FOR FY 2013 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Average FY 2012 Payment Per Discharge (2)	Average FY 2013 Payment Per Discharge (3)	All FY 2013 Changes (4)
All hospitals	3,423	10,477	10,716	2.3
By Geographic Location:				
Urban hospitals	2,497	10,881	11,153	2.5
Large urban areas (populations over 1 million)	1,373	11,503	11,803	2.6
Other urban areas (populations of 1 million or fewer)	1,124	10,117	10,355	2.4
Rural hospitals	926	7,845	7,868	0.3
Bed Size (Urban):				
0-99 beds	633	8,343	8,550	2.5
100-199 beds	780	9,192	9,423	2.5
200-299 beds	448	9,955	10,212	2.6
300-499 beds	430	11,133	11,428	2.6
500 or more beds	206	13,424	13,733	2.3
Bed Size (Rural):				
0-49 beds	321	6,307	6,241	-1.1
50-99 beds	347	7,335	7,214	-1.7
100-149 beds	153	7,605	7,681	1
150-199 beds	58	8,544	8,673	1.5
200 or more beds	47	9,656	9,847	2
Urban by Region:				
New England	120	11,852	12,025	1.5
Middle Atlantic	318	11,929	12,136	1.7
South Atlantic	380	9,958	10,183	2.3
East North Central	399	10,128	10,392	2.6
East South Central	151	9,590	9,765	1.8
West North Central	165	10,519	10,839	3
West South Central	372	10,152	10,391	2.4
Mountain	159	11,045	11,394	3.2
Pacific	382	13,625	14,174	4
Puerto Rico	51	5,384	5,526	2.6
Rural by Region:				
New England	23	10,465	10,376	-0.8
Middle Atlantic	69	8,345	8,334	-0.1
South Atlantic	166	7,518	7,560	0.6
East North Central	120	8,083	8,079	-0.1
East South Central	173	7,186	7,233	0.7
West North Central	98	8,344	8,358	0.2
West South Central	181	6,882	6,889	0.1
Mountain	65	8,690	8,787	1.1

	Number of Hospitals (1)	Average FY 2012 Payment Per Discharge (2)	Average FY 2013 Payment Per Discharge (3)	All FY 2013 Changes (4)
Pacific	30	10,613	10,709	0.9
Puerto Rico	1	2,151	2,213	2.9
By Payment Classification:				
Urban hospitals	2,512	10,860	11,133	2.5
Large urban areas (populations over 1 million)	1,383	11,483	11,778	2.6
Other urban areas (populations of 1 million or fewer)	1,129	10,088	10,332	2.4
Rural areas	911	8,046	8,077	0.4
Teaching Status:				
Non-teaching	2,392	8,783	8,963	2
Fewer than 100 Residents	789	10,309	10,571	2.5
100 or more Residents	242	15,381	15,737	2.3
Urban DSH:				
Non-DSH	700	9,142	9,335	2.1
100 or more beds	1,558	11,334	11,621	2.5
Less than 100 beds	345	7,706	7,899	2.5
Rural DSH:				
SCH	258	7,801	7,761	-0.5
RRC	232	8,946	9,088	1.6
100 or more beds	34	7,042	7,093	0.7
Less than 100 beds	296	6,214	6,093	-1.9
Urban teaching and DSH:				
Both teaching and DSH	825	12,413	12,720	2.5
Teaching and no DSH	139	10,146	10,375	2.3
No teaching and DSH	1,078	9,300	9,547	2.6
No teaching and no DSH	470	8,659	8,870	2.4
Rural Hospital Types:				
RRC	203	8,917	9,105	2.1
SCH	326	8,428	8,437	0.1
Former MDH	195	6,519	6,101	-6.4
SCH and RRC	118	9,737	9,868	1.4
Former MDH and RRC	18	8,576	7,505	-12.5
Type of Ownership:				
Voluntary	1,971	10,618	10,857	2.3
Proprietary	868	9,318	9,539	2.4
Government	563	11,148	11,406	2.3
Medicare Utilization as a Percent of Inpatient Days:				
0-25	376	14,621	15,111	3.4
25-50	1,834	10,970	11,239	2.4
50-65	974	8,581	8,711	1.5
Over 65	166	7,914	7,943	0.4

	Number of Hospitals (1)	Average FY 2012 Payment Per Discharge (2)	Average FY 2013 Payment Per Discharge (3)	All FY 2013 Changes (4)
Hospitals Reclassified by the Medicare Geographic Classification Review Board: FY 2013 Reclassifications:				
All Reclassified Hospitals FY 2013	654	9,828	10,037	2.1
All Non-Reclassified Hospitals FY 2013	2,769	10,644	10,891	2.3
Urban Reclassified Hospitals FY 2013	320	10,707	10,984	2.6
Urban Non-reclassified Hospitals FY 2013	2,137	10,921	11,195	2.5
Rural Reclassified Hospitals FY 2013	334	8,383	8,477	1.1
Rural Nonreclassified Hospitals FY 2013:	531	7,044	6,968	-1.1
All Section 401 Reclassified Hospitals:	46	10,030	10,083	0.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	7,497	7,349	-2
Specialty Hospitals				
Cardiac Hospitals	19	10,925	11,350	3.9

H. Effects of Other Policy Changes

In addition to those policy changes discussed above that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes. Our estimates of the likely impacts associated with these other changes are discussed below.

1. Effects of Policy on HACs, Including Infections

In section II.F. of the preamble of this final rule, we discuss our implementation of section 1886(d)(4)(D) of the Act, which requires the Secretary to identify conditions that are: (1) high cost, high volume, or both; (2) result in the assignment of a case to an MS-DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through application of evidence-based guidelines. For

discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission, unless, based on data and clinical judgment, it cannot be determined at the time of admission whether a condition is present. That is, the case will be paid as though the secondary diagnosis were not present. However, the statute also requires the Secretary to continue counting the condition as a secondary diagnosis that results in a higher IPPS payment when doing the budget neutrality calculations for MS-DRG reclassifications and recalibration. Therefore, we will perform our budget neutrality calculations as though the payment provision did not apply, but Medicare will make a lower payment to the hospital for the specific case that includes the secondary diagnosis. Thus, the provision results in cost savings to the Medicare program.

We note that the provision will only apply when one or more of the selected conditions are the only secondary diagnosis or diagnoses present on the claim that will lead to higher payment. Medicare beneficiaries will generally have multiple secondary diagnoses during a hospital stay, such that beneficiaries having one MCC or CC will frequently have additional conditions that also will generate higher payment. Only a small percentage of the cases will have only one secondary diagnosis that would lead to a higher payment. Therefore, if at least one nonselected secondary diagnosis that leads to higher payment is on the claim, the case will continue to be assigned to the higher paying MS-DRG and there will be no Medicare savings from that case. In addition, as discussed in section II.F.3. of the preamble of this final rule, it is possible to have two severity levels where the HAC does not affect the MS-DRG assignment or for an MS-DRG not to

have severity levels. In either of these circumstances, the case will continue to be assigned to the higher paying MS-DRG and there will be no Medicare savings from that case.

In section II.F. of the preamble of this final rule, we are adding two HACs for FY 2013: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Iatrogenic Pneumothorax with Venous Catheterization. Similar to the current HACs, only a very small number of discharges would have only one secondary diagnosis that would lead to a higher payment. Therefore, there will likely be very few discharges where the MS-DRG is reassigned for these proposed conditions and this would result in a minimal payment impact.

The HAC payment provision went into effect on October 1, 2008. Our savings estimates for the next 5 fiscal years are shown below:

Year	Savings (in millions)
FY 2013	$24
FY 2014	$26
FY 2015	$28
FY 2016	$30
FY 2017	$33

2. Effects of Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this final rule, we discuss four applications for add-on payments for new medical services and technologies for FY 2013, as well as the status of the new technology that was approved to receive new technology add-on payments in FY 2012. As explained in that section, add-on payments for new technology under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.I.4. of the preamble of this final rule, we are approving three of the four applications for new technology add-on payments for FY 2013. In this final rule, we also are continuing to make new technology add-on payments in FY 2013 for the AutoLITT™ (because the technology is still within the 3-year anniversary of the product's entry onto the market). We note that new technology add-on payments per case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS-DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in add-on payments for FY 2013 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. For the AutoLITT™, for FY 2011, the applicant estimated that approximately 170 Medicare beneficiaries would be eligible for the AutoLITT™. Therefore, based on the applicant's estimate from FY 2011, we currently estimate that new technology add-on payments for the AutoLITT™ will increase overall FY 2013 payments by $900,000. For Voraxaze®, for FY 2013, the applicant estimates that approximately 140 Medicare beneficiaries will be eligible for the

technology. Therefore, we currently estimate that new technology add-on payments for Voraxaze® will increase overall FY 2013 payments by $6,300,000. For Dificid™, for FY 2013, the applicant estimates that approximately 40,138 Medicare beneficiaries will be eligible for the technology. Therefore, we currently estimate that new technology add-on payments for Dificid™ will increase overall FY 2013 payments by $34,839,784. For the Zenith® F. Graft, for FY 2013, the applicant estimates that approximately 500 Medicare beneficiaries will be eligible for the technology. Therefore, we currently estimate that new technology add-on payments for the Zenith® F. Graft will increase overall FY 2013 payments by $4,085,750. The total increase in overall FY 2013 payments due to new technology add-on payment is estimated to be $46,125,534.

3. Effects of Policy Changes Relating to SCHs

In section IV.B.2. of the preamble of this final rule, we discuss our clarification of the regulations related to the termination of a hospital's status as an SCH. We are adding a provision to the regulations to clarify that if CMS determines that the hospital was incorrectly designated as an SCH, SCH status may be cancelled retroactively, consistent with the provisions at 42 CFR 405.1885. We also are specifying that if a hospital that was incorrectly designated as an SCH notifies CMS of that error, the SCH classification status may be terminated effective 30 days from CMS' date of determination. We believe it is difficult to quantify the payment impact of these clarifications because we cannot estimate the number of SCHs that will be affected by these policies. However, we believe any impact will be insignificant because the policies only affect hospitals that were incorrectly classified as SCHs. In the proposed rule, we solicited public comments

on these issues. Any public comments that we received are addressed in section IV.B.2. of the preamble of this final rule.

In section IV.B.3. of the preamble of this final rule, we discuss our addition of a provision to the regulations to allow hospitals that are currently classified as MDHs to apply for classification as SCHs upon the expiration of the MDH program on September 30, 2012. We are providing that, for any MDH that applies for SCH classification at least 30 days prior to the expiration of the MDH program and requests that SCH classification status be effective with the expiration of the MDH program, and the hospital is approved for SCH status, the effective for SCH status will be the day following the expiration of the MDH program. We believe it is difficult to quantify the payment impact of this policy because we cannot estimate the number of MDHs that will be applying for SCH status.

4. Effects of the Payment Adjustment for Low-Volume Hospitals for FY 2013

In section IV.D. of the preamble to this final rule, we discuss the provisions of the Affordable Care Act that expanded the definition of low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition for FYs 2011 and 2012. In accordance with section 1886(d)(12) of the Act, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, effective for FY 2013 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than

200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year.

Based on FY 2011 claims data (March 2012 update of the MedPAR file), we estimate that approximately 600 hospitals in our database qualified as a low-volume hospital for FY 2012, but will no longer meet the mileage and discharges criteria to qualify as a low-volume hospital under section 1886(d)(12) of the Act for FY 2013. Because we estimate that these hospitals will no longer qualify for the low-volume hospital adjustment in FY 2013 (due to the statutory change in the qualifying criteria), we project that these hospitals will experience a decrease in payments of approximately $318 million in FY 2013 as compared to the payments that they would have otherwise received in FY 2013 in absence of the statutory change in the low-volume hospital qualifying criteria.

5. Effects of Policy Changes Relating to Payment Adjustments for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME)

In section IV.F. of the preamble of this final rule, we discuss our finalization of a proposal to include ancillary labor and delivery beds in the available bed count used to determine the DSH payment adjustment and the IME payment adjustment. The impact of the changes to the DSH payment adjustment should be negligible, as the DSH payment adjustment is determined mainly by the demographic composition of an individual hospital's patient population, and not its overall bed count. However, we note that some hospitals' bed counts do not meet the minimum threshold required to qualify for the DSH payment adjustment. For these hospitals that do not meet the minimum bed count

required to qualify for the DSH payment adjustment, an increase in the number of available beds could now allow them to qualify for the DSH payment adjustment. For purposes of the IME payment adjustment, an increase in a hospital's number of available beds would result in a decrease in the resident-to-bed ratio. The inclusion of bed days associated with labor and delivery patients in the available bed count for IME will increase the available beds, decrease the resident-to-bed ratio, and, consequently, decrease IME payments to teaching hospitals, depending on the number of these hospitals' labor and delivery beds. Based on labor and delivery patient days currently reported in the Medicare hospital cost report database, we estimate that the inclusion of labor and delivery beds in the available bed day count will decrease IME payments by $40 million in FY 2013.

Comment: One commenter was unable to replicate our proposed estimate of $170 in savings due to the inclusion of labor and delivery days in the available bed day count for IME. The commenter sought additional information on how the estimate was made.

Response: We thank the commenter for the comment. In the proposed rule, we determined our estimate based on Medicare hospital cost report data from 2010, which is the most recently available data for when hospitals began reporting their labor and delivery patient days. We used these data to estimate the number of available bed days with the inclusion of the labor and delivery patient days for teaching hospitals. We then calculated the change in IME payments with the revised bed count. Because only a subset of providers had submitted their 2010 Medicare hospital cost report data at the time of our estimate, we had to extrapolate our estimate to apply to all teaching hospitals.

In the proposed rule, we inadvertently added our estimate of labor and delivery bed days to hospitals' total bed day count, not their bed day count used to determine IME payments, resulting in a greater estimate of savings. We have corrected our estimate of savings to $40 million, as stated above in this final rule.

6. Effects of the Policy Changes Relating to GME and IME

a. Effects of Clarification and Policy Regarding Timely Filing Requirements under Fee-for-Service Medicare

In section IV.E.2. of the preamble of this final rule, we discuss a clarification related to the time limits for filing claims for IME, direct GME, and nursing and allied health education payments for services furnished to MA enrollees. This clarification is intended to make clear to hospitals that they must follow the regulations governing the time limits for filing claims at § 424.44 in order to receive IME, and/or direct GME, and/or nursing or allied health education program payments associated with Medicare Advantage enrollees. Because we are not making any policy changes (but rather clarifying the existing timely filing requirements), there is no financial impact for this clarification.

In section IV.E.2. of the preamble of this final rule, we also are adopting a policy under which hospitals that are required to submit no pay bills for services furnished on a prepaid capitation basis by an MA organization, or through cost settlement with either a health maintenance organization, a competitive medical plan, a health care prepayment plan, or a demonstration, for the purpose of calculating the DPP that is used in determining the DSH payment adjustment must do so within the time limits for filing

claims at § 424.44. We do not anticipate that this policy will have any impact, as providers are already submitting no pay bills for purposes of the DPP.

b. Effects of Policy Changes Relating to New Teaching Hospitals: New Program Growth from 3 Years to 5 Years

In section IV.I.2. of the preamble of this final rule, we discuss our finalization of a proposal to extend the period a new teaching hospital has to establish its caps for direct GME and IME payment purposes from 3 years to 5 years. We are revising the regulations to state that if a new teaching hospital participates in training residents in a new program for the first time on or after October 1, 2012, that new teaching hospital's caps will be based on the products of the highest number of FTE residents training in any program year during the fifth year of each new program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The cap will be applied beginning with the sixth academic year of the first new program. We note that, in the preamble, we have also provided a formula for calculating the FTE resident cap when residents in the new program rotate to more than one hospital during the 5 years. We believe the expansion of the cap-building period from 3 years to 5 years would make our policies for the establishment of a hospital's cap more compatible with current accreditation requirements that hospitals must meet to establish new residency training programs. We estimate that these policies will cost approximately $175 million over the next 10 years. However, because these changes to the cap growth period from 3 years to 5 years will only affect new programs beginning on or after October 1, 2012,

we estimate that no cost will be incurred until FY 2016. This estimate assumes that there could be 20 new teaching hospitals each year.

c. Effects of Changes Relating to 5-Year Period Following Implementation of Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes under Section 5503 of The Affordable Care Act

In section IV.I.3. of the preamble of this final rule, we discuss our final policies related to the 5-year period following implementation of reductions and increases to hospitals' FTE resident caps for GME payment purposes under section 5503 of the Affordable Care Act. Section 5503 of the Affordable Care Act amended the Medicare statute by adding a new section 1886(h)(8) of the Act, which provides for reductions in the statutory FTE resident caps for direct GME and IME under Medicare for certain hospitals, and authorizes a "redistribution" to certain hospitals of the estimated number of FTE resident slots resulting from the reductions. The amendments made by section 5503 also specify that a hospital that receives an increase in its cap shall ensure, during the 5-year period beginning on the date of such increase (July 1, 2011), that certain requirements, referred to as the primary care average and 75-percent threshold, are met in order to retain those slots. Otherwise, the Medicare statute authorizes the Secretary to reduce the FTE caps of the hospital if the hospital fails to meet either of those requirements.

Because the statutorily directed criteria for consideration in awarding slots under section 5503 included the requirement that hospitals applying for slots demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or

after July 1, 2011, and we relied on that information in awarding slots, we proposed that a hospital that received section 5503 slots must fill at least half of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes: the first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period and/or in its third 12-month cost reporting period of the 5-year period, or lose its section 5503 slots. We also proposed that the hospital must fill all of the slots it received by its final cost reporting period beginning during the timeframe of July 1, 2011, through June 30, 2016, or lose all of its section 5503 slots after June 30, 2016. However, based on public comments received, we are instead finalizing a policy under which, regardless of whether slots are used for new programs or expansions of existing programs, the Medicare contractors will remove the applicable unused section 5503 slots for portions of cost reporting periods on or after July 1, 2016. The slots that are removed will be distributed to other hospitals. We also are finalizing an additional policy regarding slots used specifically for program expansions under which in determining the applicable unused slots for purposes of reductions for cost reporting periods on or after July 1, 2016, the slots used are equal to the lesser of the number of slots used in the fourth 12-month cost report or the final cost report.

We believe the impact of these policies regarding the timing of the use of these section 5503 slots is budget neutral. We believe that hospitals will take the steps necessary to comply with the section 5503 requirements to ensure, to the best of their ability, that they will not lose their section 5503 slots. We also believe that section 5503 slots are valuable enough to hospitals that it is worthwhile for hospitals to fill as many of

their section 5503 slots as possible in accordance with the policy in this final rule, because not doing so would mean the loss of unused section 5503 slots after Year 5 ends. Furthermore, section 1886(h)(8)(B)(iii) of the Act instructs the Secretary to redistribute positions that are removed from hospitals that fail to meet the requirements at section 1886(h)(8)(B)(ii) of the Act; therefore, the section 5503 slots would ultimately be filled and paid for by Medicare regardless. Thus, there will be neither an additional cost due to these policies nor savings related to these policies.

d. Preservation of Resident Cap Positions from Closed Hospitals (Section 5506 of the Affordable Care Act)

In section IV.I.4. of the preamble of this final rule, we discuss our clarifications of existing policy related to section 5506 of the Affordable Care Act. Section 5506 amended the Medicare statute to add a provision that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the total number of FTE resident cap slots distributed is not to exceed the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively. The regulations and application process regarding section 5506 were implemented in the November 24, 2010 final rule with comment period (75 FR 72212). The provisions included in the preamble of this final rule are generally administrative in nature, related to the rules regarding the application of section 5506, minor changes or clarifications to the ranking criteria on the applications, changes or clarifications

regarding the effective dates of slots awarded under section 5506, and reiteration that the regulations at § 413.79(h) regarding temporary FTE resident caps for displaced residents, and the attending exemption from the 3-year rolling average and resident-to-bed ratio cap are being preserved. Therefore, there is no financial impact for these section 5506 provisions.

7. Effects of Changes Relating to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

In section IV.J. of the preamble of this final rule, we discuss finalizing our proposal to amend two existing regulations to conform these regulations to the final policy we adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51597) with regard to pension costs for Medicare cost-finding purposes. Because we are making only conforming changes to the regulations and not further modifying the policy we finalized, there is no impact on hospitals for these changes for FY 2013.

8. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.K. of the preamble of this final rule, we discuss our implementation of section 410A of Pub. L. 108-173, as amended, which requires the Secretary to conduct a demonstration that would modify reimbursement for inpatient services for up to 30 rural community hospitals. Section 410A(c)(2) requires that "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented." As discussed in section IV.K. of the preamble of this final rule, in the IPPS final rules for each of the previous 8 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we are adjusting the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are applying budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration . . . was not implemented" but does not identify the range across which aggregate payments must be held equal.

We are adjusting the national IPPS rates according to the methodology set forth elsewhere in this final rule. The adjustment to the national IPPS rates to account for

estimated demonstration cost for FY 2013 for the 7 "pre-expansion" participating hospitals that are currently participating in the demonstration and the 16 additional hospitals participating as a result of the expansion of the demonstration under the Affordable Care Act is $34,288,129. We note that we proposed that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (2007, 2008, 2009, or 2010) were made available prior to this FY 2013 IPPS/LTCH PPS final rule, we would incorporate into the FY 2013 budget neutrality offset amount the difference between the final cost of the demonstration in any of these years and the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. The estimated amount of $34,288,129 does not account for any differences between the cost of the demonstration program for hospitals participating in the demonstration for FYs 2007 through 2010 and the amounts that were offset by the budget neutrality adjustment for these years because the specific numeric value associated with this component of the adjustment to the national IPPS rates cannot be known at this time. This is because the large majority of settled cost reports beginning in FYs 2007 through 2010 for the hospitals participating in the demonstration during those years also are not available at this time.

9. Effects of Change in Effective Date for Policies Relating to Hospital Services Furnished under Arrangements

In section IV.L. of the preamble of this final rule, we discuss that, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), we limited the circumstances under which a hospital may furnish services to Medicare beneficiaries "under

arrangements." Under the revised policy, "routine services" (that is, bed, board, and nursing and other related services) must be provided in the hospital in which the patient is a registered inpatient in order for the services to be considered as being provided by the hospital. Routine services furnished to Medicare beneficiaries as inpatients of the hospital are considered services furnished by the hospital. Only diagnostic and therapeutic services (that is, ancillary services) may be provided under arrangements outside the hospital. We have become aware that a number of affected hospitals need additional time to restructure existing arrangements and establish necessary operational protocols to comply with this requirement. Therefore, as we proposed, we are postponing the effective date of the revised policy change from services provided on or after October 1, 2011, to cost reporting periods beginning in FY 2014. We have determined that the impact of this effective date change is negligible.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the March 2012 update of the FY 2011 MedPAR file and the March 2012 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2012 update of the most recently available hospital cost report data (FYs 2009 and 2010) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment as described below. (As discussed in greater detail in section V.E. of the preamble of this final rule, at this time, we are not adopting our proposal to make an additional -0.8 percent adjustment to the national capital Federal rate in FY 2013 to account for the effect of changes in case-mix resulting from documentation and coding changes that do not reflect real changes in the case-mix in light of the adoption of MS-DRGs. However, the cumulative documentation and coding adjustment factor of 0.9479 applied in determining the FY 2012 capital Federal rate remains applied to that rate. We also note, as we proposed, we are not making any further adjustments to the Puerto Rico-specific capital rate in FY 2013 to account for changes in documentation and coding.)

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources.

We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2012 update of the FY 2011 MedPAR file, we simulated payments under the capital IPPS for FY 2012 and FY 2013 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (Indian Health Service hospitals and hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating capital IPPS payments in FY 2013 is as follows:

(Standard Federal Rate) x (DRG weight) x (GAF) x (COLA for hospitals located in Alaska and Hawaii) x (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may also receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index will increase by 0.5 percent in both FYs 2012 and 2013.

- We estimate that the Medicare discharges will be approximately 12.5 million in FY 2012 and 12.9 million in FY 2013.

- The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this final rule, the update is 1.2 percent for FY 2013.

- In addition to the FY 2013 update factor, the FY 2013 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9998, and an outlier adjustment factor of 0.9362.

2. Results

We used the actuarial model described above to estimate the potential impact of our changes for FY 2013 on total capital payments per case, using a universe of 3,423 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the March 2012 update of the FY 2011 MedPAR file, the March 2012 update to the PSF, and the most recent cost report data from the March 2012 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2012 and estimated total payments per case for FY 2013 based on the FY 2013 payment policies. Column 2 shows estimates of payments per case under our model for FY 2012. Column 3 shows estimates of payments per case under our model for FY 2013. Column 4 shows the total percentage change in payments from FY 2012 to FY 2013. The change represented in Column 4 includes the 1.2 percent

update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2013 are expected to increase as compared to capital payments per case in FY 2012. However, the capital Federal rate for FY 2013 will increase approximately 1.0 percent as compared to the FY 2012 capital Federal rate. The changes to the GAFs are expected to result, on average, in a slight decrease in capital payments for most regions with certain exceptions. The regional variations in the estimated change in capital payments are consistent with the changes in payments due to changes in the wage index (and policies affecting the wage index) shown in Table I in section I. of this Appendix.

We also are estimating a slight increase in outlier payments in FY 2013 as compared to FY 2012. This is primarily because of the decrease to the outlier fixed-loss amount (discussed in section II.A.4.f. of the Addendum to this final rule). In addition, this estimated increase in outlier payments is based on the FY 2011 claims from the March 2012 update of the MedPAR file, and we are currently estimating that FY 2013 capital outlier payments will be slightly more than the projected 6.18 percent used to determine the outlier offset that we applied in determining the FY 2012 capital Federal rate.

The net impact of these changes, as discussed above, is an estimated 1.8 percent change in capital payments per discharge from FY 2012 to FY 2013 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, all hospitals are expected to experience an increase in capital IPPS payments per case in FY 2013 as compared to FY 2012. These increases are primarily due to the estimated increase in capital outlier payments. Capital IPPS payments per case for large urban hospitals are estimated to increase 2.0 percent, while other urban hospitals are expected to experience a 1.7 percent increase. Rural hospitals, on average, are expected to experience a 1.5 percent increase in capital payments per discharge from FY 2012 to FY 2013.

The comparisons by region show that the estimated increases in capital payments per discharge from FY 2012 to FY 2013 in urban areas ranges from a 0.8 percent increase for the New England urban region to a 3.2 percent increase for the Pacific urban region. For urban regions, the changes to the GAFs are expected to have a slightly negative effect on capital IPPS payments per discharge. However, for the Pacific urban region, as well as the Mountain urban region and the Puerto Rico urban region, a large part of the expected increase in capital IPPS payments per discharge is due to the GAFs. This is primarily due to changes in the wage index for hospitals located in that area as discussed in section I. of this Appendix.

Whereas the Pacific urban region is estimated to experience the largest increase in capital IPPS payment per discharge, the estimated increase for the Pacific rural region is the lowest at 0.4 percent. The largest percentage increase in capital payments per discharge from FY 2012 to FY 2013 for rural regions is estimated for the Mountain rural region to be 2.9 percent. The Puerto Rico rural region is estimated to experience a 2.5 percent increase in capital payments per discharge in FY 2013 compared to FY 2012.

Hospitals of all type of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are estimated to experience an increase in capital payments per case from FY 2012 to FY 2013. The increase in capital payments for both voluntary and proprietary hospitals is estimated at 1.8 percent, and government hospitals are estimated to experience a 2.0 percent increase in capital payments per case from FY 2012 to FY 2013.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2013. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified for FY 2013, we show the average capital payments per case for reclassified hospitals for FY 2013. As with all other categories, reclassified hospitals are expected to experience an increase in capital payments. The estimated percentage increase for urban reclassified hospitals is 2.0 percent, and 1.9 percent for urban nonreclassified hospitals. Rural reclassified hospitals are estimated to experience a 1.6 percent increase in capital payments per discharge from FY 2012 to FY 2013, while rural nonreclassified hospitals are estimated to experience a 1.3 percent increase in capital payments per case. Other reclassified hospitals (that is, hospitals reclassified under section 1886(d)(8)(B) of the Act) are expected to experience a 1.0 percent increase in capital payments from FY 2012 to FY 2013.

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2012 PAYMENTS COMPARED TO FY 2013 PAYMENTS]

	Number of Hospitals	Average FY 2012 Payments/ Case	Average FY 2013 Payments/ Case	Percentage Change
By Geographic Location:				
All hospitals	3,423	794	809	1.8
Large urban areas (populations over 1 million)	1,373	876	894	2.0
Other urban areas (populations of 1 million of fewer)	1,124	777	790	1.7
Rural areas	926	550	558	1.5
Urban hospitals	2,497	832	847	1.9
0-99 beds	633	678	692	1.9
100-199 beds	780	717	730	1.8
200-299 beds	448	769	783	1.8
300-499 beds	430	846	863	1.9
500 or more beds	206	1,002	1,020	1.8
Rural hospitals	926	550	558	1.5
0-49 beds	321	439	445	1.2
50-99 beds	347	505	513	1.6
100-149 beds	153	545	551	1.1
150-199 beds	58	613	622	1.6
200 or more beds	47	669	681	1.7
By Region:				
Urban by Region	2,497	832	847	1.9
New England	120	901	908	0.8
Middle Atlantic	318	884	895	1.3
South Atlantic	380	772	784	1.5
East North Central	399	797	813	2.1
East South Central	151	726	734	1.1
West North Central	165	822	842	2.4
West South Central	372	784	797	1.7
Mountain	159	856	877	2.5
Pacific	382	1,008	1,040	3.2
Puerto Rico	51	377	386	2.4
Rural by Region	926	550	558	1.5
New England	23	743	759	2.1
Middle Atlantic	69	573	582	1.5
South Atlantic	166	537	544	1.3
East North Central	120	570	581	2.0
East South Central	173	503	509	1.2
West North Central	98	581	588	1.2
West South Central	181	490	496	1.2
Mountain	65	575	592	2.9
Pacific	30	711	714	0.4
Puerto Rico	1	153	157	2.5
By Payment Classification:				
All hospitals	3,423	794	809	1.8
Large urban areas (populations over 1 million)	1,383	875	893	2.0
Other urban areas (populations of 1 million of fewer)	1,129	776	789	1.7
Rural areas	911	560	568	1.3
Teaching Status:				
Non-teaching	2,392	677	690	1.8
Fewer than 100 Residents	789	786	801	1.8
100 or more Residents	242	1,125	1,147	1.9
Urban DSH:				
100 or more beds	1,558	853	870	1.9
Less than 100 beds	345	596	609	2.1

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2012 PAYMENTS COMPARED TO FY 2013 PAYMENTS]

	Number of Hospitals	Average FY 2012 Payments/ Case	Average FY 2013 Payments/ Case	Percentage Change
Rural DSH:				
Sole Community (SCH/EACH)	258	503	511	1.6
Referral Center (RRC/EACH)	232	624	632	1.2
Other Rural:				
100 or more beds	34	521	526	0.8
Less than 100 beds	296	449	454	1.2
Urban teaching and DSH:				
Both teaching and DSH	825	924	942	1.9
Teaching and no DSH	139	824	836	1.5
No teaching and DSH	1,078	718	732	2.0
No teaching and no DSH	470	737	750	1.7
Rural Hospital Types:				
Non special status hospitals	2,395	836	851	1.9
RRC/EACH	64	732	749	2.3
SCH/EACH	38	736	746	1.4
SCH, RRC and EACH	17	784	800	2.1
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2013 Reclassifications:				
All Urban Reclassified	320	816	832	2.0
All Urban Non-Reclassified	2,137	836	852	1.9
All Rural Reclassified	334	592	602	1.6
All Rural Non-Reclassified	531	484	490	1.3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	55	548	553	1.0
Type of Ownership:				
Voluntary	1,971	808	822	1.8
Proprietary	868	714	727	1.8
Government	563	819	835	2.0
Medicare Utilization as a Percent of Inpatient Days:				
0-25	376	1,036	1,064	2.8
25-50	1,834	833	848	1.8
50-65	974	664	674	1.5
Over 65	166	606	614	1.3

J. Effects of Payment Rate Changes and Policy Changes under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2013. In the preamble, we specify the statutory authority for the provisions that are presented, identify those policies, and present rationales for our decisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Currently, there are 428 LTCHs included in this impacts analysis which includes data for 82 nonprofit (voluntary ownership control) LTCHs and 323 proprietary LTCHs. Of the remaining 23 LTCHs, 14 LTCHs are government-owned and operated and the ownership type of the other 9 LTCHs is unknown. In the impact analysis, we used the payment rate, factors, and policies presented in this final rule, including the 1.8 percent annual update, which is based on the full increase of the LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act, a one-time prospective adjustment factor of 0.98734 (approximately -1.3 percent), which will not apply to payments for discharges occurring on or before December 28, 2012 (consistent with the statute), the update to the MS-LTC-DRG classifications and relative weights, the update to the wage index values and labor-related share, the expiration of the statutory delay in the application of very short-stay outlier policy under § 412.529(c)(3), effective

for discharges occurring on or after December 29, 2012 (that is, the option for certain short-stay outlier cases to be paid under the "blended payment" will be replaced with the "IPPS comparable per diem amount" as discussed in section VII.E.3. of the preamble of this final rule), and the best available claims and CCR data to estimate the change in payments for FY 2013.

The standard Federal rate for FY 2012 was $40,222.05. For FY 2013, we are establishing a standard Federal rate of $40,397.96 that reflects the 1.8 percent annual update to the standard Federal rate, and the area wage budget neutrality factor of 0.999265, which ensures that the changes in the wage indexes and labor-related share do not influence aggregate payments. Furthermore, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately -1.3 percent) will not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, will not reflect that adjustment and, instead, will be paid based on a standard Federal rate of $40,915.95.

Based on the best available data for the 428 LTCHs in our database, we estimate that the annual update to the standard Federal rate for FY 2013 (discussed in section V.A.2. of the Addendum to this final rule) and the changes to the area wage adjustment for FY 2013 (discussed in section V.B. of the Addendum to this final rule), in addition to an estimated increase in HCO payments and an estimated decrease in SSO payments, will result in an increase in estimated payments from FY 2012 of approximately $92 million.

Based on the 428 LTCHs in our database, we estimate that the FY 2013 LTCH PPS payments will be approximately $5.52 billion, as compared to estimated FY 2012 LTCH PPS payments of approximately $5.43 billion. Because the combined distributional effects and estimated changes to the Medicare program payments are over approximately $100 million, this final rule is considered a major economic rule, as defined in this section. We note that the approximately $92 million for the projected increase in estimated aggregate LTCH PPS payments from FY 2012 to FY 2013 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also will affect overall payment changes. It also does not include the estimated effect of the 1-year extension of the moratorium on the application of the "25-percent threshold" payment adjustment policy on LTCH PPS payments, which is discussed below in section I.J.b.3. of this Appendix.

The projected 1.7 percent increase in estimated payments per discharge from FY 2012 to FY 2013 is attributable to several factors, including the 1.8 percent annual update to the standard Federal rate, the one-time prospective adjustment factor for FY 2013 of 0.98734 (approximately -1.3 percent) to the standard Federal rate, which is not applicable to payments for discharges occurring on or before December 28, 2012, consistent with the statute, and projected increases in estimated HCO payments and decreases in SSO payments due to a change in the SSO payment methodology effective for discharges occurring on or after December 29, 2012 (as described in section VII.E.3. of the preamble of this final rule). As Table IV shows, the change attributable solely to the annual update to the standard Federal rate (1.8 percent), including the one-time

prospective adjustment factor for FY 2013 (approximately -1.3 percent), which is not applicable to payments for discharges occurring before December 29, 2012, is projected to result in an increase of 0.7 percent in payments per discharge from FY 2012 to FY 2013, on average, for all LTCHs. This estimated increase of 0.7 percent reflects the 1.8 percent annual update for payments in FY 2013, and the -1.3 percent one-time prospective adjustment factor for FY 2013, which will not apply in determining payments for discharges occurring on or before December 28, 2012, and also includes estimated payments for SSO cases that are paid using special methodologies that are not affected by the annual update to the standard Federal rate. Therefore, the projected increase in payments based on the standard Federal rate is less than the 1.8 percent annual update for FY 2013. Because we are applying an area wage level budget neutrality factor to the standard Federal rate, the annual update to the wage data and labor-related share does not impact the increase in payments.

As discussed in section V.B. of the Addendum to this final rule, we are updating the wage index values for FY 2013 based on the most recent available data. In addition, we are decreasing the labor-related share from 70.199 percent to 63.096 percent under the LTCH PPS for FY 2013, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs based on the FY 2009-based LTCH-specific market basket. We also are applying an area wage level budget neutrality factor of 0.999265, which reduces the standard Federal rate by less than 0.1 percent. Therefore, the changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments.

We project that LTCHs will experience a decrease in aggregate payments of 0.5 percent in FY 2013 as a result of the expiration of the statutory delay in the application of the very short-stay outlier policy under § 412.529(c)(3), effective for discharges occurring on or after December 29, 2012. Generally, very short-stay outliers are cases that have a length of stay that is less than or equal to one standard deviation from the geometric mean average length of stay of the same DRG under the IPPS. Under the moratorium, very short-stay outliers are paid the lowest of: (1) the LTC-DRG payment; (2) 100 percent of cost; (3) 120 percent of the LTCH per diem payment; or (4) a blend of 120 percent of the LTCH per diem amount and the "IPPS comparable per diem amount" (the "blended payment"). With the expiration of the moratorium, in the case of very short-stay outliers, effective for discharges on or after December 29, 2012, the "blended payment" will be replaced with only the "IPPS comparable per diem amount," which results in a decrease in payments for many of these cases.

Table IV below shows the impact of the payment rate and the policy changes on LTCH PPS payments for FY 2013 presented in this final rule by comparing estimated FY 2012 payments to estimated FY 2013 payments. The projected increase in payments per discharge from FY 2012 to FY 2013 is 1.7 percent (shown in Column 9). This projected increase in payments is attributable to the impacts of the change to the standard Federal rate (0.7 percent in Column 6), the end of the moratorium on delaying the implementation of the very short-stay outlier policy (-0.5 percent in Column 8), as well as the effect of the estimated increase in payments for HCO cases and SSO cases (1.1 percent and 0.2 percent, respectively). That is, estimated total HCO payments are

projected to increase from FY 2012 to FY 2013 in order to ensure that the estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2013. An analysis of the most recent available LTCH PPS claims data (that is, FY 2011 claims data from the March 2012 update of the MedPAR file) indicates that the FY 2012 HCO threshold of $17,931 (as established in the FY 2012 IPPS/LTCH PPS final rule) may result in HCO payments in FY 2012 that fall below the estimated 8 percent. Specifically, we currently estimate that HCO payments will be approximately 6.9 percent of the estimated total LTCH PPS payments in FY 2012. We estimate that the impact of the increase in HCO payments will result in approximately a 1.1 percent increase in estimated payments from FY 2012 to FY 2013, on average, for all LTCHs. Furthermore, in calculating the estimated increase in payments from FY 2012 to FY 2013 for HCOs, we increased estimated costs by the applicable market basket percentage increase as projected by our actuaries. This increase in estimated costs also results in a projected increase in SSO payments of 0.2 percent relative to last year. However, the expiration of the statutory moratorium on the application of the very short-stay outlier policy, effective December 29, 2012, which replaces the "blended payment" option with the "IPPS comparable per diem amount" option for certain SSO cases (as described in section VII.E.3. of the preamble of this final rule) is expected to result in a -0.5 percent change in aggregate payments. The net result of these projected changes in SSO payments in FY 2013 is an estimated change in aggregate payments of -0.3 percent. We note that estimated payments for all SSO cases comprise approximately 12 percent of the estimated total LTCH PPS payments, and estimated payments for HCO cases comprise

approximately 8 percent of the estimated total FY 2013 LTCH PPS payments. Payments for HCO cases are based on 80 percent of the estimated cost of the case above the HCO threshold, while the majority of the payments for SSO cases (approximately 59 percent) are based on the estimated cost of the case.

As we discuss in detail throughout this final rule, based on the most recent available data, we believe that the provisions of this final rule relating to the LTCH PPS will result in an increase in estimated aggregate LTCH PPS payments and that the resulting LTCH PPS payment amounts will result in appropriate Medicare payments.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 3.3 percent increase in estimated payments per discharge for FY 2013 as compared to FY 2012 for rural LTCHs that will result from the changes presented in this final rule, as well as the effect of estimated changes to HCO and SSO payments. This estimated impact is based on the data for the 27 rural LTCHs in our database (out of 428 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2012 to FY 2013 for rural LTCHs is primarily due to the higher than average impacts from the changes to the area wage level adjustment, specifically, the decrease in the labor-related share from 70.199 to 63.096. Although we applied an area wage level budget neutrality factor for changes to the wage indexes and labor-related share to ensure that there is no change in aggregate LTCH PPS payments due to those changes, we estimate rural hospitals will

experience a 1.1 percent increase in payments due to the changes to the area wage level adjustment, as shown in Column 7 below. Rural hospitals generally have a wage index of less than 1; therefore, a decrease to the labor-related share results in their wage index reducing a smaller portion of the standard Federal rate, resulting in an estimated increase in payments in FY 2013 as compared to FY 2012.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs "maintain budget neutrality." We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

As discussed above in section I.J.1. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2013 relative to FY 2012 of approximately $92 million based on the 428 LTCHs in our database.

b. Expiration of Statutory Delay on Full Implementation of the "25 Percent Threshold" Payment Adjustment and 1-Year Extension

As discussed in section VII.E.2. of the preamble of this final rule, the statutory delay in the full application of the "25 percent threshold" payment adjustment for LTCHs under § 412.534 and § 412.536 will expire for cost reporting periods beginning on or

after July 1, 2012, or October 1, 2012, as applicable. We are establishing a 1-year extension of the moratorium on the application of the "25 percent threshold" payment adjustment policy as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013 (and for discharges occurring on or after October 1, 2012, through the end of the cost reporting period of LTCHs with cost reporting periods beginning on or after July 1, 2012, and before September 30, 2012, as explained in section VII.E.2. of the preamble of this final rule). We estimate that this policy will result in a payment impact of approximately $170 million to LTCHs.

c. Impact on Providers

The basic methodology for determining a per discharge LTCH PPS payment is set forth under § 412.515 through § 412.536. In addition to the basic MS-LTC-DRG payment (the standard Federal rate multiplied by the MS-LTC-DRG relative weight), we make adjustments for differences in area wage levels, the COLA for Alaska and Hawaii, and SSOs. Furthermore, LTCHs may also receive HCO payments for those cases that qualify based on the threshold established each year.

To understand the impact of the changes to the LTCH PPS payments presented in this final rule on different categories of LTCHs for FY 2013, it is necessary to estimate payments per discharge for FY 2012 using the rates, factors (including the FY 2012 GROUPER (Version 29.0), and relative weights and the policies established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51781 and 51838 through

51844). It is also necessary to estimate the payments per discharge that will be made under the LTCH PPS rates, factors, policies, and GROUPER (Version 30.0) for FY 2013 (as discussed in section VII. of the preamble and section V. of the Addendum to this final rule). These estimates of FY 2012 and FY 2013 LTCH PPS payments are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for SSO and HCO cases in each year. We also evaluated the change in estimated FY 2012 payments to estimated FY 2013 payments (on a per discharge basis) for each category of LTCHs. We are establishing a standard Federal rate for FY 2013 of $40,397.96 that includes the 1.8 percent annual update, the area wage budget neutrality factor, and the one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately -1.3 percent) that will not apply to payments for discharges occurring on or before December 29, 2012, consistent with statute. Payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, will not reflect that one-time prospective adjustment and instead will be paid based on a standard Federal rate of $40,915.95.

Therefore, we modeled payments so that claims with discharge dates prior to January will be paid on the basis of a rate that does not reflect the one-time prospective adjustment, and claims with discharges in January or after will reflect the standard Federal rate for FY 2013 that reflects the one-time prospective adjustment. Furthermore, because the statutory moratorium on the application of the very short-stay outlier policy will expire effective for discharges occurring on or after December 29, 2012, we modeled payments so that claims that will qualify for a payment under the very short-stay outlier

policy with discharge dates in October, November, and December are paid based on the "blended payment" option, if applicable, and claims that will qualify for a payment under the very short-stay outlier policy with discharges in January through September are paid based on the "IPPS comparable per diem amount," if applicable (as described in section VII.E.3. of the preamble of this final rule).

Hospital groups were based on characteristics provided in the OSCAR data, FY 2008 through FY 2009 cost report data in HCRIS, and PSF data. Hospitals with incomplete characteristics were grouped into the "unknown" category. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

To estimate the impacts of the payment rates and policy changes among the various categories of existing providers, we used LTCH cases from the FY 2011 MedPAR file to estimate payments for FY 2012 and to estimate payments for FY 2013 for 428 LTCHs. We believe that the discharges based on the FY 2011 MedPAR data for the 428 LTCHs in our database, which includes 323 proprietary LTCHs, provide sufficient representation in the MS-LTC-DRGs containing discharges for patients who received LTCH care for the most commonly treated LTCH patients' diagnoses.

d. Calculation of Prospective Payments

For purposes of this impact analysis, to estimate per discharge payments under the LTCH PPS, we simulated payments on a case-by-case basis using LTCH claims from the FY 2011 MedPAR files. For modeling estimated LTCH PPS payments for FY 2012, we used the FY 2012 standard Federal rate (that is, $40,222.05 effective for LTCH discharges occurring on or after October 1, 2011, through September 30, 2012).

For modeling estimated LTCH PPS payments for FY 2013, we used the FY 2013 standard Federal rate of $40,397.96, which includes the one-time prospective adjustment of 0.98734 for FY 2013 for payments for discharges occurring on or after December 29, 2012, and through September 30, 2013. As noted above, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately -1.3 percent) will not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, will not reflect that adjustment and instead will be paid based on a standard Federal rate of $40,915.95; therefore, for the purpose of payment modeling, claims with discharges occurring during October through December were modeled using this payment rate.

The FY 2013 standard Federal rate of $40,397.96 includes the application of an area wage level budget neutrality factor of 0.999265 (as discussed in section V.B.5. of the Addendum to this final rule). As noted above, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, this

payment rate will not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, will be paid based on a standard Federal rate of $40,915.95, which also includes the area wage level budget neutrality factor of 0.999265.

Furthermore, in modeling estimated LTCH PPS payments for both FY 2012 and FY 2013 in this impact analysis, we applied the FY 2012 and the FY 2013 adjustments for area wage levels and the COLA for Alaska and Hawaii. Specifically, we adjusted for differences in area wage levels in determining estimated FY 2012 payments using the current LTCH PPS labor-related share of 70.199 percent (76 FR 51766) and the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2012 IPPS/LTCH PPS final rule (and available via the Internet (76 FR 51813)). We also applied the FY 2012 COLA factors shown in the table in section V.C. of the Addendum to that final rule (76 FR 51810) to the FY 2012 nonlabor-related share (29.801 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining the estimated FY 2013 payments using the FY 2013 LTCH PPS labor-related share of 63.096 percent and the FY 2013 wage index values presented in Tables 12A and 12B listed in section VI. of the Addendum to this final rule (and available via the Internet). We also applied the FY 2013 COLA factors shown in the table in section V.C. of the Addendum to this final rule to the FY 2013 nonlabor-related share (36.904 percent) for LTCHs located in Alaska and Hawaii.

As discussed above, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated increase in payments for HCO cases (as described in section V.D. of the Addendum to this final rule). In modeling payments for SSO and HCO cases in FY 2013, we applied an inflation factor of 1.050 (determined by OACT) to estimate the costs of each case using the charges reported on the claims in the FY 2011 MedPAR files and the best available CCRs from the March 2012 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2013 in this impact analysis, we used the FY 2013 fixed-loss amount of $15,408 (as discussed in section V.D. of the Addendum to this final rule). Finally, in modeling payments for SSO cases, we included the expiration of the statutory moratorium on application of the very short-stay outlier, effective for discharges occurring on or after December 29, 2012, under which the "blended payment" option of the SSO payment formula will be replaced with the "IPPS comparable per diem amount" for very short-stay outlier cases as discussed in section VII.E.3. of the preamble of this final rule.

These impacts reflect the estimated "losses" or "gains" among the various classifications of LTCHs from FY 2012 to FY 2013 based on the payment rates and policy changes presented in this final rule. Table IV illustrates the estimated aggregate impact of the LTCH PPS among various classifications of LTCHs.

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases.

- The fourth column shows the estimated payment per discharge for FY 2012 (as described above).

- The fifth column shows the estimated payment per discharge for FY 2013 (as described above).

- The sixth column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule) and the one-time prospective adjustment factor for FY 2013 (which is not applicable to payments for discharges occurring before December 29, 2012, consistent with the statute).

- The seventh column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 for changes to the area wage level adjustment (that is, the wage indexes and labor-related share), including the application of an area wage level budget neutrality factor (as discussed in section V.B.5. of the Addendum to this final rule).

- The eighth column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 due to the expiration of the delay in the application of the "very short-stay" SSO policy that allowed for certain SSO cases to be paid under a "blended payment amount" based on the LTCH per diem rate and IPPS comparable per diem rate during the moratorium.

- The ninth column shows the percentage change in estimated payments per discharge from FY 2012 (Column 4) to FY 2013 (Column 5) for all changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV: IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2013 (ESTIMATED FY 2012 PAYMENTS COMPARED TO ESTIMATED FY 2013 PAYMENTS*)

LTCH Classification (1)	Number of LTCHs (2)	Number of LTCH PPS Cases (3)	Average FY 2012 LTCH PPS Payment Per Case (4)	Average FY 2013 LTCH PPS Payment Per Case[1] (5)	Percent Change in Estimated Payments Per Discharge from FY 2012 to FY 2013 for the Annual Update to the Federal Rate [2] (6)	Percent Change in Estimated Payments Per Discharge from FY 2012 to FY 2013 for Changes to the Area Wage Level Adjustment with Budget Neutrality[3] (7)	Percent Change in Estimated Payments Per Discharges due to Expiration of Statutory Moratorium on Application of the 'Very' Short-Stay SSO Payment Methodology[4] (8)	Percent Change in Payments Per Discharge from FY 2012 to FY 2013 for All Changes[5] (9)
ALL PROVIDERS	428	140,159	38,742	39,399	0.7	0	-0.5	1.7
BY LOCATION:								
RURAL	27	6,396	34,526	35,659	0.7	1.1	-0.4	3.3
URBAN	401	133,763	38,944	39,578	0.7	0	-0.5	1.6
LARGE	202	77,764	40,984	41,594	0.7	-0.2	-0.5	1.5
OTHER	199	55,999	36,111	36,778	0.7	0.2	-0.5	1.8
BY PARTICIPATION DATE:								
BEFORE OCT. 1983	17	5,929	34,169	34,984	0.7	-0.2	-0.3	2.4
OCT. 1983 - SEPT. 1993	44	16,804	41,914	42,623	0.7	-0.1	-0.6	1.7
OCT. 1993 - SEPT. 2002	185	65,360	37,993	38,623	0.7	0	-0.5	1.7
AFTER OCTOBER 2002	173	50,870	39,150	39,812	0.7	0	-0.5	1.7
UNKNOWN PARTICIPATION DATE	9	1,196	40,450	40,888	0.6	-0.3	-0.8	1.1
BY OWNERSHIP TYPE:								
VOLUNTARY	82	20,035	38,941	39,835	0.7	0.2	-0.6	2.3
PROPRIETARY	323	117,083	38,626	39,238	0.7	0	-0.5	1.6
GOVERNMENT	14	1,773	43,976	44,744	0.7	-0.3	-0.7	1.7
UNKNOWN OWNERSHIP TYPE	9	1,268	38,982	39,964	0.7	0.7	-0.7	2.5
BY REGION:								
NEW ENGLAND	15	7,408	33,812	34,518	0.7	-0.3	-0.3	2.1
MIDDLE ATLANTIC	31	8,034	41,519	41,977	0.7	-0.1	-0.5	1.1
SOUTH ATLANTIC	60	16,835	41,536	42,072	0.7	0	-0.6	1.3
EAST NORTH CENTRAL	70	20,888	39,944	40,672	0.7	0.4	-0.6	1.8
EAST SOUTH CENTRAL	30	8,563	39,072	39,949	0.7	0.6	-0.5	2.2
WEST NORTH CENTRAL	26	6,076	40,080	40,829	0.7	0.5	-0.6	1.9

LTCH Classification (1)	Number of LTCHs (2)	Number of LTCH PPS Cases (3)	Average FY 2012 LTCH PPS Payment Per Case (4)	Average FY 2013 LTCH PPS Payment Per Case[1] (5)	Percent Change in Estimated Payments Per Discharge from FY 2012 to FY 2013 for the Annual Update to the Federal Rate [2] (6)	Percent Change in Estimated Payments Per Discharge from FY 2012 to FY 2013 for Changes to the Area Wage Level Adjustment with Budget Neutrality[3] (7)	Percent Change in Estimated Payments Per Discharges due to Expiration of Statutory Moratorium on Application of the 'Very' Short-Stay SSO Payment Methodology[4] (8)	Percent Change in Payments Per Discharge from FY 2012 to FY 2013 for All Changes[5] (9)
WEST SOUTH CENTRAL	139	51,703	34,421	35,198	0.8	0.2	-0.5	2.3
MOUNTAIN	32	7,002	42,021	42,400	0.7	-0.8	-0.5	0.9
PACIFIC	25	13,650	48,383	48,680	0.7	-1.1	-0.4	0.6
BY BED SIZE:								
BEDS: 0-24	29	3,335	34,101	34,837	0.8	0.7	-0.5	2.2
BEDS: 25-49	200	46,342	38,118	38,834	0.7	0.3	-0.5	1.9
BEDS: 50-74	116	38,300	38,722	39,346	0.7	-0.1	-0.5	1.6
BEDS: 75-124	46	21,448	42,047	42,606	0.7	-0.3	-0.5	1.3
BEDS: 125-199	23	16,534	37,343	38,005	0.7	-0.1	-0.5	1.8
BEDS: 200 +	14	14,200	38,563	39,240	0.7	-0.4	-0.4	1.8

[1] Estimated FY 2013 LTCH PPS payments based on the payment rate and policy changes presented in the preamble and the Addendum to this final rule.
[2] Percent change in estimated payments per discharge from FY 2012 to FY 2013 for the annual update to the standard Federal rate and the one-time prospective adjustment factor for FY 2013 (which will not apply to payments for discharges occurring before December 29, 2012, consistent with the statute), as discussed in section V.A.2. of the Addendum to this final rule.
[3] Percent change in estimated payments per discharge from FY 2012 to FY 2013 for changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this final rule).
[4] Percent change in estimated payments per discharges due to the expiration of the statutory moratorium on application of the "very short-stay" SSO payment option, effective for discharges occurring on or after December 29, 2012, under which the "blended payment" option of the SSO payment formula will be replaced with the "IPPS comparable per diem amount" for very short-stay outlier cases as discussed in section VII.E.3. of the preamble of this final rule.
[5] Percent change in estimated payments per discharge from FY 2012 LTCH PPS (shown in Column 4) to FY 2013 LTCH PPS (shown in Column 5), including all of the changes presented in the preamble and the Addendum to this final rule. Note, this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the standard Federal rate (column 6) and the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

e. Results

Based on the most recent available data for 428 LTCHs, we have prepared the following summary of the impact (as shown above in Table IV) of the LTCH PPS payment rate and policy changes presented in this final rule. The impact analysis in

Table IV shows that estimated payments per discharge are expected to increase approximately 1.7 percent, on average, for all LTCHs from FY 2012 to FY 2013 as a result of the payment rate and policy changes presented in this final rule, including the expiration of the statutory moratorium on application of the "very short-stay" SSO policy which utilizes the "IPPS comparable per diem amount" payment option, effective for discharges occurring on or after December 29, 2012 (discussed in section VII.E.3. of the preamble of this final rule) and an estimated increase in HCO payments. This estimated 1.7 percent increase in LTCH PPS payments per discharge from the FY 2012 to FY 2013 for all LTCHs (as shown in Table IV) was determined by comparing estimated FY 2013 LTCH PPS payments (using the payment rate and policies discussed in this final rule) to estimated FY 2012 LTCH PPS payments (as described above in section I.J.1. of this Appendix).

We are establishing a standard Federal rate of $40,397.96 for FY 2013. Specifically, we are updating the standard Federal rate for FY 2013 by 1.8 percent, which is based on the latest estimate of the LTCH PPS market basket increase (2.6 percent), the reduction of 0.7 percentage point for the MFP adjustment, and the 0.1 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. In addition, we are applying a one-time prospective adjustment factor for FY 2013 of 0.98734 (approximately -1.3 percent) to the standard Federal rate. However, this reduction will not apply to payments for discharges occurring before December 29, 2012, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act. Therefore, payments for discharges occurring on or after October

1, 2012, and on or before December 28, 2012, will not reflect that adjustment and instead will be paid based on a standard Federal rate of $40,915.95. We noted earlier in this section that, for most categories of LTCHs, as shown in Table IV (Column 6), the impact of the increase of 1.8 percent in the annual update to the standard Federal rate and the application of the one-time prospective adjustment for FY 2013 of approximately -1.3 percent, which will not apply to payments for discharges occurring before December 29, 2012, consistent with the statute, is projected to result in approximately a 0.7 percent increase in estimated payments per discharge for all LTCHs from FY 2012 to FY 2013. That is, for approximately the first 3 months of FY 2013, payments will not reflect the one-time prospective adjustment factor for FY 2013 such that payments will be based on the annual update to the standard Federal rate of 1.8 percent, and for the remaining 9 months of FY 2013, payments will be based on a standard Federal rate that reflects the FY 2013 annual update of 1.8 percent and the one-time prospective adjustment for FY 2013 of approximately -1.3 percent. In addition, our estimate of the changes in payments due to the update to the standard Federal rate also reflects estimated payments for SSO cases that are paid using special methodologies that are not affected by the update to the standard Federal rate. For these reasons, we estimate that payments will increase by 0.7 percent due to the annual update to the standard Federal rate and the application of the one-time prospective adjustment for FY 2013 (which is not applicable to payments for discharges occurring before December 29, 201, consistent with the statute)..

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 6 percent of the LTCHs are identified as being located in a rural area, and approximately 5 percent of all LTCH cases are treated in these rural hospitals. The impact analysis presented in Table IV shows that the average percent increase in estimated payments per discharge from FY 2012 to FY 2013 for all hospitals is 1.7 percent for all changes. For rural LTCHs, the percent change for all changes is estimated to be 3.3 percent, while for urban LTCHs, we estimate the increase will be 1.6 percent. Large urban LTCHs are projected to experience an increase of 1.5 percent in estimated payments per discharge from FY 2012 to FY 2013, while other urban LTCHs are projected to experience an increase of 1.8 percent in estimated payments per discharge from FY 2012 to FY 2013, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) after October 2002. Based on the most recent available data, the category of LTCHs with the largest percentage of the LTCH cases (approximately 47 percent) are in hospitals that began participating in the Medicare program between October 1993 and September 2002, and are projected to experience nearly the average increase (1.7 percent) in estimated payments per discharge from FY 2012 to FY 2013, as shown in Table IV.

In the participation category where LTCHs began participating in the Medicare program before October 1983, LTCHs are projected to experience a higher than average percent increase (2.4 percent) in estimated payments per discharge from FY 2012 to FY 2013, as shown in Table IV. Approximately 4 percent of LTCHs began participating in the Medicare program before October 1983. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993. These LTCHs are projected to experience a 1.7 percent increase in estimated payments from FY 2012 to FY 2013. LTCHs that began participating in the Medicare program after October 2002 currently represent approximately 40 percent of all LTCHs, and are projected to experience an average increase (1.7 percent) in estimated payments from FY 2012 to FY 2013.

(3) Ownership Control

Other than LTCHs whose ownership control type is unknown, LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). We expect that LTCHs in the voluntary category will experience a higher than the average increase (2.3 percent) in estimated FY 2013 LTCH PPS payments per discharge as compared to estimated payments in FY 2012 primarily because we project the estimated increase in HCO payments to be higher than the average increase for these LTCHs. The majority (75 percent) of LTCHs is identified as proprietary and these LTCHs are projected to experience a nearly average increase (1.6 percent) in estimated payments per discharge from FY 2012 to FY 2013.

Finally, government-owned and operated LTCHs are also expected to experience the average increase in payments of 1.7 percent in estimated payments per discharge from FY 2012 to FY 2013.

(4) Census Region

Estimated payments per discharge for FY 2013 are projected to increase for LTCHs located in all regions in comparison to FY 2012. Of the 9 census regions, we project that the increase in estimated payments per discharge will have the largest positive impact on LTCHs in the West South Central, East South Central, and New England regions (2.3 percent, 2.2 percent, and 2.1 percent respectively as shown in Table IV). The estimated percent increase in payments per discharge from FY 2012 to FY 2013 for those regions is largely attributable to the changes in the area wage level adjustment or updates to the MS-LTC-DRGs classifications and relative weights.

In contrast, LTCHs located in the Pacific region are projected to experience the smallest increase in estimated payments per discharge from FY 2012 to FY 2013. The average estimated increase in payments of 0.6 percent for LTCHs in the Pacific region is primarily due to estimated decreases in payments associated with the changes to the area wage level adjustment.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0-24 beds; 25-49 beds; 50-74 beds; 75-124 beds; 125-199 beds; and greater than 200 beds.

We project that small LTCHs (0-24 beds) will experience a 2.2 percent increase in payments due to increases in the area wage level adjustment while large LTCHs (200+

beds) will experience a 1.8 percent increase in payments. LTCHs with between 75 and 124 beds are expected to experience a below average increase in payments per discharge from FY 2012 to FY 2013 (1.3 percent) primarily due to an estimated decrease in their payments from FY 2012 to FY 2013 due to the area wage level adjustment.

4. Effect on the Medicare Program

As noted previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments in FY 2013 relative to FY 2012 of approximately $92 million (or approximately 1.7 percent) for the 428 LTCHs in our database. In addition, the effects of the extension of the moratorium on the application of the "25 percent threshold" payment adjustment policy, as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning or after October 1, 2012, and before October 1, 2013 (and for discharges occurring on or after October 1, 2012, through the end of the cost reporting period of LTCHs with cost reporting periods beginning on or after July 1, 2012, and before September 30, 2012, as explained in section VII.E.2. of the preamble of this final rule), will result in a payment impact of approximately $170 million to LTCHs.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries under the LTCH PPS, but we

continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

K. Effects of Requirements for Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of this final rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for FY 2015. We now estimate that approximately 95 hospitals may not receive the full annual percentage increase in any fiscal year. At the time that the analysis was prepared, 70 hospitals did not receive the full annual percentage increase in FY 2012.

For the FY 2015 payment determination, we will remove one chart-abstracted measure, and 16 claims based measures, beginning with January 1, 2012 discharges. We believe that these changes will not have a significant effect on our estimate. We believe that most of these hospitals will be either small rural or small urban hospitals. However, at this time, information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for FY 2015.

In section VIII.A.6. of this final rule, we are finalizing for the FY 2015 payment determination, supplements to the chart validation process for the Hospital IQR Program. As a part of these supplements, we are finalizing, for FY 2015 payment determinations and subsequent years, to separate validation for chart-abstracted and HAI measures and to also validate two additional HAI measures, CAUTI and SSI. Starting with the FY 2015 payment determination, we are finalizing a modest increase to the current Hospital IQR Program validation sample of 18 cases per quarter (currently three each for SCIP, AMI, HF, PN, ED/IMM, and candidate CLABSI) to 27 cases per quarter (3 each for SCIP, AMI, HF, PN, ED/IMM, and up to 12 records combined for CLABSI, CAUTI,

and SSI). However, in order not to increase the Hospital IQR validation program's overall burden to hospitals, while expanding some of the requirements, and targeting hospitals with higher levels of concern for data quality, we are reducing the total sample size of hospitals included in the annual validation random sample from 800 eligible hospitals to up to 600 eligible hospitals. This includes 400 hospitals in the base random sample and up to 200 hospitals in the target sample. The requirement of an additional 9 charts per hospital submitted for validation, combined with the decreased sample size, will result in approximately 1,800 additional charts per quarter being submitted to CMS by all selected hospitals. We provide payment to hospitals for the cost of sending charts to the CDAC contractor at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Our experience shows that the average chart received by the CDAC contractor is approximately 275 pages. Thus, we estimate that we would expend approximately $66,600 per quarter to collect the additional charts we need to validate all measures.

The total requirement of 27 charts per hospital would result in approximately 16,200 charts per quarter being submitted to CMS. Using the assumptions discussed above, for the FY 2015 Hospital IQR Program, we estimate that we would have expenditures of approximately $599,400 per quarter related to the validation requirement. Given that we pay for the data collection effort, we believe that a requirement for 27 charts per hospital per quarter represents a minimal burden to participating hospitals selected for validation.

L. Effects of PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preamble of this final rule, we discuss our proposed and final policies to implement the quality data reporting program for PPS-exempt hospitals (PCHs), which we refer to as the PCHQR Program. The PCHQR Program is established under section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act. These quality reporting requirements will affect all PCHs participating in Medicare. In this final rule, PCHs will be required to register with the CDC, the CMS contractor, and QualityNet Web sites and take the proper training in order to be adequately prepared to use the respective systems to submit the data. The anticipated burden to these PCHs consists of the following: (1) the initial registration of the facility with CDC, the CMS contractor, and CMS; (2) training of the appropriate staff members on how to use the CDC agency-based data collection mechanism (CDC/NHSN), the CMS contractor-based collection mechanism for the cancer-specific quality measure data, and CMS (QualityNet) program; (3) the time required for collection and aggregation of data; (4) the time required for entry of the data into the CDC's NHSN data warehouse, CMS contractor's quality measure data warehouse, and QualityNet databases by the PCH's representative.

All PCHs that currently do not already report data to the NHSN will be required to register with the CDC, the CMS contractor, and the CMS/QualityNet and take the proper training in order to be adequately prepared to use the CDC's NHSN data warehouse, the CMS contractor's collection mechanism for data submission, and the CMS QualityNet Web site.

Those PCHs that already report the HAI measures to the NHSN will not be significantly affected because we intend to align our reporting infrastructure with that used by the NHSN. However, for PCHs that do not currently report the two HAI measures to the NHSN, at this time, we have no way to estimate how many PCHs will participate in the PCHQR program. Therefore, we are unable to estimate the burden for these PCHs.

Aside from the statutory requirements, it is important to note that one of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be shared with appropriate health care related organizations and used to further the development of health care quality, which, in turn, helps to further our objectives and goals. Health care organizations can use their health care quality data for many purposes such as in their risk management programs, health care acquired infection prevention programs and research and development of medical programs, among others.

Even more importantly, we intend to share the information obtained from the PCHQR Program with the public as is required under the statute. These data will be displayed on the Hospital Compare Web site. The goals of making these data available to the public in a public user-friendly and relevant format, include, but are not limited to: (1) keeping the public informed of the quality of care that is being provided in PCHs as a whole; (2) keeping the public informed of the quality of care being provided in specific PCHs; (3) allowing the public to compare and contrast the data about specific PCHs, thus enabling the public to make informed health care decisions regarding PCHs; and

(4) providing information about current trends in health care. There are many other public uses for these quality data concerning PCHs. Further, keeping the public informed of quality of care provided in health care has always been of high priority to CMS.

We also seek to align the new PCHQR Program reporting requirements with current HHS high priority conditions and topics and to ultimately provide a comprehensive assessment of the quality of health care delivered in a variety of settings.

We did not receive any public comments on the anticipated effects of the PCHQR Program.

M. Effects of Hospital Value-Based Purchasing (VBP) Program Requirements

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent.

We previously published a detailed analysis of the FY 2013 Hospital VBP Program's impact, based on scoring for two quality domains, in the Hospital Inpatient VBP Program final rule (76 FR 26542 through 26545). As we indicated in the FY 2013 IPPS/LTCH PPS proposed rule, because we are not making any changes to the FY 2013 Hospital VBP Program, we do not believe we must provide an additional regulatory impact analysis for the FY 2013 Hospital VBP Program. In this final rule, we are setting

forth the operational details of the payment adjustment. We believe that these operational details do not have a regulatory impact or financial impact beyond policies already finalized. They specify how CMS intends to ensure that the value-based incentive payments made to all hospitals in a fiscal year are equal, in total, to the reduced base operating DRG payment amounts.

In section VIII.C. of the preamble of this final rule, we discuss our proposal and final policy to add requirements for the Hospital VBP Program. In addition to certain operational and payment details for the FY 2013 Hospital VBP Program, we are making a number of additional changes related to the FY 2015 and the FY 2016 Hospital VBP Program, including measures, performance periods, performance standards, domain weighting, and other topics.

Specifically, with respect to the FY 2015 Hospital VBP Program, as we proposed, we are adding two additional measures in the Outcome domain, an AHRQ Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We also are adding a measure of Medicare Spending per Beneficiary in the Efficiency domain.

With respect to the FY 2016 Hospital VBP Program, as we proposed, we are adopting four measures: three 30-day mortality measures adopted for FY 2014 and proposed for FY 2015 - MORT-30-AMI, MORT-30-HF, and MORT-30-PN - and the AHRQ PSI composite measure in the Outcome domain. All of these measures are required for the Hospital IQR Program; therefore, their inclusion in the Hospital VBP

Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

For future program years, we intend to consider the impacts of Hospital VBP Program policies in the applicable IPPS/LTCH PPS rulemaking vehicle. Because we are not altering the underlying scoring methodology finalized for the FY 2013 Hospital VBP Program in this final rule, we do not believe it appropriate to revise the regulatory impact analysis published in the Hospital Inpatient VBP Program final rule referenced above. We intend to provide an updated analysis of the Hospital VBP Program's impacts for the FY 2014 program year in the FY 2014 IPPS/LTCH PPS rulemaking.

N. Effects of New Measures Added to the LTCH Quality Reporting (LTCHQR) Program

In section VIII.D. of the preamble of this final rule, we discuss the implementation of section 3004(a) of the Affordable Care Act, which added section 1886(m)(5) to the Act. Section 1886(m)(5) of the Act, further provides that in the case of an LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to the standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by 2 percentage points. The initial requirements for this LTCH Quality Reporting (LTCHQR) Program were finalized in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51839 through 51840), we estimated that only a few LTCHs would not receive the full payment update in any fiscal

year as a result of not submitting data under the LTCH quality reporting program. At this time, the LTCHQR Program has not been fully implemented, as data collection will not begin until October 1, 2012. However, we believe that statements we made in the FY 2012 IPPS/LTCH PPS final rule regarding the number and types of LTCHs that may not receive the full payment update as a result of failing to submit data to the Secretary under the LTCHQR Program remain valid. We believe that a majority of LTCHs will submit data because they will view the new quality reporting program as an important step in improving the quality of care patients receive in these facilities. We believe that most LTCHs will quickly and easily adapt to this new quality reporting program and find that the benefits of this program outweigh the burdens.

In section VIII.D.3.d. of the preamble of this final rule, for FY 2015, as we proposed, we have retained the three quality measures that were finalized for use in the LTCHQR Program in the FY 2012 IPPS/LTCH PPS final rule. These measures are: (1) Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51780 through 51781), we estimated that the total yearly cost to all LTCH that are paid under the LTCH PPS to report these data (including: NHSN registration and training for the CAUTI and CLABSI quality measures; data submission for all three measures, and monitoring data submission) will be approximately $756,326. In section XI.B.9. of the preamble of this final rule, we have adopted this same burden estimate.

It is important to note that, as part of its endorsement maintenance process under NQF's Patient Safety Measures Project (http://www.qualityforum.org/projects/patient safety_measures.aspx), the NQF reviewed the CAUTI and CLABSI measures that we adopted in the FY 2012 IPPS/LTCH final rule. As a result of this review, the NQF expanded the scope of endorsement of these measures to include additional care settings, including LTCHs. As proposed, in this final rule, we are specifying that the CAUTI and CLABSI measures will be adopted in their expanded form for the FY 2014 payment determination and all subsequent fiscal year payment determinations.

We do not believe that the total burden estimate, in the amount of $756,326, that was made in the FY 2012 IPPS/LTCH PPS final rule would be affected by the expansion of the CAUTI and CLABSI measures. We made this statement because these expanded measures are essentially the same measures we adopted in the FY 2012 IPPS/LTCH PPS final rule, except that the measure names have been changed and the scope of endorsement expanded so as to be applicable to the LTCH setting. The expanded CAUTI and CLABSI measures make no changes to the way that these data are to be collected and reported by LTCHs. Thus, use of the expanded CAUTI and CLABSI measures will place no additional financial burden on LTCHs. In addition, we believe that this financial burden should remain relatively stable over the first several years of this quality reporting program, subject to normal inflationary increases, such as increased labor wage rates.

In section VIII.D.3.d. of the preamble of this final rule, for the FY 2016 LTCHQR Program, as proposed, we are adding two additional quality measures to the LTCHQR Program. These quality measures are: (1) Percent of Nursing Home Residents Who

Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (2) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). Data for the staff immunization measure will be reported by LTCHs to NHSN. Data for the patient influenza vaccination measure will be collected using the LTCH CARE Data Set. While we are still in the process of identifying and developing the specific data items that will be necessary for these measures, we believe that the number of data items will be limited. Therefore, we anticipate little, if any, change in burden associated with these two measures.

As we noted previously, the LTCHQR Program has not been fully implemented, as data collection will not begin until October 1, 2012. At this time, we provide estimates of the costs associated with the collection and submission of data in section XI.B.9. of the preamble of this final rule.

In the FY 2013 IPPS/LTCH PPS proposed rule, we invited public comment on the impact that the proposed measures would have on LTCHs. The public comments that we received addressed the burden estimates associated with the proposed measures. We are addressing these public comments in section XI.B.9. of the preamble of this final rule, where we discuss in detail the information collection requirements and the burden associated with those requirements.

O. Effects of Quality Reporting Requirements for Ambulatory Surgical Centers (ASCs)

In section XIV.K. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized quality reporting measures for the CYs 2014, 2015, and 2016 payment determinations and other requirements for the ASC Quality

Reporting (ASCQR) Program. In section VIII.E. of the preamble of this final rule, we discuss proposed and final policies for ASCs to report quality data under the ASCQR Program in order to be eligible to receive the full ASC annual payment update. We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016 because we do not have data that will allow us to make a reasonable estimate. ASCs have not yet submitted quality data to CMS; therefore, there are no data from previous program operations on which to base an estimate. Further, data from other quality programs do not allow us to make a reasonable estimate. Although we might be able to make a reasonable estimate based on data from other programs with respect to the structural and process of care measures, we are unable to estimate the number of ASCs that will not be eligible to receive the full ASC annual payment update with respect to the submission of QDCs for the claims-based measures. There are two other quality data reporting programs that utilize QDCs reported on claims similar to what we finalized in the ASCQR Program: the Physician Quality Reporting System (PQRS) and the E-Prescribing Incentive Program. However, these programs do not have comparable reporting incentives. The PQRS currently has no penalty for not meeting reporting requirements, and the E-Prescribing Incentive Program until CY 2012 was solely incentive-based, rather than penalty-based.

We did not receive any public comments regarding the effects of the proposed requirements for the ASCQR Program.

P. Effects of Requirements for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In section VIII.F. of the preamble of this final rule, we discuss our proposed and final policies to implement the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

1. General Background and Intent for Implementation of the IPFQR Program

We intend to achieve several goals as we develop and implement the proposed IPFQR Program. One goal of the IPFQR Program is to implement the statutory requirements of section 1886(s)(4) of the Act as added by sections 3401(f)(4) and 10322(a) of the Affordable Care Act. However, in addition, it is important to note that one of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be shared with appropriate health care related organizations and used to further the development of health care quality, which, in turn, helps to further CMS' objectives and goals. Health care organizations can use such health care quality data for many purposes such as in their risk management programs, health care acquired infection prevention programs and research and development of medical programs, among others.

More importantly, as required by the Act, we intend to share the information obtained from the IPFQR Program with the public. These data will be displayed on the CMS Web site. The goals of making these data available to the public in a properly risk-adjusted, public user-friendly and relevant format, include, but are not limited to: (1) keeping the public informed of the quality of care that is being provided in IPFs as a whole; (2) keeping the public informed of the quality of care being provided in specific IPFs; (3) allowing the public to compare and contrast the data about specific IPFs, thus

enabling the public to make informed health care decisions regarding IPFs; and (4) providing information about current trends in health care. There are certainly many other public uses for these quality data concerning IPFs. However, giving the public access to information about the quality of care in specific facilities and keeping the public informed of trends in health care has always been of high priority to CMS.

We also seek to align the new IPFQR Program reporting requirements with current HHS high priority conditions and topics and to ultimately provide a comprehensive assessment of the quality of health care delivered in a variety of settings.

2. Anticipated Effects

This final rule will affect all IPFs participating in Medicare. The facilities will have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the data. The anticipated burden to these providers consists of the following: (1) the initial registration of the facility with QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection and aggregation of data; and (4) the time required for entry of the data into the QualityNet database by the IPF's representative.

We have estimated the burdens associated with IPFs reporting aggregated-level data on QualityNet. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data, aggregation of the data, as well as training for submitting the aggregate-level data through QualityNet. We estimate that the annual hourly burden to each IPF for the collection,

submission, and training of personnel for submitting all quality measures is approximately 821 hours in a year for each IPF. Thus, the average hourly burden to each IPF is approximately 68 hours per month. At this time, we have no way to estimate how many IPFs will participate in the program. Therefore, we cannot estimate the financial impact.

As we proposed in the FY 2013 IPPS/LTCH PPS proposed rule, we are adopting the quality measures, abstraction methods, population, sampling, and reporting approaches used by TJC. One reason we selected this approach was to minimize the burden on IPFs. There were 1,741 existing IPFs, of which 450 (approximately 26 percent) are currently reporting the proposed measures to TJC. For these IPFs, we estimate that the burden will be minimal.

We did not receive any public comments on the anticipated effects of the proposals for the IPFQR Program.

Q. Effects of Requirements for Provider and Practitioner Medical Record Deadlines and Claims Denials

In section X. of the preamble of this final rule, we discuss our proposed and finalized changes for practitioners to follow in responding to requests for medical records from Quality Improvement Organizations (QIOs). These changes require practitioners to adhere to the 21-day and 30-day timeframes in the regulations, which are currently only applicable to providers. In addition, the changes will give QIOs the authority to effectuate claim denials for practitioners who fail to submit the medical records within these timeframes. QIOs have authority to carry out claim denials for providers who fail

to submit medical records, but similar provisions do not exist for practitioners. In fact, to this point, the QIOs' only option for practitioners who fail to submit medical records has been to refer the matter to the HHS Inspector General, and it seems appropriate to identify a step, short of recommending sanctions, for the QIOs to pursue.

On average, QIOs request approximately 2,000 medical records from practitioners each year. In general, requests for medical records from both practitioners and providers are ultimately fulfilled, but the average response time is considerably longer for practitioners than for providers. Because we are working to improve the QIOs' response time in completing various review activities, the application of the timeframes to practitioners is an important step in our efforts. In addition, given that the QIOs have the need for and the statutory authority to request medical records within a reasonable period of time, they have relied on the same 21-day and 30-day timeframes for practitioners. We believe that having the regulatory timeframe and authority to carry out claims denials for providers have generally resulted in providers complying with medical record requests within the required timeframes. In line with this, we believe that having this same regulatory authority for practitioners will result in practitioners complying with medical record requests within their required timeframes, which should, in turn, greatly reduce the potential for any claims denials. Moreover, because vendors are increasingly being used by providers and practitioners to respond to requests for medical records, the increasing effectiveness of this process could further diminish any impact of the regulatory changes. As we noted in the proposed rule, we believe the impact will be

insignificant. However, at this time, we cannot determine the precise number of claim denials that could occur for practitioners as a result of these changes.

We did not receive any public comments on our proposed statement of impact.

R. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

S. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the MS-DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows an overall increase of 2.3 percent in operating payments. We estimate that operating payments will increase by approximately $2.45 billion in FY 2013 relative to FY 2012. In addition, we estimate a savings of $24 million associated with the HACs policies in FY 2013, which is an additional $2 million in savings than in FY 2012. In FY 2012, pursuant to section 1109 of the Affordable Care Act, we distributed an additional $250 million to qualifying hospitals resulting in a decrease of $250 million in payments to hospitals in FY 2013 relative to FY 2012. Furthermore, we estimate that the expiration of the expansion of low-volume payments under sections 3125 and 10314 of the Affordable Care Act in FY 2013 will result in a decrease in payments of approximately $318 million compared to low-volume payments made in FY 2012. We estimate that

new technology add-on payments will increase payments by approximately $46.1 million. Finally, we estimate that our finalized policies to count labor and delivery bed days in the available bed day count for IME and DSH payments will reduce IME payments by approximately $40 million for FY 2013. These estimates, combined with our FY 2013 operating estimate of $2.45 billion, will result in an increase of approximately $1.87 billion for FY 2013. We estimate that capital payments will experience a 1.8 percent increase in payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be a $154 million increase in capital payments in FY 2013 compared to FY 2012. The cumulative operating and capital payments should result in a net increase of approximately $2.04 billion to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2013. In the impact analysis, we are using the rates, factors, and policies presented in this final rule, including updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2013. Accordingly, based on the best available data for the 428 LTCHs in our database, we estimate that FY 2013 LTCH PPS payments will increase approximately $92 million relative to FY 2012. In addition, we estimate that extension of the moratorium on the application of the “25 percent threshold” payment adjustment policy, as provided by section 114(c) of the MMSEA, as amended by section

4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, will result in a payment impact of approximately $170 million to LTCHs.

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Table V below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

Table V.—Accounting Statement: Classification of Estimated Expenditures under the IPPS from FY 2012 to FY 2013

Category	Transfers
Annualized Monetized Transfers	$2.04 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers
Total	$2.04 billion

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis for the changes we are making under the LTCH PPS for this final rule projects an increase in estimated aggregate payments in FY 2013 relative to FY 2012 of approximately $92 million for the 428 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore,

as required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Table VI below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to changes to the LTCH PPS. Table VI provides our best estimate of the estimated increase in Medicare payments under the LTCH PPS as a result of the provisions presented in this final rule based on the data for the 428 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

TABLE VI.—Accounting Statement: Classification of Estimated Expenditures from the FY 2012 LTCH PPS to the FY 2013 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	Positive transfer--Estimated increase in expenditures: $92 million

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $34.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 33 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site

at:

http://www.sba.gov/contractingopportunities/sizestandardtopics/tableofsize/index.html.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this final rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. Medicare fiscal intermediaries and MACs are not considered to be small entities. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this final rule constitutes our regulatory flexibility analysis. In the FY 2013 IPPS/LTCH PPS proposed rule, we solicited public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses are presented throughout this final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer

than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the final policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold level is approximately $136 million. This final rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

VI. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this final rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific rate for SCHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2013, we plan to include the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2013

A. FY 2013 Inpatient Hospital Update

Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2013 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas (which is based on IHS Global Insight Inc.'s (IGI's) second quarter 2012 forecast of the FY 2006-based IPPS market basket), subject to a reduction of 2.0 percentage points if the hospital fails to submit quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.1 percentage point. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that the application of the multifactor productivity adjustment and the additional FY 2012 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.H.1 of the preamble of the proposed rule, we proposed a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 0.8 percent (77 FR 27975 and 27976). Also, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27975 and 27976), based on IGI's first quarter 2012 forecast of the FY 2013 market basket increase, we proposed an applicable percentage increase to the FY 2012 operating standardized amount of 2.1 percent (that is, the proposed FY 2013 estimate of the market basket rate-of-increase of

3.0 percent less an adjustment of 0.8 percentage points for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with section 1886(b)(3)(B)(viii) of the Act and our rules. For hospitals that fail to submit quality data, we proposed an applicable percentage increase to the operating standardized amount of 0.1 percent (that is, the proposed FY 2013 estimate of the market basket rate-of increase of 3.0 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.8 percentage points for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

For this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.H.1. of the preamble of this final rule, we are making an MFP adjustment of 0.7 percent. Based on IGI's second quarter 2012 forecast of the FY 2013 market basket increase, we are providing for an applicable percentage increase to the FY 2012 operating standardized amount of 1.8 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent less an adjustment of 0.7 percentage point for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with section 1886(b)(3)(B)(viii) of the Act and our rules. For hospitals that fail to submit quality data, we are providing for an applicable percentage increase to the operating standardized amount of -0.2 percent (that is, the FY 2013 estimate of the market basket rate-of increase of 2.6 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.7 percentage point for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

B. Update for SCHs for FY 2013

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2013 applicable percentage increase in the hospital-specific rate for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rate for SCHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are providing for an applicable percentage increase to the hospital-specific rate applicable to SCHs of 1.8 percent for hospitals that submit quality data or -0.2 percent for hospitals that fail to submit quality data.

C. FY 2013 Puerto Rico Hospital Update

Section 401(c) of Pub. L. 108-173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are providing for an

applicable percentage increase to the Puerto Rico-specific standardized amount of 1.8 percent.

D. Update for Hospitals Excluded from the IPPS

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's and cancer hospitals. Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40, which also uses section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, cancer hospitals, and RNHCIs are the remaining three types of hospitals still reimbursed under the reasonable cost methodology. We are providing that the FY 2013 rate-of-increase percentage applicable to the target amount for children's hospitals, cancer hospitals, and RNHCIs is the percentage increase in the IPPS operating market basket. For this final rule, the current estimate of the FY 2013 IPPS operating market basket percentage increase is 2.6 percent.

E. Update for LTCHs

Section 123 of Pub. L. 106-113, as amended by section 307(b) of Pub. L. 106-554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section VII. of the preamble of this final rule, we are establishing an update to the LTCH PPS standard Federal rate for FY 2013 based on the full LTCH

PPS market basket increase estimate (for this final rule, estimated to be 2.6 percent), subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.1 percentage point. The productivity adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.7 percent for FY 2013. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2013 be reduced by the "other adjustment" at section 1886(m)(4)(C) of the Act, which is 0.1 percentage point. Therefore, based on IGI's second quarter 2012 forecast of the FY 2013 market basket increase, we are providing for an annual update to the LTCH PPS standard Federal rate of 1.8 percent (that is, the current FY 2013 estimate of the market basket rate-of-increase of 2.6 percent less an adjustment of 0.7 percentage point for economy-wide productivity and less 0.1 percentage point). Accordingly, we are applying an update factor of 1.018 in determining the LTCH PPS standard Federal rate for FY 2013. Furthermore, we are phasing in a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) by applying a factor of 0.98734 (or approximately -1.3 percent) in FY 2013, which will not be applicable to payments for LTCH PPS discharges occurring on or before December 28, 2012 (consistent with current law).

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to one percent for FY 2013. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend

update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, we are recommending an applicable percentage increase to the standardized amount of 1.8 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 2.6 percent less an adjustment of 0.7 percentage point for MFP and less 0.1 percentage point). We are recommending that the same applicable percentage increase apply to SCHs and the Puerto Rico-specific standardized amount.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update for children's hospitals, cancer hospitals, and RNHCIs of 2.6 percent.

For FY 2013, consistent with policy set forth in section VII. of the preamble of this final rule, we are recommending an update of 1.8 percent to the LTCH PPS standard Federal rate.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2012 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates equal to one percent. MedPAC expects Medicare margins to remain low in 2012. At the same time,

MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care. MedPAC also recommended that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2013 and MedPAC's recommendation of a 1.0 percent update to gradually recover past overpayments due to documentation and coding changes.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to one percent, for FY 2013, as discussed above, sections 3401(a) and 10319(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act. Section 1886(b)(3)(B) of the Act, as amended by these sections, sets the requirements for the FY 2013 applicable percentage increase. Therefore, we have provided for an applicable percentage increase for FY 2013 of 1.8 percent, provided the hospital submits quality data, consistent with these statutory requirements.

With regard to MedPAC's recommendation that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2013 and MedPAC's recommendation of a 1.0 percent update to gradually recover past overpayments due to documentation and coding changes, we refer readers to section II.D. of the preamble of this final rule for a complete discussion of the FY 2013 documentation and coding adjustments. In section II.D. of the preamble of this final rule, we are making a prospective adjustment of 1.9 percent to the FY 2013 standardized amount to remove the remaining effect of documentation and coding that occurred in FY 2008 and FY 2009. We note that section 7(b)(1)(B) of Pub. L. 110-90

authorized recoupments of overpayments due to documentation and coding changes for FY 2008 and FY 2009, and under this authority, such recoupments had to be made no later than FY 2012. Accordingly, any recoupments of overpayments due to documentation and coding changes beyond the authority of section 7(b)(1)(B) of Pub. L. 110-90 would require changes to current law by Congress.

We also note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

[FR Doc. 2012-19079 Filed 08/01/2012 at 4:15 pm; Publication Date: 08/31/2012]