DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1624-F]

RIN 0938-AS45

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2016

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

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2016 as required by the statute. As required by section 1886(j)(5) of the Act, this rule includes the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2016. This final rule also finalizes policy changes, including the adoption of an IRF-specific market basket that reflects the cost structures of only IRF providers, a 1-year phase-in of the revised wage index changes, a 3-year phase-out of the rural adjustment for certain IRFs, and revisions and updates to the quality reporting program (QRP).

DATES: Effective Date: These regulations are effective on October 1, 2015**.**

Applicability Dates: The updated IRF prospective payment rates are applicable for IRF discharges occurring on or after October 1, 2015, and on or before September 30, 2016

(FY 2016). The updated quality measures and reporting requirements under the IRF QRP are effective for IRF discharges occurring on or after October 1, 2016.

FOR FURTHER INFORMATION CONTACT:

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Catherine Kraemer, (410) 786-0179, for information about the revised wage index.

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SUPPLEMENTARY INFORMATION:

The IRF PPS Addenda along with other supporting documents and tables referenced in this final rule are available through the Internet on the CMS website at http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/.

Executive Summary

A. Purpose

This final rule updates the prospective payment rates for IRFs for FY 2016 (that is, for discharges occurring on or after October 1, 2015, and on or before September 30, 2016) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). As required by section 1886(j)(5) of the Act, this rule includes the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2016. This final rule also finalizes policy changes, including the adoption of an IRF-specific market basket that reflects the cost structures of only IRF

providers, a 1-year phase-in of the revised wage index changes, a 3-year phase-out of the rural adjustment for certain IRFs, and revisions and updates to the quality measures and reporting requirements under the IRF QRP.

B. Summary of Major Provisions

In this final rule, we use the methods described in the FY 2015 IRF PPS final rule (79 FR 45872) to propose updates to the federal prospective payment rates for FY 2016 using updated FY 2014 IRF claims and the most recent available IRF cost report data, which is FY 2013 IRF cost report data. We are also finalizing an IRF-specific market basket that reflects the cost structures of only IRF providers. The IRF-specific market basket will be used to update the IRF PPS base payment rate and to determine the FY 2016 labor-related share. We are also phasing in the revised wage index changes, phasing out the rural adjustment for certain IRFs and revising and updating quality measures and reporting requirements under the IRF QRP.

C. Summary of Impacts

Provision Description	**Transfers**
FY 2016 IRF PPS payment rate update	The overall economic impact of this final rule is an estimated $135 million in increased payments from the Federal government to IRFs during FY 2016.
Provision Description	**Costs**
New quality reporting program requirements	The total costs in FY 2016 for IRFs as a result of the new quality reporting requirements are estimated to be $24,042,291.01.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Acronyms, Abbreviations, and Short Forms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviation, and short forms used and their corresponding terms in alphabetical order.

The Act	The Social Security Act
ADC	Average Daily Census
The Affordable Care Act	Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted on March 23, 2010)
AHA	American Hospital Association
AHE	Average Hourly Earnings
AHIMA	American Health Information Management Association
ASAP	Assessment Submission and Processing
ASCA	Administrative Simplification Compliance Act (Pub. L. 107-105, enacted on December 27, 2002)
BEA	Bureau of Economic Analysis
BLS	U.S. Bureau of Labor Statistics
CAH	Critical Access Hospitals
CARE	Continuity Assessment Record and Evaluation
CAUTI	Catheter-Associated Urinary Tract Infection
CBSA	Core-Based Statistical Area
CCR	Cost-to-Charge Ratio
CDC	The Centers for Disease Control and Prevention

CDI	Clostridium difficile Infection
CFR	Code of Federal Regulations
CMG	Case-Mix Group
CMS	Centers for Medicare & Medicaid Services
CPI	Consumer Price Index
DSH	Disproportionate Share Hospital
DSH PP	Disproportionate Share Patient Percentage
ECI	Employment Cost Index
EHR	Electronic Health Record
ESRD	End-Stage Renal Disease
FFS	Fee-for-Service
FR	Federal Register
FY	Federal Fiscal Year
GDP	Gross Domestic Product
HAI	Healthcare Associated Infection
HCP	Health Care Personnel
HHS	U.S. Department of Health & Human Services
HIE	Health Information Exchange
HIPAA	Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191, enacted on August 21, 1996)
HOMER	Home Office Medicare Records
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification

ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
IGI	IHS Global Insight
IMPACT Act	Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113-185, enacted on October 6, 2014)
I-O	Input-Output
IPF	Inpatient Psychiatric Facility
IQR	Inpatient Quality Reporting Program
IRF	Inpatient Rehabilitation Facility
IRF-PAI	Inpatient Rehabilitation Facility-Patient Assessment Instrument
IRF PPS	Inpatient Rehabilitation Facility Prospective Payment System
IRF QRP	Inpatient Rehabilitation Facility Quality Reporting Program
IRVEN	Inpatient Rehabilitation Validation and Entry
LIP	Low-Income Percentage
LOS	Length of Stay
LPN	Licensed Practical Nurse
LTCH	Long-Term Care Hospital
MAC	Medicare Administrative Contractor
MAP	Measure Applications Partnership
MA (Medicare Part C)	Medicare Advantage
MedPAC	Medicare Payment Advisory Commission
MDS	Minimum Data Set
MFP	Multifactor Productivity
MLN	Medicare Learning Network

MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173, enacted on December 29, 2007)
MRSA	Methicillin-Resistant Staphylococcus aureus
MSA	Metropolitan Statistical Area
MUC	Measures under Consideration
NAICS	North American Industry Classification System
NHSN	National Healthcare Safety Network
NPP	National Priorities Partnership
NPUAP	National Pressure Ulcer Advisory Panel
NQF	National Quality Forum
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
OT	Occupational Therapists
PAC	Post-Acute Care
PAI	Patient Assessment Instrument
PLI	Professional Liability Insurance
POA	Present on Admission
PPI	Producer Price Index
PPS	Prospective Payment System
PRA	Paperwork Reduction Act of 1995 (Pub. L. 104-13, enacted on May 22, 1995)
PRRB	Provider Reimbursement Review Board

PT	Physical Therapist
QIES	Quality Improvement Evaluation System
QM	Quality Measure
QRP	Quality Reporting Program
RIA	Regulatory Impact Analysis
RIC	Rehabilitation Impairment Category
RFA	Regulatory Flexibility Act (Pub. L. 96-354, enacted on September 19, 1980)
RN	Registered Nurse
RPL	Rehabilitation, Psychiatric, and Long-Term Care market basket
RSRR	Risk-standardized readmission rate
SDTI	Suspected Deep Tissue Injuries
SIR	Standardized Infection Ratio
SLP	Speech-Language Pathologist
SOC	Standard Occupational Classification System
SNF	Skilled Nursing Facilities
SRR	Standardized Risk Ratio
SSI	Supplemental Security Income
TEP	Technical Expert Panel

I. Background

A. Historical Overview of the IRF PPS

Section 1886(j) of the Act provides for the implementation of a per-discharge PPS for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (collectively,

hereinafter referred to as IRFs). Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs), but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. Although a complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880), we are providing below a general description of the IRF PPS for FYs 2002 through 2015.

Under the IRF PPS from FY 2002 through FY 2005, as described in the FY 2002 IRF PPS final rule (66 FR 41316), the federal prospective payment rates were computed across 100 distinct case-mix groups (CMGs). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget-neutral conversion factor). For a detailed discussion of the budget-neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted federal prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted federal prospective payment rates.

For cost reporting periods that began on or after January 1, 2002, and before October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the federal IRF PPS rate and the payment that the IRFs would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the federal IRF PPS rate.

We established a CMS website as a primary information resource for the IRF PPS which is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html. The website may be accessed to download or view publications, software, data specifications, educational materials, and other information pertinent to the IRF PPS.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting

amendments to the FY 2006 IRF PPS final rule (70 FR 57166) that we published on September 30, 2005, we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB) Core-Based Statistical Area (CBSA) market definitions, modifications to the CMGs, tier comorbidities, and CMG relative weights, implementation of a new teaching status adjustment for IRFs, revision and rebasing of the market basket index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket index used to update IRF payments was a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166).

In the FY 2007 IRF PPS final rule (71 FR 48354), we further refined the IRF PPS case-mix classification system (the CMG relative weights) and the case-level adjustments, to ensure that IRF PPS payments would continue to reflect as accurately as possible the costs of care. For a detailed discussion of the FY 2007 policy revisions, please refer to the FY 2007 IRF PPS final rule (71 FR 48354).

In the FY 2008 IRF PPS final rule (72 FR 44284), we updated the federal prospective payment rates and the outlier threshold, revised the IRF wage index policy, and clarified how we

determine high-cost outlier payments for transfer cases. For more information on the policy changes implemented for FY 2008, please refer to the FY 2008 IRF PPS final rule (72 FR 44284), in which we published the final FY 2008 IRF federal prospective payment rates.

After publication of the FY 2008 IRF PPS final rule (72 FR 44284), section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173, enacted on December 29, 2007) (MMSEA), amended section 1886(j)(3)(C) of the Act to apply a zero percent increase factor for FYs 2008 and 2009, effective for IRF discharges occurring on or after April 1, 2008. Section 1886(j)(3)(C) of the Act required the Secretary to develop an increase factor to update the IRF federal prospective payment rates for each FY. Based on the legislative change to the increase factor, we revised the FY 2008 federal prospective payment rates for IRF discharges occurring on or after April 1, 2008. Thus, the final FY 2008 IRF federal prospective payment rates that were published in the FY 2008 IRF PPS final rule (72 FR 44284) were effective for discharges occurring on or after October 1, 2007, and on or before March 31, 2008; and the revised FY 2008 IRF federal prospective payment rates were effective for discharges occurring on or after April 1, 2008, and on or before September 30, 2008. The revised FY 2008 federal prospective payment rates are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.

In the FY 2009 IRF PPS final rule (73 FR 46370), we updated the CMG relative weights, the average length of stay values, and the outlier threshold; clarified IRF wage index policies regarding the treatment of "New England deemed" counties and multi-campus hospitals; and revised the regulation text in response to section 115 of the MMSEA to set the IRF compliance percentage at 60 percent (the "60 percent rule") and continue the practice of including

comorbidities in the calculation of compliance percentages. We also applied a zero percent market basket increase factor for FY 2009 in accordance with section 115 of the MMSEA. For more information on the policy changes implemented for FY 2009, please refer to the FY 2009 IRF PPS final rule (73 FR 46370), in which we published the final FY 2009 IRF federal prospective payment rates.

In the FY 2010 IRF PPS final rule (74 FR 39762) and in correcting amendments to the FY 2010 IRF PPS final rule (74 FR 50712) that we published on October 1, 2009, we updated the federal prospective payment rates, the CMG relative weights, the average length of stay values, the rural, LIP, teaching status adjustment factors, and the outlier threshold; implemented new IRF coverage requirements for determining whether an IRF claim is reasonable and necessary; and revised the regulation text to require IRFs to submit patient assessments on Medicare Advantage (MA) (Medicare Part C) patients for use in the 60 percent rule calculations. Any reference to the FY 2010 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2010, please refer to the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712), in which we published the final FY 2010 IRF federal prospective payment rates.

After publication of the FY 2010 IRF PPS final rule (74 FR 39762), section 3401(d) of the Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted on March 23, 2010), as amended by section 10319 of the same Act and by section 1105 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152, enacted on March 30, 2010) (collectively, hereafter referred to as "The Affordable Care Act"), amended section 1886(j)(3)(C) of the Act and added section 1886(j)(3)(D) of the Act. Section 1886(j)(3)(C) of the Act requires the Secretary to estimate a multi-factor productivity adjustment to the market basket increase

factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 to 2019.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act defined the adjustments that were to be applied to the market basket increase factors in FYs 2010 and 2011. Under these provisions, the Secretary was required to reduce the market basket increase factor in FY 2010 by a 0.25 percentage point adjustment. Notwithstanding this provision, in accordance with section 3401(p) of the Affordable Care Act, the adjusted FY 2010 rate was only to be applied to discharges occurring on or after April 1, 2010. Based on the self-implementing legislative changes to section 1886(j)(3) of the Act, we adjusted the FY 2010 federal prospective payment rates as required, and applied these rates to IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2010. Thus, the final FY 2010 IRF federal prospective payment rates that were published in the FY 2010 IRF PPS final rule (74 FR 39762) were used for discharges occurring on or after October 1, 2009, and on or before March 31, 2010, and the adjusted FY 2010 IRF federal prospective payment rates applied to discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The adjusted FY 2010 federal prospective payment rates are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.

In addition, sections 1886(j)(3)(C) and (D) of the Act also affected the FY 2010 IRF outlier threshold amount because they required an adjustment to the FY 2010 RPL market basket increase factor, which changed the standard payment conversion factor for FY 2010. Specifically, the original FY 2010 IRF outlier threshold amount was determined based on the original estimated FY 2010 RPL market basket increase factor of 2.5 percent and the standard

payment conversion factor of $13,661. However, as adjusted, the IRF prospective payments are based on the adjusted RPL market basket increase factor of 2.25 percent and the revised standard payment conversion factor of $13,627. To maintain estimated outlier payments for FY 2010 equal to the established standard of 3 percent of total estimated IRF PPS payments for FY 2010, we revised the IRF outlier threshold amount for FY 2010 for discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The revised IRF outlier threshold amount for FY 2010 was $10,721.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act also required the Secretary to reduce the market basket increase factor in FY 2011 by a 0.25 percentage point adjustment. The FY 2011 IRF PPS notice (75 FR 42836) and the correcting amendments to the FY 2011 IRF PPS notice (75 FR 70013) described the required adjustments to the FY 2011 and FY 2010 IRF PPS federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2011. It also updated the FY 2011 federal prospective payment rates, the CMG relative weights, and the average length of stay values. Any reference to the FY 2011 IRF PPS notice in this final rule also includes the provisions effective in the correcting amendments. For more information on the FY 2010 and FY 2011 adjustments or the updates for FY 2011, please refer to the FY 2011 IRF PPS notice (75 FR 42836 and 75 FR 70013).

In the FY 2012 IRF PPS final rule (76 FR 47836), we updated the IRF federal prospective payment rates, rebased and revised the RPL market basket, and established a new quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act. We also revised regulation text for the purpose of updating and providing greater clarity. For more information on the policy changes implemented for FY 2012, please refer to the FY 2012 IRF

PPS final rule (76 FR 47836), in which we published the final FY 2012 IRF federal prospective payment rates.

The FY 2013 IRF PPS notice (77 FR 44618) described the required adjustments to the FY 2013 federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after October 1, 2012, and on or before September 30, 2013. It also updated the FY 2013 federal prospective payment rates, the CMG relative weights, and the average length of stay values. For more information on the updates for FY 2013, please refer to the FY 2013 IRF PPS notice (77 FR 44618).

In the FY 2014 IRF PPS final rule (78 FR 47860), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also updated the facility-level adjustment factors using an enhanced estimation methodology, revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine "presumptive compliance," revised sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI), revised requirements for acute care hospitals that have IRF units, clarified the IRF regulation text regarding limitation of review, updated references to previously changed sections in the regulations text, and revised and updated quality measures and reporting requirements under the IRF quality reporting program. For more information on the policy changes implemented for FY 2014, please refer to the FY 2014 IRF PPS final rule (78 FR 47860), in which we published the final FY 2014 IRF federal prospective payment rates.

In the FY 2015 IRF PPS final rule (79 FR 45872), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also further revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine "presumptive compliance," revised sections of the IRF-PAI, and revised

and updated quality measures and reporting requirements under the IRF quality reporting program. For more information on the policy changes implemented for FY 2015, please refer to the FY 2015 IRF PPS final rule (79 FR 45872) and the FY 2015 IRF PPS correction notice (79 FR 59121).

B. Provisions of the Affordable Care Act Affecting the IRF PPS in FY 2012 and Beyond

The Affordable Care Act included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was previously discussed, section 3401(d) of the Affordable Care Act also added section 1886(j)(3)(C)(ii)(I) (providing for a "productivity adjustment" for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment for FY 2016 is discussed in section VI.D. of this final rule. Section 3401(d) of the Affordable Care Act requires an additional 0.2 percentage point adjustment to the IRF increase factor for FY 2016, as discussed in section VI.D. of this final rule. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Section 3004(b) of the Affordable Care Act also addressed the IRF PPS program. It reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) and inserted a new section 1886(j)(7), which contains requirements for the Secretary to establish a quality reporting program for IRFs. Under that program, data must be submitted in a form and manner and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the application of a 2 percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. Application of the 2 percentage point reduction may result in an update that is less than 0.0 for a

fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

Under section 1886(j)(7)(D)(i) and (ii) of the Act, the Secretary is generally required to select quality measures for the IRF quality reporting program from those that have been endorsed by the consensus-based entity which holds a performance measurement contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). So long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization, section 1886(j)(7)(D)(ii) of the Act authorizes the Secretary to select non-endorsed measures for specified areas or medical topics when there are no feasible or practical endorsed measure(s).

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF PPS quality reporting data available to the public. In so doing, the Secretary must ensure that IRFs have the opportunity to review any such data prior to its release to the public.

C. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule, upon the admission and discharge of a Medicare Part A Fee-for-Service patient, the IRF is required to complete the appropriate sections of a patient assessment instrument (PAI), designated as the IRF-PAI. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF-PAI upon the admission and discharge of each Medicare Part C (Medicare Advantage) patient, as described in the FY 2010 IRF PPS final rule. All required data must be electronically encoded into the IRF-PAI software product. Generally, the software product includes patient classification programming called the Grouper software. The Grouper

software uses specific IRF-PAI data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The Grouper software produces a 5-character CMG number. The first character is an alphabetic character that indicates the comorbidity tier. The last 4 characters are numeric characters that represent the distinct CMG number. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the Grouper software, are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.

Once a Medicare Fee-for-Service Part A patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191, enacted on August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107-105, enacted on December 27, 2002) (ASCA) permits, a paper claim (a UB-04 or a CMS-1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a Medicare Advantage patient is discharged, in accordance with the Medicare Claims Processing Manual, chapter 3, section 20.3 (Pub. 100-04), hospitals (including IRFs) must submit an informational-only bill (TOB 111), which includes Condition Code 04 to their MAC. This will ensure that the Medicare Advantage days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF low-income percentage adjustment) for Fiscal Year 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amends section 1862(a) of the Act by adding paragraph (22), which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment

under Part A or Part B for any expenses 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, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial "in such unusual cases as the Secretary finds appropriate." For more information, see the "Medicare Program; Electronic Submission of Medicare Claims" final rule (70 FR 71008). Our instructions for the limited number of Medicare claims submitted on paper are available at http://www.cms.gov/manuals/downloads/clm104c25.pdf.

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 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 covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at http://www.cms.gov/ElectronicBillingEDITrans/ and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The MAC processes the claim through its software system. This software system includes pricing programming called the "Pricer" software. The Pricer software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after

October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

II. Summary of Provisions of the Proposed Rule

In the FY 2016 IRF PPS proposed rule (80 FR 23332), we proposed to update the IRF federal prospective payment rates for FY 2016, adopt an IRF-specific market basket that will be used to determine the market basket update and labor-related share, phase in the revised wage index changes for all IRFs, phase out the rural adjustment for certain IRFs, and revise and update quality measures and reporting requirements under the IRF QRP.

The proposed updates to the IRF federal prospective payment rates for FY 2016 were as follows:

- Update the FY 2016 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section III of the FY 2016 IRF PPS proposed rule (80 FR 23332, 23337 through 23341).

- Describe the continued use of FY 2014 facility-level adjustment factors as discussed in section IV of the FY 2016 IRF PPS proposed rule (80 FR 23332 at 23341).

- Adopt the proposed IRF-specific market basket, as discussed in section V of the FY 2016 IRF PPS proposed rule (80 FR 23332, 23341 through 23358).

- Update the FY 2016 IRF PPS payment rates by the proposed market basket increase factor, based upon the most current data available, with a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act and a proposed productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V of the FY 2016 IRF PPS proposed rule (80 FR 23332, 23355 through 23356).

- Update the FY 2016 IRF PPS payment rates by the FY 2016 wage index and the labor-related share in a budget-neutral manner and discuss the proposed wage adjustment transition as discussed in section V of the FY 2016 IRF PPS proposed rule (80 FR 23332, 23356 through 23357).

- Describe the calculation of the IRF standard payment conversion factor for FY 2016, as discussed in section V of the FY 2016 IRF PPS proposed rule (80 FR 23332, 23364 through 23365).

- Update the outlier threshold amount for FY 2016, as discussed in section VI of the FY 2016 IRF PPS proposed rule (80 FR 23332 at 23367).

- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2016, as discussed in section VI of the FY 2016 IRF PPS proposed rule (80 FR 23332, 23367 through 23368).

- Discuss implementation of International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for the IRF PPS as discussed in section VII of the FY 2016 IRF PPS proposed rule (80 FR 23332 at 23368).

- Describe proposed revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section VIII of the FY 2016 IRF PPS proposed rule (80 FR 23332, 23368 through 23389).

III. Analysis and Responses to Public Comments

We received 85 timely responses from the public, many of which contained multiple comments on the FY 2016 IRF PPS proposed rule (80 FR 23332). We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists,

clinicians, health care industry organizations, and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

IV. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2016

As specified in §412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. Relative weights account for the variance in cost per discharge due to the variance in resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care, as well as provider efficiency.

In the FY 2016 IRF PPS proposed rule (80 FR 23332, 23337 through 23341), we proposed to update the CMG relative weights and average length of stay values for FY 2016. As required by statute, we always use the most recent available data to update the CMG relative weights and average lengths of stay. For FY 2016, we proposed to use the FY 2014 IRF claims and FY 2013 IRF cost report data. These data are the most current and complete data available at this time. Currently, only a small portion of the FY 2014 IRF cost report data are available for analysis, but the majority of the FY 2014 IRF claims data are available for analysis.

In the FY 2016 IRF PPS proposed rule, we proposed to apply these data using the same methodologies that we have used to update the CMG relative weights and average length of stay values each fiscal year since we implemented an update to the methodology to use the more detailed CCR data from the cost reports of IRF subprovider units of primary acute care hospitals,

instead of CCR data from the associated primary care hospitals, to calculate IRFs' average costs per case, as discussed in the FY 2009 IRF PPS final rule (73 FR 46372). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process used to calculate the CMG relative weights for this final rule is as follows:

Step 1. We estimate the effects that comorbidities have on costs.

Step 2. We adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step.

Step 3. We use the adjusted costs from the second step to calculate CMG relative weights, using the hospital-specific relative value method.

Step 4. We normalize the FY 2016 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2015 IRF PPS final rule (79 FR 45872).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we proposed to update the CMG relative weights for FY 2016 in such a way that total estimated aggregate payments to IRFs for FY 2016 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the standard payment amount. To calculate the appropriate budget neutrality factor for use in updating the FY 2016 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2016 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2016 by applying the changes to the CMG relative weights (as discussed in this final rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (.9981) that would maintain the same total estimated aggregate payments in FY 2016 with and without the changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor (.9981) to the FY 2015 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.G. of this final rule, we discuss the use of the existing methodology to calculate the standard payment conversion factor for FY 2016.

In Table 1, "Relative Weights and Average Length of Stay Values for Case-Mix Groups," we present the CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2016. The average length of stay for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

TABLE 1: Relative Weights and Average Length of Stay Values for Case-Mix Groups

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0101	Stroke M>51.05	0.8080	0.7077	0.6589	0.6304	10	9	9	8
0102	Stroke M>44.45 and M<51.05 and C>18.5	1.0165	0.8904	0.8290	0.7931	11	10	10	10
0103	Stroke M>44.45 and M<51.05 and C<18.5	1.1428	1.0010	0.9320	0.8916	12	13	12	11
0104	Stroke M>38.85 and M<44.45	1.2349	1.0817	1.0071	0.9635	13	13	12	12
0105	Stroke M>34.25 and M<38.85	1.4494	1.2696	1.1820	1.1309	14	15	14	14
0106	Stroke M>30.05 and M<34.25	1.6160	1.4155	1.3179	1.2609	16	16	15	15
0107	Stroke M>26.15 and M<30.05	1.8101	1.5855	1.4762	1.4122	18	17	17	17
0108	Stroke M<26.15 and A>84.5	2.2978	2.0126	1.8739	1.7927	23	23	21	21

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0109	Stroke M>22.35 and M<26.15 and A<84.5	2.0953	1.8353	1.7088	1.6348	21	20	19	19
0110	Stroke M<22.35 and A<84.5	2.7602	2.4177	2.2511	2.1536	28	27	24	24
0201	Traumatic brain injury M>53.35 and C>23.5	0.8012	0.6584	0.5941	0.5613	9	9	8	8
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5	1.0535	0.8656	0.7812	0.7380	11	11	10	9
0203	Traumatic brain injury M>44.25 and C<23.5	1.2056	0.9906	0.8940	0.8445	11	13	10	11
0204	Traumatic brain injury M>40.65 and M<44.25	1.3292	1.0922	0.9856	0.9311	13	13	12	12
0205	Traumatic brain injury M>28.75 and M<40.65	1.5900	1.3064	1.1790	1.1138	15	16	14	13
0206	Traumatic brain injury M>22.05 and M<28.75	1.8962	1.5580	1.4060	1.3282	17	18	17	16
0207	Traumatic brain injury M<22.05	2.5238	2.0737	1.8714	1.7679	30	24	20	19
0301	Non-traumatic brain injury M>41.05	1.1171	0.9325	0.8551	0.7979	10	11	10	10
0302	Non-traumatic brain injury M>35.05 and M<41.05	1.3867	1.1576	1.0615	0.9906	13	13	12	12
0303	Non-traumatic brain injury M>26.15 and M<35.05	1.6159	1.3489	1.2370	1.1543	16	15	14	14
0304	Non-traumatic brain injury M<26.15	2.1493	1.7942	1.6453	1.5353	22	20	18	17
0401	Traumatic spinal cord injury M>48.45	0.9696	0.8252	0.7557	0.6985	10	10	9	9
0402	Traumatic spinal cord injury M>30.35 and M<48.45	1.4217	1.2100	1.1081	1.0242	14	14	13	13
0403	Traumatic spinal cord injury M>16.05 and M<30.35	2.2684	1.9306	1.7679	1.6342	28	22	20	19
0404	Traumatic spinal cord injury M<16.05 and A>63.5	3.9720	3.3805	3.0957	2.8615	47	37	33	34
0405	Traumatic spinal cord injury M<16.05 and A<63.5	3.5415	3.0141	2.7602	2.5514	43	39	28	27
0501	Non-traumatic spinal cord injury M>51.35	0.8672	0.6911	0.6417	0.5890	9	7	8	8
0502	Non-traumatic spinal cord injury M>40.15 and M<51.35	1.1393	0.9079	0.8430	0.7738	11	11	10	10
0503	Non-traumatic spinal cord injury M>31.25 and M<40.15	1.4419	1.1491	1.0669	0.9794	14	13	13	12
0504	Non-traumatic spinal cord injury M>29.25 and M<31.25	1.6555	1.3192	1.2249	1.1244	15	16	14	13

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0505	Non-traumatic spinal cord injury M>23.75 and M<29.25	1.9346	1.5417	1.4315	1.3140	19	17	16	16
0506	Non-traumatic spinal cord injury M<23.75	2.7197	2.1673	2.0123	1.8472	27	24	22	21
0601	Neurological M>47.75	1.0412	0.8216	0.7667	0.6928	10	10	9	9
0602	Neurological M>37.35 and M<47.75	1.3339	1.0525	0.9822	0.8875	12	12	11	11
0603	Neurological M>25.85 and M<37.35	1.6581	1.3083	1.2209	1.1031	15	14	13	13
0604	Neurological M<25.85	2.1767	1.7175	1.6028	1.4482	20	18	17	16
0701	Fracture of lower extremity M>42.15	0.9659	0.8088	0.7660	0.6958	11	9	9	9
0702	Fracture of lower extremity M>34.15 and M<42.15	1.2529	1.0491	0.9936	0.9025	13	12	12	11
0703	Fracture of lower extremity M>28.15 and M<34.15	1.5022	1.2579	1.1913	1.0821	14	14	14	13
0704	Fracture of lower extremity M<28.15	1.9534	1.6357	1.5492	1.4071	18	18	17	16
0801	Replacement of lower extremity joint M>49.55	0.8034	0.6328	0.5741	0.5302	8	8	7	7
0802	Replacement of lower extremity joint M>37.05 and M<49.55	1.0561	0.8318	0.7547	0.6970	10	10	9	9
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5	1.4245	1.1220	1.0180	0.9401	13	13	12	11
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5	1.2739	1.0033	0.9103	0.8407	12	11	11	10
0805	Replacement of lower extremity joint M>22.05 and M<28.65	1.5355	1.2094	1.0973	1.0134	15	14	12	12
0806	Replacement of lower extremity joint M<22.05	1.9083	1.5031	1.3637	1.2594	17	16	15	14
0901	Other orthopedic M>44.75	0.9563	0.7692	0.7050	0.6426	10	9	9	8
0902	Other orthopedic M>34.35 and M<44.75	1.2714	1.0226	0.9372	0.8544	13	12	11	11
0903	Other orthopedic M>24.15 and M<34.35	1.5876	1.2770	1.1704	1.0669	15	14	13	13
0904	Other orthopedic M<24.15	2.0060	1.6135	1.4788	1.3480	19	18	16	16
1001	Amputation, lower extremity M>47.65	1.0684	0.9367	0.8341	0.7526	11	11	10	10

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
1002	Amputation, lower extremity M>36.25 and M<47.65	1.3349	1.1704	1.0421	0.9404	13	13	12	11
1003	Amputation, lower extremity M<36.25	1.9160	1.6798	1.4958	1.3497	18	19	17	16
1101	Amputation, non-lower extremity M>36.35	1.3933	1.3933	1.1068	1.0400	14	14	12	12
1102	Amputation, non-lower extremity M<36.35	1.8119	1.8119	1.4393	1.3524	16	20	15	16
1201	Osteoarthritis M>37.65	0.9863	0.9576	0.8720	0.8135	9	11	10	10
1202	Osteoarthritis M>30.75 and M<37.65	1.2107	1.1755	1.0704	0.9986	12	14	13	12
1203	Osteoarthritis M<30.75	1.4934	1.4500	1.3203	1.2318	14	16	15	14
1301	Rheumatoid, other arthritis M>36.35	1.1791	0.9716	0.9161	0.8365	9	11	10	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35	1.4946	1.2315	1.1612	1.0603	14	14	13	13
1303	Rheumatoid, other arthritis M<26.15	1.9625	1.6171	1.5248	1.3923	21	18	16	16
1401	Cardiac M>48.85	0.9069	0.7453	0.6740	0.6065	9	9	8	8
1402	Cardiac M>38.55 and M<48.85	1.2018	0.9877	0.8932	0.8037	11	11	11	10
1403	Cardiac M>31.15 and M<38.55	1.4475	1.1896	1.0757	0.9680	13	13	12	12
1404	Cardiac M<31.15	1.8371	1.5098	1.3653	1.2286	17	17	15	14
1501	Pulmonary M>49.25	1.0526	0.8479	0.7807	0.7512	11	10	9	9
1502	Pulmonary M>39.05 and M<49.25	1.3349	1.0754	0.9901	0.9527	12	12	11	11
1503	Pulmonary M>29.15 and M<39.05	1.6150	1.3010	1.1978	1.1526	15	13	13	13
1504	Pulmonary M<29.15	2.0063	1.6163	1.4881	1.4319	21	17	15	15
1601	Pain syndrome M>37.15	1.1376	0.8365	0.8218	0.7556	11	10	10	9
1602	Pain syndrome M>26.75 and M<37.15	1.4940	1.0985	1.0792	0.9923	14	13	12	12
1603	Pain syndrome M<26.75	1.9109	1.4050	1.3803	1.2692	15	15	15	15
1701	Major multiple trauma without brain or spinal cord injury M>39.25	1.0705	0.9081	0.8286	0.7711	10	10	11	9
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25	1.3897	1.1788	1.0756	1.0010	13	14	12	12

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
1703	Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05	1.5913	1.3498	1.2317	1.1463	19	15	14	14
1704	Major multiple trauma without brain or spinal cord injury M<25.55	2.0891	1.7721	1.6169	1.5048	21	20	18	17
1801	Major multiple trauma with brain or spinal cord injury M>40.85	1.2783	0.9685	0.8849	0.7874	14	12	11	10
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85	1.8807	1.4248	1.3019	1.1584	18	17	15	14
1803	Major multiple trauma with brain or spinal cord injury M<23.05	3.0933	2.3435	2.1413	1.9054	32	27	22	21
1901	Guillain Barre M>35.95	1.1826	1.0281	0.9998	0.8741	16	11	12	11
1902	Guillain Barre M>18.05 and M<35.95	2.2408	1.9481	1.8945	1.6563	26	22	21	20
1903	Guillain Barre M<18.05	3.7479	3.2583	3.1687	2.7703	52	32	27	32
2001	Miscellaneous M>49.15	0.9252	0.7603	0.7013	0.6348	9	9	9	8
2002	Miscellaneous M>38.75 and M<49.15	1.2002	0.9863	0.9097	0.8234	11	11	10	10
2003	Miscellaneous M>27.85 and M<38.75	1.4943	1.2280	1.1327	1.0253	14	14	13	12
2004	Miscellaneous M<27.85	1.9243	1.5814	1.4586	1.3203	18	18	16	15
2101	Burns M>0	1.7151	1.7151	1.3313	1.2915	18	18	15	15
5001	Short-stay cases, length of stay is 3 days or fewer				0.1556				2
5101	Expired, orthopedic, length of stay is 13 days or fewer				0.7236				8
5102	Expired, orthopedic, length of stay is 14 days or more				1.6315				17
5103	Expired, not orthopedic, length of stay is 15 days or fewer				0.7734				8
5104	Expired, not orthopedic, length of stay is 16 days or more				1.9277				21

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the

application of the revisions for FY 2016 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. Note that, because we proposed to implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2016 would not be affected as a result of the CMG relative weight revisions. However, the revisions would affect the distribution of payments within CMGs and tiers.

TABLE 2: Distributional Effects of the Changes to the CMG Relative Weights (FY 2015 Values Compared with FY 2016 Values)

Percentage Change	Number of Cases Affected	Percentage of Cases Affected
Increased by 15% or more	170	0.0
Increased by between 5% and 15%	2,830	0.7
Changed by less than 5%	387,215	99.1
Decreased by between 5% and 15%	416	0.1
Decreased by 15% or more	0	0.0

As Table 2 shows, 99 percent of all IRF cases are in CMGs and tiers that would experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the proposed revisions for FY 2016. The largest estimated increase in the CMG relative weight values that affects the largest number of IRF discharges would be a 0.2 percent increase in the CMG relative weight value for CMG 0704--Fracture of lower extremity, with a motor score less than 28.15-in the "no comorbidity" tier. In the FY 2014 claims data, 19,356 IRF discharges (5.0 percent of all IRF discharges) were classified into this CMG and tier.

The largest decrease in a CMG relative weight value affecting the largest number of IRF cases would be a 0.9 percent decrease in the CMG relative weight for CMG 0604—Neurological, with a motor score less than 25.85-in the "no comorbidity" tier. In the FY 2014

IRF claims data, this change would have affected 9,295 cases (2.4 percent of all IRF cases).

The changes in the average length of stay values for FY 2016, compared with the FY 2015 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

We received 1 comment on the proposed update to the CMG relative weights and average length of stay values for FY 2016, which is summarized below.

Comment: One commenter requested that we provide more detail about the use of the CCR data in the CMG relative weight calculations. Additionally, the commenter requested that we outline the methodology used to calculate the average length of stay values in the FY 2016 IRF PPS proposed rule.

Response: As we discussed in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), a key variable used to calculate the CMG relative weights is a facility's average cost per case, which is obtained by averaging the estimated cost per case for every patient discharged from the facility in a given fiscal year. To obtain the estimated cost per case for a given IRF patient, we start by pulling the appropriate charges from the Medicare claim for that patient. Then, we calculate the appropriate CCRs from the Medicare cost report submitted by the facility. The CCRs are then multiplied by the charges from the Medicare claim to obtain the estimated IRF cost for the case. This variable is used as the dependent variable in the regression analysis to estimate the CMG relative weights.

As we also discussed in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), the methodology for calculating the average length of stay values is available for download from the IRF PPS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Research.html.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to update the CMG relative weight and average length of stay values for FY 2016, as shown in Table 1 of this final rule. These updates are effective October 1, 2015.

V. Continued Use of FY 2014 Facility-Level Adjustment Factors

Section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust the per unit payment rate "by such . . . factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities." Under this authority, we currently adjust the federal prospective payment amount associated with a CMG to account for facility-level characteristics such as an IRF's LIP, teaching status, and location in a rural area, if applicable, as described in §412.624(e).

Based on the substantive changes to the facility-level adjustment factors that were adopted in the FY 2014 final rule (78 FR 47860, 47868 through 47872), in the FY 2015 final rule (79 FR 45872, 45882 through 45883) we froze the facility-level adjustment factors at the FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice and comment rulemaking). For FY 2016, we will continue to hold the adjustment factors at the FY 2014 levels as we continue to monitor the most current IRF claims data available and continue to evaluate and monitor the effects of the FY 2014 changes.

VI. FY 2016 IRF PPS Payment Update

A. Background

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services, which is referred to as a market basket index. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF federal

prospective payment rates for each FY. Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. In addition, sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act require the application of a 0.2 percentage point reduction to the market basket increase factor for FY 2016. Thus, in the FY 2016 IRF PPS proposed rule (80 FR 23341), we proposed to update the IRF PPS payments for FY 2016 by a market basket increase factor based upon the most current data available, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act.

We have utilized various market baskets through the years in the IRF PPS program. When we implemented the IRF PPS in January 2002, it used the Excluded Hospital with Capital market basket (which was based on 1992 Medicare cost reports for Medicare participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals) as an "input price index" (66 FR 41427 through 41430). Although ''market basket'' technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. Accordingly, the term ''market basket,'' as used in this document, refers to an input price index.

Beginning with the FY 2006 IRF PPS final rule (70 FR 47908), we adopted a 2002-based RPL market basket for the IRF PPS. This market basket reflected the operating and capital cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. Cancer and children's hospitals were excluded 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 and not through a PPS. Also, the 2002 cost structures for cancer and

children's hospitals were noticeably different than the cost structures of freestanding IRFs, freestanding IPFs, and LTCHs. See the FY 2006 IRF PPS final rule (70 FR 47908) for a complete discussion of the 2002-based RPL market basket.

In the FY 2010 IRF proposed rule (74 FR 21062), we expressed an interest in exploring the feasibility of creating a stand-alone IRF, or IRF-specific, market basket that reflects the cost structures of only IRF providers. But, as we noted in that discussion, Medicare cost report data revealed differences between cost levels and cost structures for freestanding and hospital-based IRF facilities. As we were unable at that time to fully understand these differences even after reviewing explanatory variables such as geographic variation, case mix, urban/rural status, share of low income patients, teaching status, and outliers (short stay and high-cost), we noted that we would continue to research ways to reconcile the differences and solicited public comment for additional information that might help us to better understand the reasons for the observed variations (74 FR 21062). We summarized the public comments we received and our responses in the FY 2010 IRF PPS final rule (74 FR 39762, 39776 through 39778). Despite receiving comments from the public on this issue, however, we were still unable to sufficiently reconcile the observed variations, and, therefore, were unable to establish a stand-alone IRF market basket at that time.

Beginning with the FY 2012 IRF PPS, we used a rebased RPL market basket, which was named the 2008-based RPL market basket, reflecting the updated operating and capital cost structures for freestanding IRFs, freestanding IPFs, and LTCHs (76 FR 47849 through 47860). In doing so, we updated the base year from 2002 to 2008; adopted a more specific composite chemical price proxy; broke the professional fees cost category into two separate categories (Labor-related and Nonlabor-related); and added two additional cost categories (Administrative

and Business Support Services and Financial Services), which were previously included in the residual All Other cost category. The FY 2012 IRF PPS proposed rule (76 FR 24229 through 24241) and FY 2012 IRF PPS final rule (76 FR 47849 through 47860) contain a complete discussion of the development of the 2008-based RPL market basket.

In the meantime, as stated in the FY 2016 IRF PPS proposed rule, we have continued to work to address our concerns regarding the development of a stand-alone IRF market. For the reasons described below, we believe using data from hospital-based and freestanding providers to derive IRF-specific market basket cost weights is appropriate, despite differences in facility versus unit cost levels and cost structures. Therefore, for FY 2016, we proposed to create and adopt a 2012-based IRF-specific market basket, using both freestanding and hospital-based IRF Medicare cost report data.

We received a total of 17 comments on our proposal to adopt an IRF-specific market basket. Several commenters supported the proposed stand-alone IRF market basket; while several other commenters raised concerns regarding the data and methodologies used to derive the proposed IRF-specific market basket. In particular, several commenters stated that CMS was using a flawed methodology for allocating overhead costs to hospital-based IRF units. In support of this comment, one of these commenters attached an analytic report they had commissioned. This report outlined how the commenters came to believe that there were overhead costs allocation errors, and what could be done to fix those errors. Other commenters, on the overhead cost allocation issue, suggested that CMS continue using the RPL market basket, or make changes to the calculation of the proposed IRF-specific market basket cost weights. Several of these latter commenters requested that CMS allow for an additional round of comments on the revised IRF-specific market basket.

The commissioned report was authored by Dobson DaVanzo & Associates, LLC (Dobson DaVanzo).[1] Dobson DaVanzo's analysis replicated the CMS methodology described in the FY 2016 proposed rule to determine the major cost category weights for the proposed IRF-specific market basket using Medicare Cost Reports (form CMS-2552-10). As many of the commenters on the IRF-specific market basket referenced the Dobson DaVanzo report, the report and its conclusions regarding the allocation issue were clearly available to a significant segment of the industry.

The Dobson DaVanzo report raised two main concerns with the proposed cost weight methodology proposed in the FY 2016 IRF proposed rule (80 FR 23341). Their first concern was in regards to the proposed methodology for calculating wages and salaries for hospital-based IRFs – they asserted that CMS erroneously omitted overhead wages and salaries allocated to ancillary departments. Having identified this issue, Dobson DaVanzo then suggested a method to fix the methodology to account for these omitted costs. The second concern regarded the proposed use of certain IRF-specific data in the calculation of employee benefits and contract labor costs instead of the IPPS hospital data that had been used in both of the RPL market baskets. We provide a more detailed description of these concerns in section VI.C.1.a.i. through section VI.C.1.a.iii of this final rule.

Based on the public comments regarding flaws in the proposed methodology, and the suggested means of fixing those flaws as reflected in the Dobson DaVanzo report, we performed a detailed review of the entire proposed methodology for allocating overhead costs to hospital-based units, as well as Dobson DaVanzo's suggested fixes for deriving overhead wages and

[1] "Analysis of CMS Proposed Inpatient Rehabilitation Facility Specific Market Basket", submitted to HealthSouth Corporation by Dobson|DaVanzo, May 22, 2015. The public reference for this comment letter is: CMS-2015-0053-0004, and can be retrieved from the following link: http://www.regulations.gov/#!documentDetail;D=CMS-2015-0053-0004 (last accessed July 16, 2015).

salaries attributable to the ancillary cost centers for hospital-based IRFs. In doing so, we confirmed that the proposed methodology only calculated overhead wages and salaries attributable to the routine inpatient hospital-based IRF unit; we agree with the commenters that the proposed method inadvertently omitted the overhead wages and salaries attributable to ancillary departments. In analyzing Dobson DaVanzo's suggestions to fix this error, we identified two related data errors that had not been specifically identified by Dobson DaVanzo. The first data-related error was in regard to the ratio of overhead wages and salaries to total overhead costs for the total facility, and the second related to the inclusion of capital costs in total overhead costs that are then allocated to overhead wages and salaries. To address these data errors, we effected slight technical modifications to their suggested corrections for the proposed methodology. The additional data errors that we identified, and the technical corrections to address those errors are described in detail in section VI.C.1.a.i. through section VI.C.1.a.ii of this final rule.

As amended, we believe that the final methodology fully addresses commenters concerns, as well as the technical errors that we discovered while considering commenters' proposed solutions to the inadvertent omission of the overhead wages and salaries attributable to ancillary departments. Having addressed these technical errors, we do not believe there is a need to seek further public comment, or a reason to further delay implementation of an IRF-specific market basket.

We summarize general comments about the proposed methodology below. Specific technical comments are summarized and responded to in the relevant sections of this final rule.

Comment: Several commenters supported the adoption of a stand-alone IRF market basket and considered the stand-alone market basket to be an improvement over the RPL market

basket. While supportive, however, some of these commenters noted concerns with the proposed methodology for deriving some of the hospital-based costs. Many of these commenters cited the Dobson DaVanzo report, which replicated CMS's calculation of the proposed IRF-specific market basket and highlighted two concerns regarding the proposed methodologies' allocation of overhead costs to hospital-based IRFs. One concern was that there was an insufficient number of IRF Medicare cost reports to calculate reliable Employee Benefits and Contract Labor cost weights. The other concern, as noted above, was in regard to the omission of overhead wages and salaries attributable to ancillary cost centers for hospital-based IRFs. These commenters requested that CMS review the Dobson DaVanzo report findings and the suggested solution to the attribution of the overhead wage problem, and revise the proposed methodology for calculating the market basket accordingly. Our responses to these specific concerns raised by the commenters as presented in the Dobson DaVanzo report are discussed in greater detail in section VI.C.1.a.i through section VI.C.1.a.iii of this final rule.

Additionally, one commenter stated that a stand-alone IRF market basket is an integral step that must be taken as we move toward the goal of implementing the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185, enacted on October 6, 2014). The commenter stated that a stand-alone IRF market basket will help to more accurately capture the costs and resources for inpatient rehabilitation services. The commenter also believes that the creation of a stand-alone IRF market basket is an integral step in any plan to create site-neutral payments for IRFs and SNFs as discussed by the Medicare Payment Advisory Commission (MedPAC), as well as the House Ways and Means Subcommittee on Health, and the President's Budget. However, the commenter noted that they remain concerned about the disparities in costs and resources between freestanding and hospital-based IRFs and

urged CMS to stay vigilant by monitoring and analyzing cost differences between these two types of IRFs after the IRF market basket is implemented. The commenter requested that any significant data derived from CMS analysis be shared with stakeholders in periodic reports and notices of proposed rulemaking for feedback on how the IRF market basket and payment system should be refined.

Response: We appreciate the commenters' support. As always, we will continue to evaluate our methodology and its effects over time. If we identify problems that need to be addressed, we will notify the public of our findings and our proposed solutions through the rulemaking process. And, as noted above, we address the commenter's specific concerns regarding our proposed methodology's allocation of overhead costs to hospital-based IRFs and concerns about the number of IRF Medicare cost reports that are available for use in the calculation of the Employee Benefits and Contract Labor cost weights in section VI.C.1.a.i through section VI.C.1.a.iii of this final rule.

Comment: Some commenters recommended that CMS continue to use the RPL market basket methodology for deriving the Employee Benefits and Contract Labor cost weights until there are sufficient data for all IRFs, so as to more accurately represent the costs IRFs incur for these cost categories. One commenter also recommended that CMS continue to encourage all providers to report these data on the Medicare cost report. In addition, the commenters recommended that CMS develop educational materials related to the Medicare cost reports to help providers understand the importance of completing the reports, what the data are utilized for, and how to complete the reports.

Response: We address the commenters' specific concerns regarding the calculation of the cost weights in section VI.C.1 of this final rule. We have encouraged and will continue to

encourage all providers to report data completely and accurately on the Medicare cost report. Furthermore, the commenter may be interested in Change Request 6132, which was published on August 1, 2008 (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6132.pdf). This Change Request directed Medicare contractors to educate Medicare providers regarding the specific ways that CMS uses Medicare cost report data. In this Change Request, we noted that the Medicare cost reports play a central role in the development of the market baskets used to update PPS payments, as well as in the evaluation of Medicare payment adequacy. We also indicated that Medicare contractors were to supply information to providers regarding how we use the Medicare cost report data to update future PPS payments. We also stated that it is crucial that Medicare providers fill out these reports with complete and valid data. Finally, we would also note that complete instructions for the Hospital Medicare cost report (CMS Form 2552-10) are available in Chapter 40 of the Provider Reimbursement Manual on the CMS website (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html).

Comment: One commenter supported CMS' use of an IRF-specific market basket, but stated that because of the cost disparity between hospital-based and freestanding facilities, CMS should develop separate market basket update percentages for each of those two groups. The commenter stated that patients treated in hospital-based units have more complex medical conditions and require more resources to treat than those in freestanding units. The commenter stated that combining these two facilities for the purpose of establishing one market basket update could result in underpayments for Medicare patients treated in hospital-based facilities.

Response: We respectfully disagree with the suggestion that we should provide separate market basket updates for freestanding and hospital-based IRFs. In particular, the base payment

rate reflects costs for both freestanding and hospital-based facilities. Thus, we believe it is appropriate for the IRF market basket to also reflect the data for both facility types.

Comment: Several commenters suggested that CMS should postpone implementation of a new IRF-specific market basket until CMS can ensure that the IRF-specific market basket accurately reflects costs for freestanding and hospital-based IRFs. Most of these commenters cited the two main concerns noted in the Dobson DaVanzo report regarding our proposed methodology's allocation of overhead costs to hospital-based IRFs and concerns about the number of IRF Medicare cost reports that are available for use in the calculation of the Employee Benefits and Contract Labor cost weights. The commenters stated that until these two concerns are addressed, and calculations are corrected by CMS, the implementation of the IRF-specific market basket should be postponed. The commenters also asked that IRFs be provided with an opportunity to analyze and comment on the recalculated cost weights prior to CMS' implementation of the IRF-specific market basket.

Response: We respectfully disagree with the commenters' request to postpone implementation of the IRF market basket. The primary data sources for the IRF market basket cost weights are the Medicare cost reports for both freestanding and hospital-based IRFs. We proposed specific methodologies for deriving the cost weights using these Medicare cost reports in the proposed rule. Commenters provided valuable feedback on those specific methodologies and, as discussed above, and in greater detail below, we are making modifications to the methodology based on these comments in this final rule (detailed discussion can be found in section VI.C.1 of this final rule). In sum, we believe that using IRF facilities' (freestanding and hospital-based) cost report data to establish an IRF-specific market basket is a technical

improvement from the current 2008-based RPL market basket, which is based on 2008 data for freestanding IRFs, freestanding IPFs, and LTCHs.

In addition, as discussed in sections VI.C.1.a.i. through section VI.C.1.a.ii of this final rule, we evaluated the comments provided on the proposed rule, and based on these comments, we are making technical corrections to errors in our proposed methodology for deriving the Wages and Salaries and Employee Benefits cost weights. As described in those sections, these modifications are made either at the suggestion of comments, or in response to errors identified in the course of our considering commenters' suggested solutions to the issues that were raised in their public comments (specifically the Dobson DaVanzo report). Both sets of corrections will resolve the identified inaccuracies in the proposed calculation of the cost weights. And, as these methodological and technical changes are straightforward and in direct response to public comments and suggestions within the public comments, we do not believe a second round of rulemaking is required.

Comment: One commenter stated that the CMS methodology for hospital-based IRFs assumes that the provision of, and intensity of, services are uniform between all payers and within each ancillary and overhead cost center. The commenter stated that this assumption may not be accurate and could therefore lead to the use of inaccurate data to develop the underlying cost weights. Several commenters stated that 78 percent of IRF providers are hospital-based units and cited the Dobson DaVanzo report, which estimated that "67 percent of the expenditure weights will be based on data for hospital-based units" and concluded that "using potentially unreliable allocated data that will account for more than two-thirds of the market basket information could be problematic and perhaps introduce error into the IRF-specific market basket."

Response: We respectfully disagree with the commenter's suggestion that the derivation of the IRF market basket is based on unreliable allocated data. Using the IRF Medicare cost report data, we proposed specific methodologies for deriving the cost weights in the proposed rule. As discussed in section VI.C.1.a.i of this final rule, based on comments on that specific methodology, suggested solutions to issues identified in that methodology, and our further evaluation of those proposed solutions, we are making modifications to our proposed methodology to address the issues identified by commenters. We believe that our revised methodology is based on a set of reasonable assumptions and results in a set of cost weights that is more representative of the universe of IRF providers compared to the 2008-based RPL market basket cost weights.

Comment: One commenter noted that the LTCH PPS, IPF PPS, and IRF PPS all arrived at the same 2.7 percent market basket update. The commenter questioned whether the extensive work performed by CMS to develop three specific market basket updates that generally produce the same result justifies the departure from the RPL methodology.

Response: We respectfully disagree with the commenter's suggestion that we should not develop different market baskets due to the market basket updates being similar. The IRF-specific market basket cost weights and price proxies are intended to reflect the cost structures of, and price pressures faced by, IRF providers. These cost weights and price proxies are used to develop the market basket update and labor-related share. While the proposed updates rounded to the same value for FY 2016, there may be years when they do not. Also, the proposed labor-related share differed between IRF (80 FR 23356), IPF (80 FR 25032), and LTCH providers (80 FR 24474), and we believe that using a labor-related share based on cost

data for the specific type of facility is a technical improvement over using a labor-related share based on the RPL market basket, which combines the 3 types of freestanding facilities together.

Final Decision: We reviewed all of the public comments regarding the proposed creation of an IRF-specific market basket. Where noted above, we have summarized and responded to each of the specific technical comments in the relevant methodology discussion in section VI.C.1 of this final rule, and as indicated in those discussions, we are making several changes to the proposed methodologies based on these comments.

After consideration of the public comments, we are finalizing the creation and adoption of a 2012-based IRF market basket because we believe that the use of this 2012-based IRF market basket to update IRF PPS payments is a technical improvement over the current 2008-based RPL market basket, as the major cost weights are based on Medicare cost report data from both freestanding and hospital-based IRFs and do not include costs from either IPF or LTCH providers, which could have different cost structures than IRFs.

In the following discussion, we provide an overview of the proposed IRF market basket and describe the methodologies we proposed to use to determine the operating and capital portions of the proposed 2012-based IRF market basket. For each proposed methodology, we indicate whether we received any public comments, and we include responses to comments, if applicable. We then provide the methodology we are finalizing for the 2012-based IRF market basket.

B. Overview of the 2012-Based IRF Market Basket

The 2012-based IRF 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 of goods and services

(that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in 3 steps. First, a base period is selected (in this final rule, the base period is FY 2012), total base period costs are estimated for a set of mutually exclusive and exhaustive cost categories, and the proportion of total costs that each cost category represents is calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance where we have selected price proxies for the various market baskets, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). In cases where a publicly available price series is not available (for example, a price index for malpractice insurance), we have collected price data from other sources and subsequently developed our own index to capture changes in prices for these types of costs. Finally, the cost weight for each cost category is multiplied by the established price proxy. The sum of these products (that is, the cost weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket for the given time period. Repeating this step for other periods produces a series of market basket levels over time. Dividing the composite index level of one period by the composite index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, 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 IRF services. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an IRF hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the IRF, but would not be factored into the price

change measured by a fixed-weight IRF 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 IRFs purchase (hospital inputs) to furnish inpatient care between base periods.

C. Creating an IRF-Specific Market Basket

As explained in the FY 2016 IRF PPS proposed rule (80 FR 23341 through 23342), we have been investigating the creation of a stand-alone, IRF-specific, market basket that reflects the cost structures of only IRF providers to replace the RPL market basket. The major cost weights for the 2008-based RPL market basket were calculated using Medicare cost report data for those providers that complete a stand-alone Medicare cost report. We define a "major cost weight" as one for which we are able to obtain data from the Medicare cost report for that particular cost category (for example, Wages and Salaries). However, the Medicare cost report data does not collect detailed input cost data for the more detailed cost categories for which we would like to capture input price pressures (for example, Chemicals). Therefore, a public data source is used to identify the costs associated with these more detailed cost categories. For the 2008-based RPL market basket, we used only data from stand-alone Medicare cost reports due to concerns regarding our ability to incorporate Medicare cost report data for hospital-based providers. In the FY 2015 IRF PPS final rule (79 FR 45884 through 45886), we presented several of these concerns (as restated below) but explained that we would continue to research the possibility of creating an IRF-specific market basket to update IRF PPS payments.

Since the FY 2015 IRF PPS final rule, we performed additional research on the Medicare cost report data available for hospital-based IRFs and evaluated these concerns. We

subsequently concluded from this research that Medicare cost report data for both hospital-based IRFs and freestanding IRFs could be used to calculate the major market basket cost weights for a stand-alone IRF market basket. We developed a detailed methodology to derive market basket cost weights that are representative of the universe of IRF providers. We believe the use of an IRF market basket is a technical improvement over the RPL market basket that is currently used to update IRF PPS payments. As a result, in the FY 2016 IRF PPS proposed rule, we proposed to adopt a 2012-based IRF market basket that reflects data for both freestanding and hospital-based IRFs. Below we discuss our prior concerns and provide reasons for why we believe it is technically feasible to create a stand-alone IRF market basket using Medicare cost report data for both hospital-based and freestanding IRFs.

One concern discussed in the FY 2015 IRF PPS final rule (79 FR 45884) was that the cost level differences for hospital-based IRFs relative to freestanding IRFs were not readily explained by the specific characteristics of the individual providers and/or the patients that they served (for example, characteristics related to case mix, urban/rural status, or teaching status). To address this concern, we used regression analysis to evaluate the effect of including hospital-based IRF Medicare cost report data in the calculation of cost distributions (which refers to how costs for certain categories relate to total costs for a particular provider). A more detailed description of these regression models can be found in the FY 2015 IRF final rule (79 FR 45884 through 45885). Based on this analysis, we concluded that the inclusion of those IRF providers with unexplained variability in costs would not significantly impact the cost weights and, therefore, should not be a major cause of concern.

Another concern regarding the incorporation of hospital-based IRF data into the calculation of the market basket cost weights was the complexity of the Medicare cost report

data for these providers. The freestanding IRFs independently submit a Medicare cost report for their facilities, making it relatively straightforward to obtain the cost categories necessary to determine the major market basket cost weights for such facilities. However, Medicare cost report data submitted for a hospital-based IRF are embedded in the Medicare cost report submitted for the entire hospital facility in which the IRF is located. To use Medicare cost report data from these providers, we needed to determine the appropriate adjustments to apply to the data to ensure that the cost weights we use would represent only the hospital-based IRF (not the hospital as a whole). Over the past year, we worked to develop detailed methodologies to calculate the major cost weights for both freestanding and hospital-based IRFs. We described our proposed methodologies and the resulting cost weights in section V.C.1 of the proposed rule (80 FR 23332, 23343 through 23349), and we welcomed public comments on these proposals.

We also evaluated the differences in cost weights for hospital-based and freestanding IRFs and found the most significant differences occurred for wages and salaries and pharmaceutical costs. Specifically, the hospital-based IRF wages and salaries cost shares tend to be lower than those of freestanding IRFs while hospital-based IRF pharmaceutical cost shares tend to be higher than those of freestanding IRFs. The proposed methodology for deriving costs for each of these categories can be found in section V.C.1 of the proposed rule.

Our research led to the conclusion that it is appropriate to include hospital-based IRF data in the calculation of the major cost weights for an IRF market basket. We proposed methodologies to estimate proposed cost weights for a combined sample of freestanding and hospital-based IRF providers, thus reflecting the cost structure of the universe of IRF providers. We believe this proposed methodology is a technical improvement over the RPL market basket

that relied solely on freestanding IRF, freestanding IPF, and LTCH cost structures. In the sections below, we summarize and respond to the comments we received on these specific proposals.

1. Development of Cost Categories and Weights for the 2012-Based IRF Market Basket

a. Use of Medicare Cost Report Data

We proposed a 2012-based IRF market basket that consisted of seven major cost categories derived from the FY 2012 Medicare cost reports (CMS Form 2552-10) for freestanding and hospital-based IRFs. These categories were Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (PLI), Capital, and a residual category. The residual category reflects all remaining costs that are not captured in the other six cost categories. The FY 2012 cost reports include providers whose cost reporting period began on or after October 1, 2011, and prior to September 30, 2012. We selected FY 2012 as the base year because the Medicare cost reports for that year were the most recent, complete set of Medicare cost report data available for IRFs at the time of development of the proposed IRF market basket.

Since our goal was to establish cost weights that were reflective of case mix and practice patterns associated with the services IRFs provide to Medicare beneficiaries, we proposed to limit the cost reports used to establish the 2012-based IRF market basket to those from facilities that had a Medicare average length of stay (LOS) that was relatively similar to their facility average LOS. We believe that this trim eliminates statistical outliers and ensures a more accurate market basket that reflects the costs generally incurred during a Medicare-covered stay. We proposed to define the Medicare average LOS for freestanding IRFs based on what the IRFs reported on line 14 of Worksheet S-3, Part I. We proposed to define the Medicare average LOS

for hospital-based IRFs based on what was reported on line 17 of Worksheet S-3, Part I. We then used the cost reports from IRFs with a Medicare average LOS within 15 percent (that is, 15 percent higher or lower) than the facility average LOS for IRFs to establish the sample of providers used to estimate the 2012-based IRF market basket cost weights. We applied this LOS edit to the data for IRFs to exclude providers that serve a population whose LOS would indicate that the patients served are not consistent with a LOS of a typical Medicare patient. This process resulted in the exclusion of about eight percent of the freestanding and hospital-based IRF Medicare cost reports. Of those excluded, about 18 percent were freestanding IRFs and 82 percent were hospital-based IRFs. This ratio is relatively consistent with the ratio of the universe of freestanding to hospital-based IRF providers. In the FY 2012 IRF PPS final rule (76 FR 47850), the same process was used to derive the 2008-based RPL market basket.

We did not receive any specific comments on our proposed LOS edit methodology.

Final Decision: We are finalizing the LOS edit methodology as proposed.

We also proposed to use the cost reports for IRFs that were not excluded through this process to calculate the costs for six of the seven major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital) for the market basket.

Similar to the 2008-based RPL market basket major cost weights, the resulting 2012-based IRF market basket cost weights reflect Medicare allowable costs (routine, ancillary and capital) - costs that are eligible for reimbursement through the IRF PPS. We proposed to define Medicare allowable costs for freestanding facilities as cost centers (CMS Form 2552-10): 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91 and 93. We proposed to define Medicare allowable costs for hospital-based facilities as cost centers (CMS Form 2552-

10): 40, 50 through 76 (excluding 52 and 75), 90 through 91 and 93.

For freestanding IRFs, total Medicare allowable costs would be equal to the total costs as reported on Worksheet B, part I, column 26. For hospital-based IRFs, total Medicare allowable costs would be equal to total costs for the IRF inpatient unit after the allocation of overhead costs (Worksheet B, part I, column 26, line 41) and a proportion of total ancillary costs. We calculated the portion of ancillary costs attributable to the hospital-based IRF for a given ancillary cost center by multiplying total facility ancillary costs for the specific cost center (as reported on Worksheet B, Part I, column 26) by the ratio of IRF Medicare ancillary costs for the cost center (as reported on Worksheet D-3, column 3 for hospital-based IRFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D-3, column 3 for all relevant PPS (that is, IPPS, IRF, IPF and SNF)). We proposed to use these methods to derive levels of total costs for IRF providers.

We did not receive any specific public comments on our proposed methodology for deriving total costs for freestanding and hospital-based IRFs.

Final Decision: We are finalizing our methodology for calculating total costs as proposed.

With this work complete, we then set about deriving cost levels for six of the seven major cost categories.

(i) Wages and Salaries Costs

For freestanding IRFs, we proposed to derive wages and salaries costs as the sum of inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost center) salaries as reported on Worksheet A, column 1. Since overhead salary costs are attributable to the entire IRF, we proposed to only include the proportion attributable to the Medicare allowable

cost centers. We proposed to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of Medicare allowable area salaries to total salaries (Worksheet A, column 1, line 200) times total overhead salaries. In the FY 2012 IRF PPS final rule (76 FR 47850), a similar methodology was used to derive wages and salaries costs in the 2008-based RPL market basket.

As stated in the proposed rule, for hospital-based IRFs, we proposed to derive wages and salaries costs as the sum of inpatient unit wages and salaries (Worksheet A, column 1, line 41) and a portion of salary costs attributable to total facility ancillary and overhead cost centers as these cost centers are shared with the entire facility. We proposed to calculate the portion of ancillary salaries attributable to the hospital-based IRF for a given ancillary cost center by multiplying total facility ancillary salary costs for the specific cost center (as reported on Worksheet A, column 1) by the ratio of IRF Medicare ancillary costs for the cost center (as reported on Worksheet D-3, column 3 for hospital-based IRFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D-3, column 3 for all relevant PPS units [that is, IPPS, IRF, IPF and SNF]). For example, if hospital-based IRF Medicare physical therapy costs represent 30 percent of the total Medicare physical therapy costs for the entire facility, then 30 percent of total facility physical therapy salaries (as reported in Worksheet A, column 1, line 66) would be attributable to the hospital-based IRF. We believe it is appropriate to use only a portion of the ancillary costs in the market basket cost weight calculations since the hospital-based IRF only utilizes a portion of the facility's ancillary services. We believe the ratio of reported IRF Medicare costs to reported total Medicare costs provides a reasonable estimate of the ancillary services utilized, and costs incurred, by the hospital-based IRF.

We also proposed to calculate the portion of overhead salary costs attributable to

hospital-based IRFs by multiplying the total overhead costs attributable to the hospital-based IRF (sum of columns 4-18 on Worksheet B, part I, line 41) by the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4-18) to total facility overhead costs (as reported on Worksheet A, column 7, lines 4-18). This methodology assumes the proportion of total costs related to salaries for the overhead cost center is similar for all inpatient units (that is, acute inpatient or inpatient rehabilitation).

We received nine comments on our proposed methodology for deriving wages and salaries costs.

Comment: Several commenters expressed concern about the accuracy of our wages and salaries calculations for hospital-based IRFs. Some of these commenters cited the Dobson DaVanzo report, which replicated and analyzed our proposed methodology for calculating wages and salaries costs for hospital-based and freestanding IRFs. Commenters especially noted one of the report's two main concerns, namely our proposed methodology's allocation of overhead costs to hospital-based IRFs (regarding our having allocated overhead wages and salaries associated with the routine portion of the IRF unit, that is, Worksheet B, line 41, which contains costs for only the hospital-based IRF routine department) and disregards the overhead wages and salaries associated with the ancillary departments and the number of IRF Medicare cost reports that are available for use in the calculation of the Employee Benefits and Contract Labor cost weights. Citing the report, several commenters expressed general concern that CMS is using a flawed methodology for allocating overhead costs to hospital-based IRFs. The commenters requested that we correct our methodology to include an allocation for overhead wages and salaries attributable to ancillary departments. The Dobson DaVanzo report provided a specific description of the methodology they suggested to correct for this omission. Specifically, for each

ancillary department, they computed the sum of columns 4–18 on Worksheet B, part I, which was then multiplied by the ratio of IRF Medicare ancillary costs to total Medicare (IPPS, IRF, IPF, and SNF) ancillary costs for each cost center. The sum of IRF routine and ancillary department costs was then multiplied by the ratio of facility wage and salary overhead costs (as reported on Worksheet A, column 1, lines 4–18) to facility total overhead costs (as reported on Worksheet A, column 7, lines 4–18).

Response: We appreciate commenters' detailed review of our methodology, and their having had concerns about our wages and salaries calculations. For those citing the concerns raised by the Dobson DaVanzo report, we concur that our proposed methodology did inadvertently omit the overhead wages and salaries attributable to the ancillary departments of hospital-based IRFs. Therefore, based on those commenters' request that we correct the omission as identified by the Dobson DaVanzo report, we are including in the calculation of wages and salaries costs for hospital-based IRFs an estimate of overhead wages and salaries attributable to the ancillary departments.

As finalized in this final rule, we will calculate the overhead wages and salaries attributable to each ancillary department by first calculating total noncapital overhead costs attributable to the specific ancillary department (Worksheet B, part I, columns 4-18, less Worksheet B, part II, columns 4-18). We will then identify the portion of these noncapital overhead costs for each ancillary cost center that is attributable to the hospital-based IRF. For each cost center, we then multiply total facility noncapital overhead costs by the ratio of IRF Medicare ancillary costs (as reported on Worksheet D-3, column 3, for hospital-based IRFs) to total Medicare ancillary costs (equal to the sum of Worksheet D-3, column 3, for all relevant PPS units [that is, IPPS, IRF, IPF and SNF]). Next, we identify the portion of these noncapital

overhead costs for the hospital-based IRF attributable to wages and salaries by multiplying the noncapital overhead costs by an "overhead ratio," which is defined as the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4-18) to total noncapital overhead costs (as reported on Worksheet A, columns 1 & 2, lines 4-18) for all ancillary departments. This methodology is nearly identical to the methodology suggested in the Dobson DaVanzo report with two modifications to correct data errors not noted by Dobson DaVanzo.

The Dobson DaVanzo report suggested that the ratio of total facility overhead salaries to total facility overhead costs ("overhead ratio") be made equal to facility wage and salary overhead costs (as reported on Worksheet A, column 1, lines 4–18) divided by facility total noncapital overhead costs (as reported on Worksheet A, column 7, lines 4–18). In considering this suggestion, we reviewed the overhead ratios (Worksheet A, column 1 divided by Worksheet A, column 7) by cost center, which showed that many providers reported data for these columns that resulted in an overhead ratio that exceeded 100 percent. This is a problem, as an overhead ratio exceeding 100 percent would erroneously suggest that wages and salaries costs are greater than total costs. Given this error, the suggested overhead ratio methodology would result in erroneous data being included in the calculation of estimated overhead wages and salaries. In order to address this issue, we reevaluated the numerator (wage and salaries for overhead cost centers) of the overhead ratio, and found no data errors or other concerns with Worksheet A, column 1, lines 4–18 that would explain the observed overhead ratio issue. We then reevaluated the denominator (total noncapital costs for overhead cost centers). A facility's total noncapital overhead costs are reflected in multiple columns in the Medicare cost report for the overhead cost center rows (Worksheet A, sum of columns 1 and 2; Worksheet A, column 7). Looking at those options, we noted that data from Worksheet A, columns 1 and 2, lines 4-18, was a more

reliable reflection of total noncapital overhead costs data for purposes of calculating an overhead ratio because, unlike our proposed use of Worksheet A, column 7, lines 4–18, that data results in the lowest incidence of an erroneous overhead ratio that is greater than 100 percent as compared to our other data source options. Because this is a more reliable cost report data source for total noncapital overhead costs for purposes of calculating an overhead ratio, we are changing the proposed denominator in the calculation of the overhead ratio to the sum of total overhead wages and salaries and total noncapital nonsalary overhead costs (as reported on Worksheet A, column 1 and 2, lines 4-18). As amended with this technical correction, no providers were found to have an aggregate overhead ratio in excess of 100 percent; therefore, this revision minimizes the impacts of potential misreporting in the Medicare cost report data.

Second, the Dobson DaVanzo report's suggested methodology for accounting for overhead wages and salaries attributable to ancillary departments starts by computing total overhead costs using columns 4–18 on Worksheet B, part I, for each ancillary cost center. However, we found that these total overhead costs include capital costs. The inclusion of capital costs in overhead wages and salaries is erroneous in that total capital costs are accounted for in the capital cost weight of the market basket, and the inclusion of any capital costs in overhead wages and salaries would therefore double count capital costs. Furthermore, the designation of a portion of capital costs as wages and salaries would be inconsistent with the Medicare cost report instructions.

The Medicare cost report instructions define capital-related costs as "depreciation, leases and rentals for the use of facilities and/or equipment, and interest incurred in acquiring land or depreciable assets used for patient care, insurance on depreciable assets used for patient care and

taxes on land or depreciable assets used for patient care."[2] The instructions also state that providers should exclude the following from capital-related costs: "costs incurred for the repair or maintenance of equipment or facilities, amounts included in rentals or lease payments for repair and/or maintenance agreements...." Based on this definition of capital costs as reported on the Medicare cost report, we concluded that capital costs do not include direct wages and salaries costs (of which overhead salaries is a component) and that it would be erroneous to allocate a portion of capital costs to overhead wages and salaries.

Therefore, the Dobson DaVanzo report's suggested methodology would result in allocating a portion of total overhead costs (which includes capital costs) to overhead wages and salaries and, ultimately, the Wages and Salaries cost weight. In order to address this issue, we reevaluated the suggested calculation of total overhead costs in light of the available data and determined that capital costs were identified in Worksheet B, part II, columns 4-18. We further determined that excluding the capital costs reflected in Worksheet B, part II, columns 4-18, from the overhead costs reflected in Worksheet B, part I, columns 4-18, results in a calculation of total overhead costs to then allocate to wages and salaries that is accurate and consistent with the Medicare cost reporting instructions and our proposed methodologies for calculating overhead wages and salaries and the Wages and Salaries cost weight. Thus, in our final calculation as presented above we are modifying the suggested methodology to eliminate any erroneous allocation of capital costs to overhead wages and salaries. Therefore, the starting point of our corrected calculation is total noncapital overhead costs (Worksheet B, part I, columns 4-18, less Worksheet B, part II, columns 4-18 for the ancillary cost centers).

Having corrected our methodology for calculating overhead wages and salaries

[2] See the Medicare cost report instructions at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html , Chapter, 40, Page 40-259 to 40-260.

attributable to the ancillary departments for hospital-based IRFs, and in light of general comments that we had proposed a flawed methodology for allocating overhead costs to the hospital-based IRF, we reviewed the corresponding calculations in the proposed methodology for the routine inpatient hospital-based IRFs. Based on that review, we identified the same inaccuracies, which led to the incorporation of the same two modifications that we made to the Dobson DaVanzo suggested methodology discussed above for our routine inpatient hospital-based IRF calculations. These technical corrections resolve the observed data inaccuracies that we found in the calculation of overhead wages and salaries attributable to routine inpatient hospital-based IRFs.

Specifically, our proposed methodology was to calculate the portion of overhead wages and salaries costs attributable to the routine inpatient hospital-based IRF by multiplying the total overhead costs attributable to the hospital-based IRF (sum of columns 4-18 on Worksheet B, part I, line 41) by an "overhead ratio" of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4-18) to total facility noncapital overhead costs (as reported on Worksheet A, column 7, lines 4-18). As stated above, our proposed methodology erroneously produced overhead ratios that exceeded 100 percent. In order to address this erroneous result, we are, for the same reasons described above, changing the denominator in the calculation of the overhead ratio to the sum of total facility overhead salaries and total facility noncapital nonsalary costs (as reported on Worksheet A, column 1 and 2, lines 4-18).

Also, as stated above, calculating total overhead costs as the sum of columns 4-18 on Worksheet B, part I, as we proposed, would erroneously include capital costs. Capital costs, as defined by the Medicare cost report instructions, should not be included in the calculation of overhead wages and salaries for hospital-based IRFs. As proposed, our methodology for

calculating overhead wages and salaries attributable to the routine inpatient hospital-based IRF erroneously included a portion of capital costs in the Wages and Salaries cost weight. To address this inaccuracy, we are, for the same reasons described above, revising our calculation of total overhead costs to be equal to total noncapital overhead costs attributable to the hospital-based IRF (sum of columns 4-18 on Worksheet B, part I, line 41 less total capital costs as reported on Worksheet B, part II, columns 4-18, line 41).

These modifications to the calculation of overhead wages and salaries attributable to the routine inpatient hospital-based IRFs are consistent with the methodology we are finalizing for the calculation of overhead wages and salaries attributable to the ancillary departments for hospital-based IRF as described above. We note that these modifications result in changes to the calculation of employee benefits, which we discuss below.

Comment: Several commenters requested that CMS explain with greater specificity the methodology that we used to calculate the wages and salaries costs for the proposed 2012-based IRF market basket.

Response: In the proposed rule, we provided a detailed description of how we derived the wages and salaries costs for the proposed IRF market basket. This discussion in the proposed rule contained sufficient detail such that, as noted above, Dobson DaVanzo was able to replicate our calculations and determine which costs we inadvertently omitted in our calculation. Therefore, we believe that we provided sufficient detail regarding our proposed methodology. Furthermore, we provide above a detailed description of the changes to our methodology that we are making in response to comments, including those citing the Dobson DaVanzo report.

Final Decision: Based on public comments, we are changing the proposed methodology for estimating wages and salaries costs as described above and finalizing the methodology as

changed. We discuss the effect of the changes to the proposed methodology on the Wages and Salaries cost weight in section VI.C.1.b of this final rule.

(ii) Employee Benefits Costs

Effective with our implementation of CMS Form 2552-10, we began collecting employee benefits and contract labor data on Worksheet S-3, Part V. Previously, with CMS Form 2540-96, employee benefits and contract labor data were reported on Worksheet S-3, part II, which was applicable to only IPPS providers, and, therefore, these data were not available for the derivation of the RPL market basket. Due to the lack of such data, the Employee Benefits cost weight for the 2008-based RPL market basket was derived by multiplying the 2008-based RPL market basket Wages and Salaries cost weight by the ratio of the IPPS hospital market basket Employee Benefits cost weight to the IPPS hospital market basket Wages and Salaries cost weight. Similarly, the Contract Labor cost weight for the 2008-based RPL market basket was derived by multiplying the 2008-based RPL market basket Wages and Salaries cost weight by the ratio of the IPPS hospital market basket Contract Labor cost weight to the IPPS hospital market basket Wages and Salaries cost weight (see FY 2012 IRF PPS final rule (76 FR 47850 through 47851)).

For FY 2012 Medicare cost report data, while there were providers that did report data on Worksheet S-3, part V, many providers did not complete this worksheet. However, in the proposed rule (80 FR 23344), we stated that we believed we had a large enough sample to enable us to produce a reasonable Employee Benefits cost weight.

For freestanding IRFs, we proposed that employee benefits costs would be equal to the data reported on Worksheet S-3, Part V, line 2, column 2.

As stated in the proposed rule, for hospital-based IRFs, we proposed to calculate total

benefits as the sum of benefit costs reported on Worksheet S-3 Part V, line 4, column 2, and a portion of ancillary benefits and overhead benefits for the total facility. We proposed that ancillary benefits attributable to the hospital-based IRF would be calculated by multiplying ancillary salaries for the hospital-based IRF as determined in the derivation of wages and salaries for the hospital-based IRF by the ratio of total facility benefits to total facility salaries. Similarly, we proposed that overhead benefits attributable to the hospital-based IRF would be calculated by multiplying overhead wages and salaries for the hospital-based IRF as determined in the derivation of wages and salaries for the hospital-based IRF by the ratio of total facility benefits costs to total facility wages and salaries costs.

Based on public comments, as stated above, we are now including a portion of overhead wages and salaries attributable to the ancillary departments in our calculation of wages and salaries for hospital-based IRFs. That change compelled us to make corresponding corrections to the calculation of employee benefits costs. Specifically, we need to include a portion of overhead employee benefits attributable to ancillary departments for hospital-based IRFs. We are estimating overhead employee benefits attributable to the ancillary departments using the same general methodology used to calculate routine inpatient overhead and ancillary employee benefits attributable to the hospital-based unit. Overhead employee benefits attributable to the ancillary departments are calculated by multiplying overhead wages and salaries attributable to the ancillary departments by the ratio of total facility benefits to total facility salaries. Therefore, based on public comments and corrections to errors identified in our analysis of suggested solutions to concerns raised by commenters, total employee benefits for hospital-based IRFs are equal to the sum of benefit costs reported on Worksheet S-3 Part V, line 4, column 2 and a portion of ancillary benefit costs and a portion of overhead benefit costs attributable to the

routine inpatient unit and ancillary departments.

The proposed methodology calculated routine overhead benefit costs attributable to the hospital-based IRF by multiplying overhead wages and salaries attributable to the routine inpatient portion of the hospital-based IRF by the ratio of total facility benefits to total facility salaries. As stated above, however, we are making two corrections to the calculation of the overhead wages and salaries attributable to the routine inpatient hospital-based IRF to correct data errors. These changes to the calculation of routine overhead wages and salaries as provided above result in changes to the routine overhead employee benefits attributable to the hospital-based IRF. The effect of methodological changes on the Employee Benefits cost weight is discussed in more detail in sections VI.C.1.b of this final rule.

We received nine comments specific to our proposed methodology for calculating employee benefits costs.

Comment: Several commenters noted our proposal to change the methodology for determining employee benefits costs from the methodology used to determine the employee benefits costs for the 2008-based RPL market basket. As discussed in the proposed rule, under the RPL methodology, we used data from IPPS hospitals as a proxy for determining these costs for RPL facilities. Several commenters noted concern about the employee benefit cost data we relied upon, citing to the Dobson DaVanzo report, which found that only 96 of 217 freestanding IRFs (44 percent) and 268 of 819 hospitals with IRF units (33 percent) provided data on employee benefit costs. Commenters further noted that the Dobson DaVanzo report concluded that data were available for only a very few providers and the use of that data reduced the cost weight for Employee Benefits by 13 percent compared to if the cost weight were derived using the RPL market basket methodology. The report notes that this is contrary to the CMS

conclusion that there was a sufficient volume of providers and that the use of IRF specific data instead of IPPS data did not make a material difference in the cost weights for these categories. The commenters stated that CMS should, for any future IRF market basket that replaces the RPL market basket, consider using IPPS data as a proxy for these specific data elements, as was done for the RPL market basket.

Response: We believe our statement regarding the data available for our proposed methodology was misunderstood. In the proposed rule, we noted that many providers did not report Worksheet S-3, part V, data, but that we believed we had a sufficiently large sample to produce a reasonable Employee Benefits cost weight. Specifically, we found that when we recalculated the 2012 cost weight using the proposed IRF market basket methodology by reweighting the results to reflect the characteristics of the universe of IRF providers (freestanding and hospital-based), it did not have a material effect on the resulting cost weight.

We understand the commenters' concern regarding our proposed methodology as compared to what was done for the 2008-based RPL market basket. However, we believe that the use of employee benefit costs reported by IRFs is a technical improvement from the methodology used for the 2008-based RPL market basket. Specifically, this methodology calculated the Employee Benefit cost weight by multiplying the RPL market basket Wages and Salaries cost weight by the IPPS employee benefit ratio. The IPPS employee benefit ratio was equal to the 2006-based IPPS market basket Employee Benefit cost weight divided by the 2006-based IPPS market basket Wages and Salaries cost weight. Using the rebased and revised 2010-based IPPS market basket; we calculate an employee benefit ratio of 28 percent compared to the 2012-based IRF market basket with 24 percent. Much of this 4-percentage-point difference is attributable to the characteristics of the IRF facilities as compared to the IPPS. Approximately

30 percent of total costs for IRFs are attributable to for-profit facilities (70 percent are attributable to nonprofit and government facilities) while approximately 10 percent of total costs for IPPS hospitals are attributable to for-profit facilities (90 percent are attributable to nonprofit and government facilities). Both the IRF and IPPS data show that the employee benefit ratio for for-profit facilities is lower than the employee benefit ratio for nonprofit/government facilities (in the range of 6 through 8 percentage points lower), thus IRF's higher proportion of for-profit facilities compared to IPPS hospitals leads to a lower employee benefit ratio.

Final Decision: In conclusion, we believe the use of Worksheet S-3, part V data for IRFs is a technical improvement from the methodology used for the 2008-based RPL market basket, as we believe it better reflects the cost structures of IRFs. We encourage IRF providers to continue to report Worksheet S-3, part V, data and we will continue to monitor the data as the reporting improves. Therefore, having considered these public comments, we are finalizing our proposed methodology for calculating the primary Employee Benefit costs for the 2012-based IRF market basket using the Worksheet S-3, part V data we proposed. As noted above, we are also finalizing the calculation of total employee benefits for hospital-based IRFs as equal to the sum of benefit costs reported on Worksheet S-3 Part V, line 4, column 2, and a portion of ancillary benefits and a portion of overhead benefits attributable to the routine inpatient unit and ancillary departments. This is slightly different than the proposed rule as we are now incorporating a portion of overhead benefits attributable to the ancillary departments in response to public comments. In addition, as mentioned above, the changes to the calculated routine overhead salaries for the hospital-based IRF, based on public comment, would also result in changes to the routine overhead employee benefits attributable to the hospital-based IRF.

(iii) Contract Labor Costs

Similar to the RPL and IPPS market baskets, contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources. We proposed to derive the Contract Labor cost weight for the 2012-based IRF market basket using data from Worksheet S-3, part V. As previously noted, for FY 2012 Medicare cost report data, while there were providers that did report data on Worksheet S-3, part V, many providers did not complete this worksheet. However, as we said in the proposed rule (80 FR 23344), we believe that we have a large enough sample to enable us to produce a reasonable Contract Labor cost weight.

For freestanding IRFs, we proposed that contract labor costs would be based on data reported on Worksheet S-3, part V, column 1, line 2, and for hospital-based IRFs, contract labor costs would be based on line 4 of this same worksheet.

We received 9 comments on our methodology for calculating contract labor costs that were similar to the comments we received regarding employee benefits costs.

Comment: Several commenters noted our proposal to change the methodology for determining the Contract Labor cost weight from the methodology used to derive that weight for the 2008-based RPL market basket. Under the RPL methodology, CMS used data from IPPS hospitals as a proxy for determining these costs for RPL facilities. Commenters expressed concern about the number of IRFs upon which those proposals were based, with some commenters citing to the Dobson DaVanzo report, which found that only 79 of 217 freestanding IRFs (36 percent) and 131 of 819 hospitals with IRF units (16 percent) provided data on contract labor costs. Commenters further cited the Dobson DaVanzo report as evidence that there was insufficient data to produce a reasonable Contract Labor cost weight. The commenters also noted that the report found that, using the proposed IRF data as opposed to the IPPS cost weights

(as was done for the RPL market basket) reduced the cost weight for contract labor by 70 percent.

Response: We believe our statement regarding the data available for our proposed methodology was misunderstood. As the commenter noted, about 20 percent of freestanding and hospital-based IRF providers reported Worksheet S-3, part V, data on contract labor costs. As noted in the proposed rule, when we recalculated an IRF-specific Contract Labor cost weight using Worksheet S-3, part V, data, which we weighted to reflect the characteristics of the universe of IRF providers (freestanding and hospital-based), and compared that figure to the proposed IRF-specific cost weight, the reweighted cost weight produced a Contract Labor cost weight that was similar to the proposed cost weight under the IRF-specific market basket. Therefore, we concluded that the small sample size did not likely have a material effect on the Contract Labor cost weight.

We understand the commenters' concern for the methodology change. Specifically, the methodology used for the RPL market basket calculated the Contract Labor cost weight by multiplying the RPL market basket Wages and Salaries cost weight by the IPPS contract labor ratio. The IPPS contract labor ratio was equal to the 2006-based IPPS market basket Contract Labor cost weight divided by the 2006-based IPPS market basket Wages and Salaries cost weight. Using the rebased and revised 2010- based IPPS market basket, we calculated a contract labor ratio using the current RPL-based methodology of 4 percent compared to the contract labor ratio we calculated using the 2012-based IRF market basket of 2 percent. This difference appears consistent across different types of providers (for example, nonprofit vs. for-profit). As a result, we believe that the use of contract labor data directly reported by IRFs represents a technical improvement over the contract labor ratio resulting from the IPPS cost weights, as it

reflects IRF's Medicare services and the characteristics of these providers instead of the contract labor employed relative to direct wages and salaries as experienced by IPPS hospitals.

Final Decision: After consideration of the public comments, we are finalizing our methodology for deriving contract labor costs as proposed.

(iv) Pharmaceuticals Costs

In the FY 2016 IRF PPS proposed rule (80 FR 23344), for freestanding IRFs, we proposed to calculate pharmaceuticals costs using non-salary costs reported on Worksheet A, column 7, less Worksheet A, column 1, for the pharmacy cost center (line 15) and drugs charged to patients cost center (line 73).

For hospital-based IRFs, we proposed to calculate pharmaceuticals costs using a portion of the non-salary pharmacy costs and a portion of the non-salary drugs charged to patient costs reported for the total facility. Non-salary pharmacy costs attributable to the hospital-based IRF are calculated by multiplying total pharmacy costs attributable to the hospital-based IRF (as reported on Worksheet B, column 15, line 41) by the ratio of total non-salary pharmacy costs (Worksheet A, column 2, line 15) to total pharmacy costs (sum of Worksheet A, columns 1 and 2 for line 15) for the total facility. Non-salary drugs charged to patient costs attributable to the hospital-based IRF are calculated by multiplying total non-salary drugs charged to patient costs (Worksheet B, part I, column 0, line 73, plus Worksheet B, part I, column 15, line 73, less Worksheet A, column 1, line 73) for the total facility by the ratio of Medicare drugs charged to patient ancillary costs for the IRF unit (as reported on Worksheet D-3 for hospital-based IRFs, line 73, column 3) to total Medicare drugs charged to patient ancillary costs for the total facility (equal to the sum of Worksheet D-3, line 73, column 3, for all relevant PPS (that is, IPPS, IRF, IPF and SNF)).

We did not receive any specific comments on our proposed methodology for calculating pharmaceuticals costs for freestanding and hospital-based IRFs.

Final Decision: We are finalizing our methodology for calculating pharmaceuticals costs as proposed.

(v) Professional Liability Insurance Costs

In the FY 2016 IRF PPS proposed rule (80 FR 23345), for freestanding IRFs, we proposed that Professional Liability Insurance (PLI) costs (often referred to as malpractice costs) would be equal to premiums, paid losses and self-insurance costs reported on Worksheet S-2, line 118, columns 1 through 3. For hospital-based IRFs, we proposed to assume that the PLI weight for the total facility is similar to the hospital-based IRF unit since the only data reported on this worksheet is for the entire facility, as we currently have no means to identify the proportion of total PLI costs that are only attributable to the hospital-based IRF. Therefore, hospital-based IRF PLI costs would be equal to total facility PLI (as reported on Worksheet S-2, line 118, columns 1 through 3) divided by total facility costs (as reported on Worksheet A, line 200) times hospital-based IRF Medicare allowable total costs.

We did not receive any specific comments on this proposed methodology for deriving PLI costs for freestanding and hospital-based IRFs.

Final Decision: We are finalizing our methodology for calculating PLI costs as proposed.

(vi) Capital Costs

In the FY 2016 IRF PPS proposed rule (80 FR 23345), for freestanding IRFs, we proposed that capital costs would be equal to Medicare allowable capital costs as reported on Worksheet B, Part II, column 26.

For hospital-based IRFs, we proposed that capital costs would be equal to IRF inpatient

capital costs (as reported on Worksheet B, part II, column 26, line 41) and a portion of IRF ancillary capital costs. We proposed to calculate the portion of ancillary capital costs attributable to the hospital-based IRF for a given cost center by multiplying total facility ancillary capital costs for the specific ancillary cost center (as reported on Worksheet B, Part II, column 26) by the ratio of IRF Medicare ancillary costs for the cost center (as reported on Worksheet D-3, column 3 for hospital-based IRFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D-3, column 3 for all relevant PPS (that is, IPPS, IRF, IPF and SNF)). For example, if hospital-based IRF Medicare physical therapy costs represent 30 percent of the total Medicare physical therapy costs for the entire facility, then 30 percent of total facility physical therapy capital costs (as reported in Worksheet B, part II, column 26, line 66) would be attributable to the hospital-based IRF.

We did not receive any specific comments on our proposed methodology for deriving capital costs for freestanding and hospital-based IRFs.

Final Decision: We are finalizing our methodology for calculating capital costs as proposed.

b. Final Major Cost Category Computation

After we derived costs for the 6 major cost categories for each provider using the Medicare cost report data as previously described, we proposed to address data outliers using the following steps (80 FR 23345). First, we divide the costs for each of the six categories by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of IRF providers. We then remove those providers whose derived cost weights fall in the top and bottom five percent of provider specific derived cost weights to ensure the removal of outliers. After the outliers have been removed, we sum the costs for each category across all remaining

providers. We then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2012-based IRF market basket for the given category. Finally, we calculate the residual "All Other" cost weight that reflects all remaining costs that are not captured in the six cost categories listed. See Table 3 for the resulting cost weights for these major cost categories that we obtain from the Medicare cost reports. In this table, we provide the proposed cost weights, as well as the final major cost weights, after implementing the methodological changes to the calculation of the wages and salaries and employee benefits costs as described in section VI.C.1.a.i through section VI.C.1.a.ii of this final rule.

Table 3: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	2012-Based IRF Proposed (Percent)	2012-Based IRF Final (Percent)	2008-Based RPL (Percent)
Wages and Salaries	45.5	47.3	47.4
Employee Benefits[1]	10.7	11.2	12.3
Contract Labor[1]	0.8	0.8	2.6
Professional Liability Insurance (Malpractice)	0.9	0.9	0.8
Pharmaceuticals	5.1	5.1	6.5
Capital	8.6	8.6	8.4
All Other	28.4	26.1	22.0

Total may not sum to 100 due to rounding.

[1] Due to the lack of Medicare cost report data, the Employee Benefits and Contract Labor cost weights in the 2008-based RPL market basket were based on the IPPS market basket.

As discussed in section VI.C.1.a.i of this final rule, we made revisions to our proposed methodology for calculating wages and salaries costs for the IRF market basket based on public comments. The total effect of this methodology change on the 2012-based IRF market basket Wages and Salaries cost weight (which reflects freestanding and hospital-based IRFs) is an increase of about 1.9 percentage points from the proposed 2012-based IRF market basket Wages and Salaries cost weight of 45.5 percent. This overall effect can be broken down into multiple

parts. The first part is our change to include overhead wages and salaries attributable to the ancillary departments for hospital-based IRFs, which resulted in an increase of 3.2 percentage points to the aggregate Wages and Salaries cost weight. This effect is partially offset by the second part, which is our change in methodology for deriving the overhead wages and salaries attributable to the routine department of hospital-based IRFs (resulting in a decrease of 1.3 percentage points to the Wages and Salaries cost weight). The resulting final Wages and Salaries cost weight obtained directly from the Medicare cost reports for the 2012-based IRF market basket is now similar to the Wages and Salaries cost weight for the 2008-based RPL market basket.

Also as discussed in section VI.C.1.a.ii of this final rule, we made revisions to our calculation of employee benefits costs based on public comments. The total effect of this methodology change on the 2012-based IRF market basket Employee Benefits cost weight (which reflects freestanding and hospital-based IRFs) is an increase of about 0.4 percentage point from the proposed 2012-based IRF market basket Employee Benefits cost weight of 10.7 percent. This net overall effect can be broken down into two components: (1) the inclusion of overhead employee benefits attributable to the ancillary departments (resulting in an increase of 0.7 percentage point to the aggregate Employee Benefits cost weight), and (2) changes to the routine overhead employee benefits attributable to the hospital-based IRF as a result of changes to the routine overhead salaries for the hospital-based IRF (resulting in a decrease of 0.2 percentage point to the Employee Benefits cost weight).

As we did for the 2008-based RPL market basket, we proposed to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages

and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. For the proposed rule, this rounded percentage was 81 percent; therefore, we proposed to allocate 81 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 19 percent to the Employee Benefits cost weight.

We did not receive any specific comments on our methodology for allocating contract labor costs to the Wages and Salaries and Employee Benefits cost weights.

Final Decision: We are finalizing our methodology for allocating contract labor as proposed. For the final rule, after making changes to the Wages and Salaries and Employee Benefits cost weights, the rounded percentage remains 81 percent. Therefore, we are finalizing our methodology as proposed and allocating 81 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 19 percent to the Employee Benefits cost weight.

Table 4 shows the Wages and Salaries and Employee Benefit cost weights after Contract Labor cost weight allocation for the proposed 2012-based IRF market basket, the final 2012-based IRF market basket, and the 2008-based RPL market basket.

Table 4 – Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	2012-Based IRF Proposed (Percent)	2012-Based IRF Final (Percent)	2008-Based RPL (Percent)
Wages and Salaries	46.1	47.9	49.4
Employee Benefits	10.9	11.3	12.8

c. Derivation of the Detailed Operating Cost Weights

To further divide the "All Other" residual cost weight estimated from the FY 2012

Medicare cost report data into more detailed cost categories, we proposed to use the 2007 Benchmark Input-Output (I-O) "Use Tables/Before Redefinitions/Purchaser Value" for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA) (80 FR 23346). This data is publicly available at http://www.bea.gov/industry/io_annual.htm .

The BEA Benchmark I–O data are scheduled for publication every five years with the most recent data available for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA's economic accounts. Thus, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[3] BEA also produces Annual I–O estimates; however, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2007 Benchmark I–O data forward to 2012 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I–O data. We repeat this practice for each year. We then calculate the cost shares that each cost category represents of the inflated 2012 data. These resulting 2012 cost shares are applied to the All Other residual cost weight to obtain the detailed cost weights for the proposed 2012-based IRF market basket. For example, the cost for Food: Direct Purchases represents 6.5 percent of the sum of the ''All Other'' 2007 Benchmark I–O Hospital Expenditures inflated to 2012; therefore, the Food: Direct Purchases cost weight represents 6.5 percent of the proposed 2012-based IRF market basket's "All Other" cost category (28.4 percent), yielding a "final" Food: Direct Purchases proposed cost weight of 1.8 percent in the

[3] http://www.bea.gov/papers/pdf/IOmanual_092906.pdf

proposed 2012-based IRF market basket (0.065 * 28.4 percent = 1.8 percent).

Using this methodology, we proposed to derive eighteen detailed IRF market basket cost category weights from the proposed 2012-based IRF market basket residual cost weight (28.4 percent). These categories are: (1) Electricity, (2) Fuel, Oil, and Gasoline (3) Water & Sewerage (4) Food: Direct Purchases, (5) Food: Contract Services, (6) Chemicals, (7) Medical Instruments, (8) Rubber & Plastics, (9) Paper and Printing Products, (10) Miscellaneous Products, (11) Professional Fees: Labor-related, (12) Administrative and Facilities Support Services, (13) Installation, Maintenance, and Repair, (14) All Other Labor-related Services, (15) Professional Fees: Nonlabor-related, (16) Financial Services, (17) Telephone Services, and (18) All Other Nonlabor-related Services.

We did not receive any specific comments on our proposed methodology of deriving detailed market basket cost category weights from the BEA Benchmark I-O data.

Final Decision: We are finalizing our methodology for deriving the detailed market basket cost weights as proposed; however, since the methodological change to the derivation of wages and salaries costs and of employee benefits costs results in a Compensation cost weight that is slightly higher than proposed, the residual cost share weight is lower than proposed. Therefore, we are finalizing the residual cost share weight of 26.1 percent rather than the proposed residual of 28.4 percent.

d. Derivation of the Detailed Capital Cost Weights

As described in section V.C.1.a.vi of the proposed rule (80 FR 23345), we proposed a Capital-Related cost weight of 8.6 percent as obtained from the FY 2012 Medicare cost reports for freestanding and hospital-based IRF providers. We proposed to then separate this total Capital-Related cost weight into more detailed cost categories (80 FR 23346).

Using FY 2012 Medicare cost reports, we are able to group capital-Related costs into the following categories: Depreciation, Interest, Lease, and Other capital-Related costs. For each of these categories, we proposed to determine separately for hospital-based IRFs and freestanding IRFs what proportion of total capital-related costs the category represents.

For freestanding IRFs, we proposed to derive the proportions for depreciation, interest, lease, and other capital-related costs using the data reported by the IRF on Worksheet A-7, which is similar to the methodology used for the 2008-based RPL market basket.

For hospital-based IRFs, data for these four categories are not reported separately for the hospital-based IRF; therefore, we proposed to derive these proportions using data reported on Worksheet A-7 for the total facility. We assume the cost shares for the overall hospital are representative for the hospital-based IRF unit. For example, if depreciation costs make up 60 percent of total capital costs for the entire facility, we believe it is reasonable to assume that the hospital-based IRF would also have a 60 percent proportion because it is a unit contained within the total facility.

To combine each detailed Capital cost weight for freestanding and hospital-based IRFs into a single Capital cost weight for the proposed 2012-based IRF market basket, we proposed to weight together the shares for each of the categories (depreciation, interest, lease, and other capital-related costs) based on the share of total capital costs each provider type represents of the total capital costs for all IRFs for 2012. Applying this methodology, results in proportions of total capital-related costs for depreciation, interest, lease and other capital-related costs that are representative of the universe of IRF providers.

We also proposed to allocate lease costs across each of the remaining detailed capital-related cost categories as was done in the 2008-based RPL market basket. This would result in

three primary capital-related cost categories in the proposed 2012-based IRF market basket: Depreciation, Interest, and Other capital-Related costs. Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2012-based IRF market basket. Rather, we proposed to proportionally distribute these costs 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 2008-based RPL market basket, we proposed to assume that 10 percent of the lease costs as a proportion of total capital-related costs represents overhead and assign those costs to the Other Capital-Related cost category accordingly. We proposed to distribute the remaining lease costs proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-related cost categories (excluding lease expenses). This is the same methodology used for the 2008-based RPL market basket. The allocation of these lease expenses are shown in Table 5.

Finally, we proposed to further divide the Depreciation and Interest cost categories. We proposed to separate Depreciation into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment; and proposed to separate Interest into the following two categories: (1) Government/Nonprofit and (2) For-profit.

To disaggregate the Depreciation cost weight, we needed to determine the percent of total Depreciation costs for IRFs attributable to Building and Fixed Equipment, which we hereafter refer to as the "fixed percentage." For the proposed 2012-based IRF market basket, we proposed to use slightly different methods to obtain the fixed percentages for hospital-based IRFs compared to freestanding IRFs.

For freestanding IRFs, we proposed to use depreciation data from Worksheet A-7 of the FY 2012 Medicare cost reports, similar to the methodology used for the 2008-based RPL market basket. However, for hospital-based IRFs, we determined that the fixed percentage for the entire facility may not be representative of the hospital-based IRF unit due to the entire facility likely employing more sophisticated movable assets that are not utilized by the hospital-based IRF. Therefore, for hospital-based IRFs, we proposed to calculate a fixed percentage using: (1) building and fixture capital costs allocated to the hospital-based IRF unit as reported on Worksheet B, part I, line 41, and (2) building and fixture capital costs for the top five ancillary cost centers utilized by hospital-based IRFs. We proposed to weight these two fixed percentages (inpatient and ancillary) using the proportion that each capital cost type represents of total capital costs in the proposed 2012-based IRF market basket. We proposed to then weight the fixed percentages for hospital-based and freestanding IRFs together using the proportion of total capital costs each provider type represents.

To disaggregate the Interest cost weight, we needed to determine the percent of total interest costs for IRFs that are attributable to government and nonprofit facilities, which we hereafter refer to as the "nonprofit percentage," as price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. For the IRF market basket, we proposed to use interest costs data from Worksheet A-7 of the FY 2012 Medicare cost reports for both freestanding and hospital-based IRFs, similar to the methodology used for the 2008-based RPL market basket. We proposed to determine the percent of total interest costs that are attributed to government and nonprofit IRFs separately for hospital-based and freestanding IRFs. We then proposed to weight the nonprofit percentages for hospital-based and freestanding IRFs together using the proportion of total capital costs that each provider type represents.

Table 5 provides the detailed capital cost shares obtained from the Medicare cost reports. Ultimately, these detailed capital cost shares were applied to the total Capital-Related cost weight determined in section V.C.1.a.vi of the proposed rule to split out the total weight of 8.6 percent into more detailed cost categories and weights.

We did not receive any specific comments on our proposed methodology for calculating the detailed capital cost weights for the 2012-based IRF market basket.

Final Decision: We are finalizing our methodology for deriving the detailed capital cost weights as proposed. Therefore, the detailed capital cost weights for the final 2012-based IRF market basket contained in Table 5 are unchanged from the proposed rule.

Table 5—Detailed Capital Cost Weights for the 2012-based IRF Market Basket

	Cost Shares Obtained from Medicare Cost Reports	Detailed Capital Cost Shares after Allocation of Lease Expenses
Depreciation	61%	74%
Building and Fixed Equipment	39%	48%
Movable Equipment	22%	26%
Interest	13%	16%
Government/Nonprofit	8%	10%
For Profit	5%	6%
Lease	20%	n/a
Other	6%	10%

e. 2012-based IRF Market Basket Cost Categories and Weights

Table 6 shows the cost categories and weights for the proposed 2012-based IRF market

basket, the final 2012-based IRF market basket, and the 2008-based RPL market basket.

Table 6 – Proposed and Final 2012-based IRF Cost Weights Compared to 2008-based RPL Cost Weights

Cost Category	Proposed 2012-based IRF Cost Weight	Final 2012-based IRF Cost Weight	2008-based RPL Cost Weight
Total	**100.0**	**100.0**	**100.0**
Compensation	**57.0**	**59.2**	**62.3**
Wages and Salaries	46.1	47.9	49.4
Employee Benefits	10.9	11.3	12.8
Utilities	**2.3**	**2.1**	**1.6**
Electricity	1.0	1.0	1.1
Fuel, Oil, and Gasoline	1.1	1.1	0.4
Water & Sewerage	0.1	0.1	0.1
Professional Liability Insurance	**0.9**	**0.9**	**0.8**
All Other Products and Services	**31.2**	**29.1**	**27.0**
All Other Products	**14.0**	**13.3**	**15.6**
Pharmaceuticals	5.1	5.1	6.5
Food: Direct Purchases	1.8	1.7	3.0
Food: Contract Services	1.1	1.0	0.4
Chemicals	0.7	0.7	1.1
Medical Instruments	2.5	2.3	1.8
Rubber & Plastics	0.6	0.6	1.1
Paper and Printing Products	1.2	1.1	1.0
Apparel	-	-	0.2
Machinery and Equipment	-	-	0.1
Miscellaneous Products	0.9	0.8	0.3
All Other Services	**17.2**	**15.8**	**11.4**
Labor-Related Services	**8.8**	**8.0**	**4.7**
Professional Fees: Labor-related	3.8	3.5	2.1
Administrative and Facilities Support Services	0.9	0.8	0.4
Installation, Maintenance, and Repair	2.1	1.9	-
All Other: Labor-related Services	2.0	1.8	2.1
Nonlabor-Related Services	**8.5**	**7.8**	**6.7**
Professional Fees: Nonlabor-related	3.4	3.1	4.2
Financial services	3.0	2.7	0.9
Telephone Services	0.7	0.7	0.4
Postage	-	-	0.6
All Other: Nonlabor-related Services	1.4	1.3	0.6
Capital-Related Costs	**8.6**	**8.6**	**8.4**

Cost Category	Proposed 2012-based IRF Cost Weight	Final 2012-based IRF Cost Weight	2008-based RPL Cost Weight
Depreciation	**6.4**	**6.4**	**5.5**
Fixed Assets	4.1	4.1	3.3
Movable Equipment	2.3	2.3	2.2
Interest Costs	**1.4**	**1.4**	**2.0**
Government/Nonprofit	0.9	0.9	0.7
For Profit	0.5	0.5	1.3
Other Capital-Related Costs	**0.8**	**0.8**	**0.9**

Note: Detail may not add to total due to rounding.

We stated that the 2012-based IRF market basket would not include separate cost categories for Apparel, Machinery & Equipment, and Postage. Due to the small weights associated with these detailed categories and relatively stable price growth in the applicable price proxy, we proposed to include Apparel and Machinery & Equipment in the Miscellaneous Products cost category and Postage in the All-Other Nonlabor-related Services. We note that these Machinery & Equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for movable equipment are reflected in the Capital-related costs of the 2012-based IRF market basket. We also proposed to include a separate cost category for Installation, Maintenance, and Repair.

We did not receive any specific comments on our proposed list of detailed cost categories for the 2012-based IRF market basket.

Final Decision: We are finalizing our list of detailed cost categories as proposed.

2. Selection of Price Proxies

After developing the cost weights for the 2012-based IRF market basket, we proposed to select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category (80 FR 23349). For the majority of the cost weights,

we proposed to base the price proxies on U.S. Bureau of Labor Statistics (BLS) data and grouped them into one of the following BLS categories:

- Employment Cost Indexes. Employment Cost Indexes (ECIs) measure the rate of change in employment 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. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the North American Industry Classification System (NAICS), and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

- Producer Price Indexes. Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.

- Consumer Price Indexes. Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs are available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- Reliability. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable

because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

- Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

- Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

- Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and Employment Cost Index (ECIs) that we selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 6 lists all price proxies that we proposed to use for the 2012-based IRF market basket. Below is a detailed explanation of the price proxies that we proposed for each cost category weight, (80 FR 23350 through 23351). We note that many of the proxies that we proposed for the 2012-based IRF market basket are the same as those used for the 2008-based

RPL market basket. For further discussion on the 2008-based RPL market basket, see the FY 2012 IRF final rule (76 FR 47852 through 47860).

a. Price Proxies for the Operating Portion of the Proposed 2012-Based IRF Market Basket

1. Wages and Salaries

We proposed to continue to use the ECI for Wages and Salaries for All Civilian workers in Hospitals (BLS series code #CIU1026220000000I) to measure the wage rate growth of this cost category. This is the same price proxy used in the 2008-based RPL market basket.

2. Benefits

We proposed to continue to use the ECI for Total Benefits for All Civilian workers in Hospitals to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for All Civilian workers in Hospitals (BLS series code # CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2008-based RPL market basket.

3. Electricity

We proposed to continue to use the PPI for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2008-based RPL market basket.

4. Fuel, Oil, and Gasoline

We proposed to change the proxy used for the Fuel, Oil, and Gasoline cost category . The 2008-based RPL market basket uses the PPI for Petroleum Refineries (BLS series code #PCU32411-32411) to proxy these expenses.

For the 2012-based IRF market basket, we proposed to use a blend of the PPI for Petroleum Refineries and the PPI Commodity for Natural Gas (BLS series code #WPU0531).

Our analysis of the Bureau of Economic Analysis' 2007 Benchmark Input-Output data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]) showed that Petroleum Refineries expenses accounts for approximately 70 percent and Natural Gas accounts for approximately 30 percent of the Fuel, Oil, and Gasoline expenses. Therefore, we proposed a blend using of 70 percent of the PPI for Petroleum Refineries (BLS series code #PCU32411-32411) and 30 percent of the PPI Commodity for Natural Gas (BLS series code #WPU0531). We believe that these 2 price proxies are the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the 2012-based IRF market basket.

5. Water and Sewerage

We proposed to continue to use the CPI for Water and Sewerage Maintenance (BLS series code #CUUR0000SEHG01) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

6. Professional Liability Insurance

We proposed to continue to use the CMS Hospital Professional Liability Index to measure changes in PLI premiums. To generate this index, we collect commercial insurance premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2008-based RPL market basket.

7. Pharmaceuticals

We proposed to continue to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code #WPUSI07003) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

8. Food: Direct Purchases

We proposed to continue to use the PPI for Processed Foods and Feeds (BLS series code #WPU02) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

9. Food: Contract Purchases

We proposed to continue to use the CPI for Food Away From Home (BLS series code #CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

10. Chemicals

We proposed to continue to use a 4-part blended PPI composed of the PPI for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (BLS series code #PCU32518-32518), the PPI for Other Basic Organic Chemical Manufacturing (BLS series code #PCU32519-32519), and the PPI for Soap and Cleaning Compound Manufacturing (BLS series code #PCU32561-32561). We proposed updating the blend weights using 2007 Benchmark I-O data, which compared to 2002 Benchmark I-O data is weighted more toward organic chemical products and weighted less toward inorganic chemical products.

Table 7 shows the weights for each of the four PPIs used to create the blended PPI. These are the same four proxies used in the 2008-based RPL market basket; however, the blended PPI weights in the 2008-based RPL market baskets were based on 2002 Benchmark I-O data.

Table 7: Blended Chemical PPI Weights

Name	2012-based IRF Weights	2008-based RPL Weights	NAICS
PPI for Industrial Gas Manufacturing	32%	35%	325120
PPI for Other Basic Inorganic Chemical Manufacturing	17%	25%	325180
PPI for Other Basic Organic Chemical Manufacturing	45%	30%	325190
PPI for Soap and Cleaning Compound Manufacturing	6%	10%	325610

11. Medical Instruments

We proposed to use a blend for the Medical Instruments cost category. The 2007 Benchmark Input-Output data shows an approximate 50/50 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we proposed a blend composed of 50 percent of the commodity-based PPI for Surgical and Medical Instruments (BLS code #WPU1562) and 50 percent of the commodity-based PPI for Medical and Surgical Appliances and Supplies (BLS code #WPU1563). The 2008-based RPL market basket uses the single, higher level PPI for Medical, Surgical, and Personal Aid Devices (BLS series code #WPU156).

12. Rubber and Plastics

We proposed to continue to use the PPI for Rubber and Plastic Products (BLS series code #WPU07) to measure price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

13. Paper and Printing Products

We proposed to continue to use the PPI for Converted Paper and Paperboard Products (BLS series code #WPU0915) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

14. Miscellaneous Products

We proposed to continue to use the PPI for Finished Goods Less Food and Energy (BLS series code #WPUSOP3500) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

15. Professional Fees: Labor-Related

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code #CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2008-based RPL market basket.

16. Administrative and Facilities Support Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Office and Administrative Support (BLS series code #CIU2010000220000I) to measure the price growth of this category. This is the same proxy used in the 2008-based RPL market basket.

17. Installation, Maintenance, and Repair

We proposed to use the ECI for Total Compensation for Civilian workers in Installation, Maintenance, and Repair (BLS series code #CIU1010000430000I) to measure the price growth of this new cost category. Previously these costs were included in the All Other: Labor-related Services category and were proxied by the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code #CIU2010000300000I). We believe that this index better reflects the price changes of labor associated with maintenance-related services and its incorporation represents a technical improvement to the market basket.

18. All Other: Labor-Related Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code #CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

19. Professional Fees: Nonlabor-Related

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code #CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2008-based RPL market basket.

20. Financial Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Financial Activities (BLS series code #CIU201520A000000I) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

21. Telephone Services

We proposed to continue to use the CPI for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

22. All Other: Nonlabor-Related Services

We proposed to continue to use the CPI for All Items Less Food and Energy (BLS series code #CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

We did not receive any specific comments on our proposed selection of price proxies.

Final Decision: We are finalizing our selection of price proxies as proposed.

b. Price Proxies for the Capital Portion of the 2012-Based IRF Market Basket

1. Capital Price Proxies Prior to Vintage Weighting

We proposed to apply the same price proxies to the detailed capital-related cost categories as were applied in the 2008-based RPL market basket, which are described and provided in Table 7. We also proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2008-based RPL market basket and is described in section V.C.2.b.2 of the proposed rule.

We proposed to proxy the Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type), the Depreciation: Movable Equipment cost category by the PPI for Machinery and Equipment (BLS series code #WPU11), the Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index), the For-profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve), and the Other Capital-Related cost category by the CPI-U for Rent of Primary Residence (BLS series code #CUUS0000SEHA). We believe these are the most appropriate proxies for IRF capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

We did not receive any public comments on the capital-related price proxies we proposed.

Final Decision: We are finalizing our list of capital-related price proxies as proposed.

2. Vintage Weights for Price Proxies

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. The vintage-weighted capital-related portion of the 2012-based IRF 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. We proposed to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

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 non-vintage 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 IRF capital-related costs. The capital-related component of the 2012-based IRF market basket reflects the underlying stability of the capital-related acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first 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) did not include annual capital-related purchases. However, we were able to obtain data on total expenses back to 1963 from the AHA. Consequently, we proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then proposed to use 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 2012. We proposed to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derived annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data is not available that is specific to IRFs, we believe this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for IRFs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for Building and Fixed Equipment, Movable Equipment, and Interest for the 2012-based IRF market basket. We proposed to calculate the expected lives using Medicare cost report data from freestanding and hospital-based IRFs. 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 expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. We proposed to determine the expected life of building and fixed equipment separately for hospital-based IRFs and freestanding IRFs, and then weight these expected lives using the percent of total capital costs each provider type represents. We proposed to apply a similar method for movable equipment. Using these proposed methods, we determined the average expected life of building and fixed equipment to be equal to 23 years, and the average expected life of movable equipment to be equal to 11 years. For the expected life of interest, we believe vintage weights for interest should represent the average expected life of building 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. We note that for the 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 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.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we proposed to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided earlier in this final rule. For the interest vintage weights, we proposed to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we proposed to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and

interest, 23 years, and in the case of movable equipment, 11 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2012 back to 1964. These data allow us to derive twenty-seven 23-year periods of capital-related purchases for building and fixed equipment and interest, and thirty-nine 11-year periods of capital-related purchases for movable equipment. For each 23-year period for building and fixed equipment and interest, or 11-year period for movable equipment, we calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 23-year or 11-year period. This calculation is done for each year in the 23-year or 11-year period and for each of the periods for which we have data. We then calculate the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

We did not receive any specific comments on the proposed methodology for calculating the vintage weights for the 2012-based IRF market basket.

Final Decision: We are finalizing the vintage weights as proposed.

The vintage weights for the capital-related portion of the 2008-based RPL market basket and the 2012-based IRF market basket are presented in Table 8.

Table 8: 2008-Based RPL market basket and 2012-based IRF market basket Vintage Weights for Capital-Related Price Proxies

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	2012-based 23 years	2008-based 26 years	2012-based 11 years	2008-based 11 years	2012-based 23 years	2008-based 26 years
1	0.029	0.021	0.069	0.071	0.017	0.010
2	0.031	0.023	0.073	0.075	0.019	0.012
3	0.034	0.025	0.077	0.080	0.022	0.014
4	0.036	0.027	0.083	0.083	0.024	0.016
5	0.037	0.028	0.087	0.085	0.026	0.018
6	0.039	0.030	0.091	0.089	0.028	0.020

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	2012-based 23 years	2008-based 26 years	2012-based 11 years	2008-based 11 years	2012-based 23 years	2008-based 26 years
7	0.040	0.031	0.096	0.092	0.030	0.021
8	0.041	0.033	0.100	0.098	0.032	0.024
9	0.042	0.035	0.103	0.103	0.035	0.026
10	0.044	0.037	0.107	0.109	0.038	0.029
11	0.045	0.039	0.114	0.116	0.040	0.033
12	0.045	0.041	--	--	0.042	0.035
13	0.045	0.042	--	--	0.044	0.038
14	0.046	0.043	--	--	0.046	0.041
15	0.046	0.044	--	--	0.048	0.043
16	0.048	0.045	--	--	0.053	0.046
17	0.049	0.046	--	--	0.057	0.049
18	0.050	0.047	--	--	0.060	0.052
19	0.051	0.047	--	--	0.063	0.053
20	0.051	0.045	--	--	0.066	0.053
21	0.051	0.045	--	--	0.067	0.055
22	0.050	0.045	--	--	0.069	0.056
23	0.052	0.046	--	--	0.073	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.

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 8 is applied to the most recent data point. We have provided on the CMS website 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."

c. Summary of Price Proxies of the 2012-based IRF Market Basket

As stated above, we did not receive any public comments on our proposed list of operating or capital price proxies.

Final Decision: We are finalizing the list of operating and capital price proxies as proposed.

Table 9 shows both the operating and capital price proxies for the 2012-based IRF market basket.

Table 9: Price Proxies for the 2012-based IRF Market Basket

Cost Description	Price Proxies	Weight
Total - IRF12		**100.0%**
Compensation		**59.2%**
Wages and Salaries	ECI for Wages and Salaries for All Civilian workers in Hospitals	47.9%
Employee Benefits	ECI for Total Benefits for All Civilian workers in Hospitals	11.3%
Utilities		**2.1%**
Electricity	PPI for Commercial Electric Power	1.0%
Fuel, Oil, and Gasoline	Blend of the PPI for Petroleum Refineries and PPI for Natural Gas	1.1%
Water & Sewage	CPI-U for Water and Sewerage Maintenance	0.1%
Professional Liability Insurance		**0.9%**
Malpractice	CMS Hospital Professional Liability Insurance Premium Index	0.9%
All Other Products and Services		**29.1%**
All Other Products		**13.3%**
Pharmaceuticals	PPI for Pharmaceuticals for human use, prescription	5.1%
Food: Direct Purchases	PPI for Processed Foods and Feeds	1.7%
Food: Contract Services	CPI-U for Food Away From Home	1.0%
Chemicals	Blend of Chemical PPIs	0.7%
Medical Instruments	Blend of the PPI for Surgical and medical instruments and PPI for Medical and surgical appliances and supplies	2.3%
Rubber & Plastics	PPI for Rubber and Plastic Products	0.6%
Paper and Printing Products	PPI for Converted Paper and Paperboard Products	1.1%
Miscellaneous Products	PPI for Finished Goods Less Food and Energy	0.8%
All Other Services		**15.8%**
Labor-Related Services		**8.0%**
Professional Fees: Labor-related	ECI for Total compensation for Private industry workers in Professional and related	3.5%
Administrative and Facilities Support Services	ECI for Total compensation for Private industry workers in Office and administrative support	0.8%
Installation, Maintenance & Repair	ECI for Total compensation for Civilian workers in Installation, maintenance, and repair	1.9%
All Other: Labor-related Services	ECI for Total compensation for Private industry workers in Service occupations	1.8%

Cost Description	Price Proxies	Weight
Nonlabor-Related Services		**7.8%**
Professional Fees: Nonlabor-related	ECI for Total compensation for Private industry workers in Professional and related	3.1%
Financial services	ECI for Total compensation for Private industry workers in Financial activities	2.7%
Telephone Services	CPI-U for Telephone Services	0.7%
All Other: Nonlabor-related Services	CPI-U for All Items Less Food and Energy	1.3%
Capital-Related Costs		**8.6%**
Depreciation		**6.4%**
Fixed Assets	BEA chained price index for nonresidential construction for hospitals and special care facilities - vintage weighted (23 years)	4.1%
Movable Equipment	PPI for machinery and equipment - vintage weighted (11 years)	2.3%
Interest Costs		**1.4%**
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds) - vintage weighted (23 years)	0.9%
For Profit	Average yield on Moody's Aaa bonds - vintage weighted (23 years)	0.5%
Other Capital-Related Costs	CPI-U for Rent of primary residence	**0.8%**

Note: Detail may not add to total due to rounding

D. FY 2016 Market Basket Update and Productivity Adjustment

1. FY 2016 Market Basket Update

For FY 2016, we proposed to use the 2012-based IRF market basket increase factor described in section VI.C. of the proposed rule to update the IRF PPS base payment rate (80 FR 23355). Consistent with historical practice, we proposed to estimate the market basket update for the IRF PPS based on IHS Global Insight's forecast using the most recent available data. IHS Global Insight (IGI), Inc. is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and multifactor productivity (MFP).

Based on IGI's first quarter 2015 forecast with historical data through the fourth quarter of 2014, the projected proposed 2012-based IRF market basket increase factor for FY 2016 would be 2.7 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we proposed a market basket increase factor of 2.7 percent for FY 2016. 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, to determine the FY 2016 update in the final rule.

We received 5 comments on the proposed market basket increase factor for FY 2016.

Comment: A few commenters stated that although the proposed payment increase does not keep up with inflation, they supported and appreciated the proposed increase in baseline payments and suggested that CMS finalize this policy in the final rule. A few commenters stated that they generally concurred with the methodology CMS used to arrive at the net market basket update. One commenter stated that the market basket update does not account for the mandatory sequestration, and they encouraged CMS to consider the fact that the proposed rule does not account for the two-percent sequestration reduction to all lines of Medicare.

Response: We believe that the market basket update adequately accounts for price inflation pressures faced by IRF providers. The productivity adjustment to the market basket update is mandated by the Affordable Care Act, and sequestration cuts are mandated by the Federal Budget. Both the productivity adjustments and sequestration cuts are outside the scope of regulatory policymaking or the market basket payment update.

Comment: One commenter noted that, for FY 2016, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0-percent update be applied to IRF PPS payment rates. However, this commenter also acknowledged that a 0-percent update is not currently authorized under statute.

Response: As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is updating IRF PPS payment rates for FY 2016 by an adjusted market basket increase factor of 1.7 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS

payment rates for FY 2016.

Final Decision: For this final rule, we are estimating the market basket update for the IRF PPS using the most recent available data. Based on IGI's second quarter 2015 forecast with historical data through the first quarter of 2015, the projected 2012-based IRF market basket increase factor for FY 2016 is 2.4 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are finalizing a market basket increase factor of 2.4 percent for FY 2016.

For comparison, the 2008-based RPL market basket is also projected to be 2.4 percent in FY 2016; this estimate is based on IGI's second quarter 2015 forecast (with historical data through the first quarter of 2015). Table 10 compares the 2012-based IRF market basket and the 2008-based RPL market basket percent changes.

Table 10: 2012-Based IRF Market Basket and 2008-Based RPL Market Basket Percent Changes, FY 2010 through FY 2018

Fiscal Year (FY)	2012-Based IRF Market Basket Index Percent Change	2008-Based RPL Market Basket Index Percent Change
Historical data:		
FY 2010	2.1	2.2
FY 2011	2.3	2.5
FY 2012	1.8	2.2
FY 2013	2.0	2.1
FY 2014	1.8	1.8
Average 2010-2014	2.0	2.2
Forecast:		
FY 2015	1.6	2.0
FY 2016	2.4	2.4
FY 2017	2.9	2.9
FY 2018	3.1	3.1
Average 2015-2018	2.5	2.6

Note: These market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Insight, Inc. 2nd quarter 2015 forecast.

The final FY 2016 market basket increase factor based on the 2012-based IRF market basket is 0.3 percentage point lower than the proposed FY 2016 market basket increase factor. The difference between the proposed and final rule updates is primarily attributable to a

downward revision in the IHS Global Insight forecasted growth in wages and salaries for hospital workers. The revised methodology for the Wages and Salaries and Employee Benefits cost weights results in a market basket update that is 0.1 percentage point higher than if no changes to the methodology had been finalized.

2. Productivity Adjustment

According to section 1886(j)(3)(C)(i) of the Act, the Secretary shall establish an increase factor based on an appropriate percentage increase in a market basket of goods and services. As described in section V.C and V.D.1. of the proposed rule (80 FR 23342 through 23355), we proposed to estimate the IRF PPS increase factor for FY 2016 based on the proposed 2012-based IRF market basket. Section 1886(j)(3)(C)(ii) of the Act then requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the "MFP adjustment"). The BLS publishes the official measure of private nonfarm business MFP. Please see http://www.bls.gov/mfp for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market basket and MFP. As described in the FY 2012 IRF PPS final rule

(76 FR 47836, 47858 through 47859), to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the FY 2012 IRF PPS final rule, we identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series. Beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the FY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on CMS website at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html. Although we discuss the IGI changes to the MFP proxy series in this final rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our website rather than in the annual rulemaking.

Using IGI's first quarter 2015 forecast, the MFP adjustment for FY 2016 (the 10-year moving average of MFP for the period ending FY 2016) was projected to be 0.6 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we proposed to base the FY 2016 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the proposed 2012-based IRF market basket (estimated

to be 2.7 percent in the proposed rule based on IGI's first quarter 2015 forecast). We proposed to then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2016 of 0.6 percentage point (the 10-year moving average of MFP for the period ending FY 2016 based on IGI's first quarter 2015 forecast). Following application of the MFP, we further reduce the applicable percentage increase by 0.2 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act. Therefore, the estimate of the FY 2016 IRF update for the proposed rule was 1.9 percent (2.7 percent market basket update, less 0.6 percentage point MFP adjustment, less 0.2 percentage point legislative adjustment). Furthermore, we noted in the proposed rule that if more recent data were to be subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the FY 2016 market basket update and MFP adjustment in the final rule.

We did not receive any specific comments on our methodology for calculating the productivity adjustment for FY 2016. We did receive 2 comments on the application of the productivity adjustment to the market basket increase factor.

Comment: One commenter stated that while they understand that CMS is bound by the required Affordable Care Act offsets, it is unlikely that productivity improvements will be generated by rehabilitation hospital providers at a pace matching the productivity of the economy at large on an ongoing, consistent basis as currently contemplated by the Affordable Care Act. A few commenters stated that services provided in rehabilitation hospitals are very labor-intensive through the provision of hands-on care by physical therapists, occupational therapists, speech therapists, and rehabilitation nursing staff. These commenters further stated that the proposed rule would implement significant new costs related to the IRF Quality Reporting Program and

that the implementation of ICD-10-CM will increase billing and coding times. The commenters stated that as health care reform continues to take shape in the coming years, many changes discussed here, and new ones yet to be implemented, will adversely impact productivity levels in IRFs. Further, the commenters stated that while there are technologies utilized in providing therapy to patients, many of the treatment plans do not lend themselves to continual productivity improvements. The commenters claimed that it will be especially challenging for efficient providers, over time, to achieve continued efficiencies at a rate that will be required by ongoing application of productivity adjustments. As a result, the commenters respectfully requested that CMS carefully monitor the impact that these productivity adjustments will have on IRFs. One of the commenters also requested that CMS provide feedback to Congress as appropriate.

Another commenter suggested that CMS remain cognizant of the intensive labor time and costs required by state and/or federal regulations to which IRFs are bound, and which may be barriers to IRFs achieving further gains in productivity efficiencies. The commenter stated that CMS should consider the unique needs of IRFs' rehabilitation patients and their interdisciplinary teams of highly skilled health care professionals when considering the productivity adjustment factor that it will apply to IRFs. In addition, the commenter stated that CMS should be mindful of the additional labor costs that IRFs will incur as a result of having more items that must be reported on the newest version of the IRF-PAI.

Response: Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment that must be applied to the IRF PPS market basket update. We will continue to monitor the impact of the payment updates, including the effects of the productivity adjustment, on IRF provider margins as well as beneficiary access to care.

Final Decision: We are finalizing the methodology for determining the productivity

adjustment as proposed. Using IGI's second quarter 2015 forecast, the MFP adjustment for FY 2016 (the 10-year moving average of MFP for the period ending FY 2016) is projected to be 0.5 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we base the FY 2016 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the 2012-based IRF market basket (currently estimated to be 2.4 percent based on IGI's second quarter 2015 forecast). We then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2016 of 0.5 percentage point (the 10-year moving average of MFP for the period ending FY 2016 based on IGI's second quarter 2015 forecast). Following application of the MFP, we further reduce the applicable percentage increase by 0.2 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act. Therefore, the estimate of the FY 2016 IRF update for this final rule is 1.7 percent (2.4 percent market basket update, less 0.5 percentage-point MFP adjustment, less 0.2 percentage-point statutory other adjustment).

For FY 2016, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0-percent update be applied to IRF PPS payment rates. As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is updating IRF PPS payment rates for FY 2015 by an adjusted market basket increase factor of 1.7 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2016.

E. Labor-Related Share for FY 2016

Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related costs, of the prospective payment rates computed under

section 1886(j)(3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. 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 continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. As stated in the FY 2015 IRF PPS final rule (79 FR 45886), the labor-related share for FY 2015 was defined as the sum of the FY 2015 relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor- Related Services, Administrative and Business Support Services, All Other: Labor-related Services, and a portion of the Capital Costs from the 2008-based RPL market basket.

Based on our definition of the labor-related share and the cost categories in the proposed 2012-based IRF market basket, we proposed to include in the labor-related share for FY 2016 the sum of the FY 2016 relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor- Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the proposed 2012-based IRF market basket (80 FR 23356). As noted in Section VI.C.2.a of this final rule, for the 2012-based IRF market basket, we have created a separate cost category for Installation, Maintenance, and Repair services. These expenses were previously included in the "All Other" Labor-related Services cost category in the 2008-based RPL market basket, along with other services, including, but not limited to, janitorial, waste management, security, and dry cleaning/laundry services. Because these services tend to be labor-intensive and are mostly performed at the facility (and, therefore, unlikely to be purchased in the national market),

we continue to believe that they meet our definition of labor-related services.

Similar to the 2008-based RPL market basket, the 2012-based IRF market basket includes 2 cost categories for nonmedical Professional fees (including, but not limited to, expenses for legal, accounting, and engineering services). These are Professional Fees: Labor-related and Professional Fees: Nonlabor-related. For the 2012-based IRF market basket, we proposed to estimate the labor-related percentage of non-medical professional fees (and assign these expenses to the Professional Fees: Labor-related services cost category) based on the same method that was used to determine the labor-related percentage of professional fees in the 2008-based RPL market basket.

To summarize, the professional services survey found that hospitals purchase the following proportion of these four services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We proposed to apply each of these percentages to the respective Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the same methodology that we used to separate the 2008-based RPL market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. For more detail regarding this methodology, see the FY 2012 IRF final rule (76 FR 47861).

In addition to the professional services listed, we also classified expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees cost category as was done in the 2008-based RPL market basket. The NAICS 55 data are mostly comprised of corporate, subsidiary, and regional managing offices, or otherwise referred to as home offices. Since many facilities are not located in the same geographic area as their home office, we analyzed data from a variety of sources to determine what proportion of these costs should be appropriately included in the labor-related share. For the 2012-based IRF market basket, we proposed to derive the home office percentages using data for both freestanding IRF providers and hospital-based IRF providers. In the 2008-based RPL market basket, we used the home office percentages based on the data reported by freestanding IRFs, IPFs, and LTCHs.

Using data primarily from the Medicare cost reports and the Home Office Medicare Records (HOMER) database that provides the address (including city and state) for home offices, we were able to determine that 38 percent of the total number of freestanding and hospital-based IRFs 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).

The Medicare cost report requires hospitals to report their home office provider numbers. Using the HOMER database to determine the home office location for each home office provider number, we compared the location of the provider with the location of the hospital's home office. We then placed providers into one of the following 2 groups:

- Group 1—Provider and home office are located in different MSAs.
- Group 2—Provider and home office are located in the same MSA.

We found that 62 percent of the providers with home offices were classified into Group 1 (that is, different MSAs) and, thus, these providers were determined to not be located in the same

local labor market as their home office. We found that 38 percent of all providers with home offices were classified into Group 2 (that is, the same MSA). Given these results, we proposed to classify 38 percent of the Professional Fees costs into the Professional Fees: Labor-related cost category and the remaining 62 percent into the Professional Fees: Nonlabor-related Services cost category. This methodology for apportioning the Professional Fee expenses between Labor-related and Nonlabor-related categories was similar to the method used in the 2008-based RPL market basket. For more details regarding this methodology, see the FY 2012 IRF final rule (76 FR 47860 through 47863).

Using this proposed method and the IHS Global Insight, Inc. first quarter 2015 forecast for the proposed 2012-based IRF market basket, the proposed IRF labor-related share for FY 2016 is the sum of the FY 2016 relative importance of each labor-related cost category. The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2012) and FY 2016.

The sum of the relative importance for FY 2016 operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services) using the proposed 2012-based IRF market basket is 65.7 percent, as shown in Table 11. We proposed to specify the labor-related share to one decimal place, which is consistent with the IPPS labor-related share (79 FR 49990) (currently the labor-related share from the RPL market basket is specified to three decimal places).

We proposed that the portion of Capital that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2008-based RPL market basket. Since the relative importance for Capital-Related Costs is 8.4 percent of the proposed

2012-based IRF market basket in FY 2016, we proposed to take 46 percent of 8.4 percent to determine the proposed labor-related share of Capital for FY 2016. The result would be 3.9 percent, which we proposed to add to 65.7 percent for the operating cost amount to determine the total proposed labor-related share for FY 2016. Thus, the labor-related share that we proposed to use for IRF PPS in FY 2016 would be 69.6 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous IRF labor-related shares (see 76 FR 47862). By comparison, the FY 2015 labor-related share under the 2008-based RPL market basket was 69.294 percent. Therefore, the proposed change from the RPL market basket to the IRF market basket had only a minimal impact on the labor-related share for IRF providers.

We did not receive any specific comments on our proposed methodology for calculating the FY 2016 labor-related share using the 2012-based IRF market basket.

Final Decision: We are finalizing our methodology for determining the labor-related share as proposed.

As discussed in sections VI.C.1.a.i and VI.C1.a.ii of this final rule, we are revising the Wages and Salaries and Employee Benefits cost weights based on public comments we received. Using the proposed method and the IHS Global Insight, Inc. second quarter 2015 forecast for the 2012-based IRF market basket, the final IRF labor-related share for FY 2016 is the sum of the FY 2016 relative importance of each labor-related cost category. Table 11 compares the proposed FY 2016 labor-related share using the proposed 2012-based IRF market basket relative importance, the final FY 2016 labor-related share using the finalized 2012-based IRF market basket relative importance, and the FY 2015 labor-related share using the 2008-based RPL market basket.

The sum of the relative importance for FY 2016 operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services) using the final 2012-based IRF market basket is 67.1 percent, as shown in Table 11.

Since the relative importance for Capital-Related Costs is 8.4 percent of the 2012-based IRF market basket in FY 2016, we take 46 percent of 8.4 percent to determine the labor-related share of Capital for FY 2016. The result is 3.9 percent, which we add to the 67.1 percent operating cost amount to determine the total labor-related share for FY 2016. Thus, the labor-related share for IRF PPS in FY 2016 is 71.0 percent. By comparison, the FY 2015 labor-related share under the 2008-based RPL market basket was 69.294 percent. Therefore, the change from the RPL market basket to the IRF market basket results in an increase of approximately 1.7 percentage points to the labor-related share for IRF providers.

Table 11: IRF Labor-Related Share

	FY 2016 Proposed Labor-Related Share[1]	**FY 2016 Final Labor Related Share[2]**	**FY 2015 Final Labor Related Share[3]**
Wages and Salaries	46.0	47.6	48.271
Employee Benefits	11.0	11.4	12.936
Professional Fees: Labor-related	3.8	3.5	2.058
Administrative and Facilities Support Services	0.9	0.8	0.415
Installation, Maintenance, and Repair	2.1	2.0	-
All Other: Labor-related Services	1.9	1.8	2.061
Subtotal	**65.7**	**67.1**	**65.741**
Labor-related portion of capital (46%)	3.9	3.9	3.553
Total Labor-Related Share	**69.6**	**71.0**	**69.294**

1. Based on the proposed 2012-based IRF Market Basket, IHS Global Insight, Inc. 1st quarter 2015 forecast.
2. Based on the final 2012-based IRF Market Basket, IHS Global Insight, Inc. 2nd quarter 2015 forecast.
3. Federal Register 79 FR 45886.

F. Wage Adjustment

1. Background

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

For FY 2016, we proposed to maintain the policies and methodologies described in the FY 2012 IRF PPS final rule (76 FR 47836, 47863 through 47865) related to the labor market area definitions and the wage index methodology for areas with wage data (80 FR 23358). Thus, we proposed to use the CBSA labor market area definitions and the FY 2015 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2015 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2010, and before October 1, 2011 (that is, FY 2011 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We proposed to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation for the

FY 2016 IRF PPS wage index. We did not receive any comments on these proposals. Therefore, we are finalizing our proposal to use the CBSA labor market area definitions and the FY 2015 pre-reclassification and pre-floor hospital wage index data for areas with wage data. We are also finalizing our proposal to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data.

2. Update

The wage index used for the IRF PPS is calculated using the pre-reclassification and pre-floor acute care hospital wage index data and is assigned to the IRF on the basis of the labor market area in which the IRF is geographically located. IRF labor market areas are delineated based on the Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). The current CBSA labor market definitions used in FY 2015 are based on OMB standards published on December 27, 2000 (65 FR 82228).

As stated in the FY 2016 IRF PPS proposed rule (80 FR 23331), we proposed to include the 2010 Census-based CBSA changes in the IRF PPS wage index for FY 2016. On February 28, 2013, OMB issued OMB Bulletin No. 13-01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin is available online at http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf. The OMB bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town

Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data.

While the revisions OMB published on February 28, 2013 are not as sweeping as the changes made when we adopted the CBSA geographic designations in the FY 2006 IRF PPS final rule, the February 28, 2013 OMB bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs that are being split apart. However, because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications needed to be extensively reviewed and verified, these changes were not incorporated into the hospital wage index until FY 2015. In the FY 2015 IRF PPS final rule (79 FR 45886), we stated that we intended to consider changes to the wage index based on the most current OMB delineations in FY 2016. As discussed below, we are implementing the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13-01, for the IRF PPS wage index beginning in FY 2016.

3. Implementation of New Labor Market Delineations

As discussed in the FY 2015 IRF PPS proposed rule (79 FR 26308) and final rule (79 FR 45871), we delayed implementing the new OMB statistical area delineations to allow for sufficient time to assess the new changes. We believe it is important for the IRF PPS to use the latest OMB delineations available to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. While CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system (we refer readers to the CMS website at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html), no consensus has been achieved

regarding how best to implement a replacement system. As discussed in the FY 2005 IPPS final rule (69 FR 49027), while we recognize that MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose. We further believe that using the most current OMB delineations would increase the integrity of the IRF PPS wage index by creating a more accurate representation of geographic variation in wage levels. We have reviewed our findings and impacts relating to the new OMB delineations, and have concluded that there is no compelling reason to further delay implementation. Because we believe that we have broad authority under section 1886(j)(6) of the Act to determine the labor market areas used for the IRF PPS wage index, and because we also believe that the most current OMB delineations accurately reflect the local economies and wage levels of the areas in which hospitals are currently located, we proposed to implement the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13-01, for the IRF PPS wage index effective beginning in FY 2016 (80 FR 23358 through 23359). As discussed below, we proposed to implement a 1-year transition with a blended wage index for all providers and a 3 year phase-out of the rural adjustment for a subset of providers in FY 2016 to assist providers in adapting to the new OMB delineations. This proposed transition is discussed in more detail below.

We received 1 comment on the proposed policy to adopt the new OMB delineations which is summarized below.

Comment: One commenter expressed support of the proposal to adopt the new OMB delineations effective for FY 2016.

Response: We appreciate the support for our proposal to adopt the new OMB delineations. For a discussion of our policies to moderate the impact of our adoption of the new OMB delineations under the IRF PPS, we refer readers to section VI.F.4. of this final rule.

Final Decision: After consideration of the public comments we received, we are finalizing the implementation of the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, effective beginning with the FY 2016 IRF PPS wage index.

a. Micropolitan Statistical Areas

OMB defines a "Micropolitan Statistical Area" as a CBSA associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as "rural" and include them in the calculation of each state's IRF PPS rural wage index. Thus, the IRF PPS statewide rural wage index is determined using IPPS hospital data from hospitals located in non-MSA areas, and the statewide rural wage index is assigned to IRFs located in those areas. Because Micropolitan Areas tend to encompass smaller population centers and contain fewer hospitals than MSAs, we determined that if Micropolitan Areas were to be treated as separate labor market areas, the IRF PPS wage index would have included significantly more single-provider labor market areas. As we explained in the FY 2006 IRF PPS final rule (70 FR 47920 through 47921), recognizing Micropolitan Areas as independent labor markets would generally increase the potential for dramatic shifts in year-to-year wage index values because a single hospital (or group of hospitals) could have a disproportionate effect on

the wage index of an area. Dramatic shifts in an area's wage index from year to year are problematic and create instability in the payment levels from year to year, which could make fiscal planning for IRFs difficult if we adopted this approach. For these reasons, we adopted a policy to include Micropolitan Areas in the state's rural wage area for purposes of the IRF PPS wage index, and have continued this policy through the present.

Based upon the new 2010 Decennial Census data, a number of urban counties have switched status and have joined or became Micropolitan Areas, and some counties that once were part of a Micropolitan Area, have become urban. Overall, there are fewer Micropolitan Areas (541) under the new OMB delineations based on the 2010 Census than existed under the latest data from the 2000 Census (581). We believe that the best course of action would be to continue the policy established in the FY 2006 IRF PPS final rule (70 FR 47880) and include Micropolitan Areas in each state's rural wage index. These areas continue to be defined as having relatively small urban cores (populations of 10,000 to 49,999). We do not believe it would be appropriate to calculate a separate wage index for areas that typically may include only a few hospitals for the reasons discussed in the FY 2006 IRF PPS final rule (70 FR 47880), and as previously discussed. Therefore, in conjunction with our implementation of the new OMB labor market delineations beginning in FY 2016 and consistent with the treatment of Micropolitan Areas under the IPPS, we proposed to continue to treat Micropolitan Areas as "rural" and to include Micropolitan Areas in the calculation of the state's rural wage index (80 FR 23359). We did not receive any comments addressing this proposal. Therefore, we are finalizing our proposal to continue to treat Micropolitan Areas as "rural" and to include Micropolitan Areas in the calculation of the state's rural wage index.

b. Urban Counties Becoming Rural

As previously discussed, we proposed to implement the new OMB statistical area delineations (based upon the 2010 decennial Census data) beginning in FY 2016 for the IRF PPS wage index (80 FR 23359 through 23360). Our analysis shows that a total of 37 counties (and county equivalents) that are currently considered part of an urban CBSA would be considered located in a rural area, for IRF PPS payment beginning in FY 2016 with the new OMB delineations. Table 12 lists the 37 urban counties that will be rural with the implementation of the new OMB delineations.

TABLE 12: Counties That Will Transition from Urban to Rural Status

County	State	Previous CBSA	Previous Urban Area (Constituent Counties)
Greene County	IN	14020	Bloomington, IN
Anson County	NC	16740	Charlotte-Gastonia-Rock Hill, NC-SC
Franklin County	IN	17140	Cincinnati-Middletown, OH-KY-IN
Stewart County	TN	17300	Clarksville, TN-KY
Howard County	MO	17860	Columbia, MO
Delta County	TX	19124	Dallas-Fort Worth-Arlington, TX
Pittsylvania County	VA	19260	Danville, VA
Danville City	VA	19260	Danville, VA
Preble County	OH	19380	Dayton, OH
Gibson County	IN	21780	Evansville, IN-KY
Webster County	KY	21780	Evansville, IN-KY
Franklin County	AR	22900	Fort Smith, AR-OK
Ionia County	MI	24340	Grand Rapids-Wyoming, MI
Newaygo County	MI	24340	Grand Rapids-Wyoming, MI
Greene County	NC	24780	Greenville, NC
Stone County	MS	25060	Gulfport-Biloxi, MS
Morgan County	WV	25180	Hagerstown-Martinsburg, MD-WV
San Jacinto County	TX	26420	Houston-Sugar Land-Baytown, TX
Franklin County	KS	28140	Kansas City, MO-KS
Tipton County	IN	29020	Kokomo, IN
Nelson County	KY	31140	Louisville/Jefferson County, KY-IN
Geary County	KS	31740	Manhattan, KS
Washington County	OH	37620	Parkersburg-Marietta-Vienna, WV-OH

County	State	Previous CBSA	Previous Urban Area (Constituent Counties)
Pleasants County	WV	37620	Parkersburg-Marietta-Vienna, WV-OH
George County	MS	37700	Pascagoula, MS
Power County	ID	38540	Pocatello, ID
Cumberland County	VA	40060	Richmond, VA
King and Queen County	VA	40060	Richmond, VA
Louisa County	VA	40060	Richmond, VA
Washington County	MO	41180	St. Louis, MO-IL
Summit County	UT	41620	Salt Lake City, UT
Erie County	OH	41780	Sandusky, OH
Franklin County	MA	44140	Springfield, MA
Ottawa County	OH	45780	Toledo, OH
Greene County	AL	46220	Tuscaloosa, AL
Calhoun County	TX	47020	Victoria, TX
Surry County	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC

We proposed that the wage data for all hospitals located in the counties listed in Table 12 now be considered rural when their respective state's rural wage index value is calculated. This rural wage index value will be used under the IRF PPS. We did not receive any comments addressing this proposal. Therefore, we are finalizing our proposed reassignment of these counties from urban status to rural status for purposes of the wage index based on the new OMB delineations.

c. Rural Counties Becoming Urban

With the implementation of the new OMB delineations, (based upon the 2010 decennial Census data), a total of 105 counties (and county equivalents) that are currently located in rural areas will now be located in urban areas. Table 13 below lists the 105 rural counties.

TABLE 13: Counties That Will Transition from Rural to Urban Status

County	State	New CBSA	Urban Area (Constituent Counties)
Utuado Municipio	PR	10380	Aguadilla-Isabela, PR
Linn County	OR	10540	Albany, OR
Oldham County	TX	11100	Amarillo, TX
Morgan County	GA	12060	Atlanta-Sandy Springs-Roswell, GA
Lincoln County	GA	12260	Augusta-Richmond County, GA-SC
Newton County	TX	13140	Beaumont-Port Arthur, TX
Fayette County	WV	13220	Beckley, WV
Raleigh County	WV	13220	Beckley, WV
Golden Valley County	MT	13740	Billings, MT
Oliver County	ND	13900	Bismarck, ND
Sioux County	ND	13900	Bismarck, ND
Floyd County	VI	13980	Blacksburg-Christiansburg-Radford, VA
De Witt County	IL	14010	Bloomington, IL
Columbia County	PA	14100	Bloomsburg-Berwick, PA
Montour County	PA	14100	Bloomsburg-Berwick, PA
Allen County	KY	14540	Bowling Green, KY
Butler County	KY	14540	Bowling Green, KY
St. Mary's County	MD	15680	California-Lexington Park, MD
Jackson County	IL	16060	Carbondale-Marion, IL
Williamson County	IL	16060	Carbondale-Marion, IL
Franklin County	PA	16540	Chambersburg-Waynesboro, PA
Iredell County	NC	16740	Charlotte-Concord-Gastonia, NC-SC
Lincoln County	NC	16740	Charlotte-Concord-Gastonia, NC-SC
Rowan County	NC	16740	Charlotte-Concord-Gastonia, NC-SC
Chester County	SC	16740	Charlotte-Concord-Gastonia, NC-SC
Lancaster County	SC	16740	Charlotte-Concord-Gastonia, NC-SC
Buckingham County	VA	16820	Charlottesville, VA
Union County	IN	17140	Cincinnati, OH-KY-IN
Hocking County	OH	18140	Columbus, OH
Perry County	OH	18140	Columbus, OH
Walton County	FL	18880	Crestview-Fort Walton Beach-Destin, FL
Hood County	TX	23104	Dallas-Fort Worth-Arlington, TX
Somervell County	TX	23104	Dallas-Fort Worth-Arlington, TX
Baldwin County	AL	19300	Daphne-Fairhope-Foley, AL
Monroe County	PA	20700	East Stroudsburg, PA
Hudspeth County	TX	21340	El Paso, TX
Adams County	PA	23900	Gettysburg, PA

County	State	New CBSA	Urban Area (Constituent Counties)
Hall County	NE	24260	Grand Island, NE
Hamilton County	NE	24260	Grand Island, NE
Howard County	NE	24260	Grand Island, NE
Merrick County	NE	24260	Grand Island, NE
Montcalm County	MI	24340	Grand Rapids-Wyoming, MI
Josephine County	OR	24420	Grants Pass, OR
Tangipahoa Parish	LA	25220	Hammond, LA
Beaufort County	SC	25940	Hilton Head Island-Bluffton-Beaufort, SC
Jasper County	SC	25940	Hilton Head Island-Bluffton-Beaufort, SC
Citrus County	FL	26140	Homosassa Springs, FL
Butte County	ID	26820	Idaho Falls, ID
Yazoo County	MS	27140	Jackson, MS
Crockett County	TN	27180	Jackson, TN
Kalawao County	HI	27980	Kahului-Wailuku-Lahaina, HI
Maui County	HI	27980	Kahului-Wailuku-Lahaina, HI
Campbell County	TN	28940	Knoxville, TN
Morgan County	TN	28940	Knoxville, TN
Roane County	TN	28940	Knoxville, TN
Acadia Parish	LA	29180	Lafayette, LA
Iberia Parish	LA	29180	Lafayette, LA
Vermilion Parish	LA	29180	Lafayette, LA
Cotton County	OK	30020	Lawton, OK
Scott County	IN	31140	Louisville/Jefferson County, KY-IN
Lynn County	TX	31180	Lubbock, TX
Green County	WI	31540	Madison, WI
Benton County	MS	32820	Memphis, TN-MS-AR
Midland County	MI	33220	Midland, MI
Martin County	TX	33260	Midland, TX
Le Sueur County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
Mille Lacs County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
Sibley County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
Maury County	TN	34980	Nashville-Davidson—Murfreesboro—Franklin, TN
Craven County	NC	35100	New Bern, NC
Jones County	NC	35100	New Bern, NC
Pamlico County	NC	35100	New Bern, NC
St. James Parish	LA	35380	New Orleans-Metairie, LA
Box Elder County	UT	36260	Ogden-Clearfield, UT
Gulf County	FL	37460	Panama City, FL

County	State	New CBSA	Urban Area (Constituent Counties)
Custer County	SD	39660	Rapid City, SD
Fillmore County	MN	40340	Rochester, MN
Yates County	NY	40380	Rochester, NY
Sussex County	DE	41540	Salisbury, MD-DE
Worcester County	MA	41540	Salisbury, MD-DE
Highlands County	FL	42700	Sebring, FL
Webster Parish	LA	43340	Shreveport-Bossier City, LA
Cochise County	AZ	43420	Sierra Vista-Douglas, AZ
Plymouth County	IA	43580	Sioux City, IA-NE-SD
Union County	SC	43900	Spartanburg, SC
Pend Oreille County	WA	44060	Spokane-Spokane Valley, WA
Stevens County	WA	44060	Spokane-Spokane Valley, WA
Augusta County	VA	44420	Staunton-Waynesboro, VA
Staunton City	VA	44420	Staunton-Waynesboro, VA
Waynesboro City	VA	44420	Staunton-Waynesboro, VA
Little River County	AR	45500	Texarkana, TX-AR
Sumter County	FL	45540	The Villages, FL
Pickens County	AL	46220	Tuscaloosa, AL
Gates County	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
Falls County	TX	47380	Waco, TX
Columbia County	WA	47460	Walla Walla, WA
Walla Walla County	WA	47460	Walla Walla, WA
Peach County	GA	47580	Warner Robins, GA
Pulaski County	GA	47580	Warner Robins, GA
Culpeper County	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
Rappahannock County	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
Jefferson County	NY	48060	Watertown-Fort Drum, NY
Kingman County	KS	48620	Wichita, KS
Davidson County	NC	49180	Winston-Salem, NC
Windham County	CT	49340	Worcester, MA-CT

We proposed that when calculating the area wage index, the wage data for hospitals located in these counties would be included in their new respective urban CBSAs (80 FR 23360 through 23362). This urban wage index value will be used under the IRF PPS. We did not receive any

comments on this proposal. Therefore, we are finalizing our proposed reassignment of these counties from rural status to urban status for purposes of the wage index based on the new OMB delineations.

d. Urban Counties Moving to a Different Urban CBSA

As we stated in the FY 2016 IRF PPS proposed rule (80 FR 23362 through 23363), in addition to rural counties becoming urban and urban counties becoming rural, several urban counties will shift from one urban CBSA to another urban CBSA under the new OMB delineations. In other cases, applying the new OMB delineations will involve a change only in CBSA name or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 29140 (Lafayette, IN), will experience both a change to its number and its name, and would become CBSA 29200 (Lafayette-West Lafayette, IN), while all of its three constituent counties will remain the same. We are not discussing these changes in this section because they are inconsequential changes to the IRF PPS wage index. However, in other cases, adoption of the new OMB delineations shifts counties between existing and new CBSAs, changing the constituent makeup of the CBSAs.

In one type of change, an entire CBSA will be subsumed by another CBSA. For example, CBSA 37380 (Palm Coast, FL) currently is a single county (Flagler, FL) CBSA. Flagler County will be a part of CBSA 19660 (Deltona-Daytona Beach-Ormond Beach, FL) under the new OMB delineations.

In another type of change, some CBSAs have counties that will split off to become part of, or to form, entirely new labor market areas. For example, CBSA 37964 (Philadelphia Metropolitan Division of MSA 37980) currently is comprised of five Pennsylvania counties (Bucks, Chester, Delaware, Montgomery, and Philadelphia). Under the new OMB delineations,

Montgomery, Bucks, and Chester counties will split off and form the new CBSA 33874 (Montgomery County-Bucks County-Chester County, PA Metropolitan Division of MSA 37980), while Delaware and Philadelphia counties will remain in CBSA 37964.

Finally, in some cases, a CBSA will lose counties to another existing CBSA. For example, Lincoln County and Putnam County, WV, will move from CBSA 16620 (Charleston, WV) to CBSA 26580 (Huntington-Ashland, WV-KY-OH). CBSA 16620 will still exist in the new labor market delineations with fewer constituent counties. Table 14 lists the urban counties that will move from one urban CBSA to another urban CBSA under the new OMB delineations.

TABLE 14: Counties That Will Change to a Different CBSA

Prior CBSA	New CBSA	County	State
11300	26900	Madison County	IN
11340	24860	Anderson County	SC
14060	14010	McLean County	IL
37764	15764	Essex County	MA
16620	26580	Lincoln County	WV
16620	26580	Putnam County	WV
16974	20994	DeKalb County	IL
16974	20994	Kane County	IL
21940	41980	Ceiba Municipio	PR
21940	41980	Fajardo Municipio	PR
21940	41980	Luquillo Municipio	PR
26100	24340	Ottawa County	MI
31140	21060	Meade County	KY
34100	28940	Grainger County	TN
35644	35614	Bergen County	NJ
35644	35614	Hudson County	NJ
20764	35614	Middlesex County	NJ
20764	35614	Monmouth County	NJ
20764	35614	Ocean County	NJ
35644	35614	Passaic County	NJ
20764	35084	Somerset County	NJ
35644	35614	Bronx County	NY
35644	35614	Kings County	NY
35644	35614	New York County	NY

Prior CBSA	New CBSA	County	State
35644	20524	Putnam County	NY
35644	35614	Queens County	NY
35644	35614	Richmond County	NY
35644	35614	Rockland County	NY
35644	35614	Westchester County	NY
37380	19660	Flagler County	FL
37700	25060	Jackson County	MS
37964	33874	Bucks County	PA
37964	33874	Chester County	PA
37964	33874	Montgomery County	PA
39100	20524	Dutchess County	NY
39100	35614	Orange County	NY
41884	42034	Marin County	CA
41980	11640	Arecibo Municipio	PR
41980	11640	Camuy Municipio	PR
41980	11640	Hatillo Municipio	PR
41980	11640	Quebradillas Municipio	PR
48900	34820	Brunswick County	NC
49500	38660	Guánica Municipio	PR
49500	38660	Guayanilla Municipio	PR
49500	38660	Peñuelas Municipio	PR
49500	38660	Yauco Municipio	PR

If providers located in these counties move from one CBSA to another under the new OMB delineations, there may be impacts, both negative and positive, upon their specific wage index values. As discussed below, we proposed to implement a transition wage index to adjust for these possible impacts. We did not receive any comments on the proposed reassignment of the counties listed in Table 14. Therefore, we are finalizing our proposed reassignment of these counties from one urban area to another urban area for purposes of the wage index based on the new OMB delineations.

4. Transition Period

In the FY 2016 IRF PPS proposed rule (80 FR 23363) we stated that, overall, we believe implementing the new OMB delineations will result in wage index values being more representative of the actual costs of labor in a given area. Further, we recognize that some providers will have a higher wage index due to our proposed implementation of the new labor market area delineations. However, we also recognize that more providers will experience decreases in wage index values as a result of the implementation of the new labor market area delineations. We explained that in prior years, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. As discussed in the FY 2006 IRF PPS final rule (70 FR 47921 through 47926), we evaluated several options to ease the transition to the new CBSA system.

In implementing the new CBSA delineations for FY 2016, we continue to have similar concerns as those expressed in the FY 2006 IRF PPS final rule. While we believe that implementing the latest OMB labor market area delineations will create a more accurate wage index system, we recognize that IRFs may experience decreases in their wage index as a result of the labor market area changes. Our analysis for the FY 2016 IRF PPS final rule indicates that a majority of IRFs either expect no change in the wage index or an increase in the wage index based on the new CBSA delineations. However, we found that 188 facilities will experience a decline in their wage index with 29 facilities experiencing a decline of 5 percent or more based on the CBSA changes. Therefore, we believe it is appropriate to consider, as we did in FY 2006, whether or not a transition period should be used to implement these proposed changes to the wage index.

In light of the comments received during the FY 2006 rulemaking cycle on our proposal in the FY 2006 IRF PPS proposed rule (70 FR 30238 through 30240) to adopt the new CBSA definitions without a transition period, we believe that a transition period is appropriate. Therefore, in the FY 2016 proposed rule, we proposed using a similar transition methodology to that used in FY 2006. Specifically, for the FY 2016 IRF PPS, we proposed implementing a budget-neutral 1-year transition policy. Under the proposed policy, all IRF providers would receive a 1-year blended wage index using 50 percent of their FY 2016 wage index based on the proposed new OMB delineations and 50 percent of their FY 2016 wage index based on the OMB delineations used in FY 2015. We would apply this 1-year blended wage index in FY 2016 for all geographic areas to assist providers in adapting to these proposed changes. We believe a 1-year, 50/50 blend would mitigate the short-term instability and negative payment impacts due to the implementation of the new OMB delineations. This transition policy would be for a 1-year period, going into effect October 1, 2015, and continuing through September 30, 2016.

For FY 2006, it was determined that the transition to the current wage index system would have significant negative impacts upon IRFs that were originally considered rural, but would be considered urban under the new definitions. To alleviate the potentially decreased payments associated with switching from rural status to urban status in calculating the IRF area wage index for FY 2006, we implemented a 3-year budget-neutral phase-out of the rural adjustment for FY 2005 rural IRFs that became urban IRFs in FY 2006 and that experienced a loss in payment because of this redesignation. The 3-year transition period was afforded to these facilities because, as a group, they experienced a significant reduction in payments due to the labor market revisions and the loss of the rural adjustment. This adjustment was in addition to a

1-year blended wage index (comprised of a 50/50 blend of the FY 2006 MSA-based wage index and the FY 2006 CBSA-based wage index) for all IRFs.

Our analysis for the FY 2016 final rule indicates that 22 IRFs will experience a change in either rural or urban designations. Of these, 19 facilities designated as rural in FY 2015 will be designated as urban in FY 2016. While 16 of these rural IRFs that will be designated as urban under the new CBSA delineations will experience an increase in their wage index, these IRFs will lose the 14.9 percent rural adjustment. In many cases, this loss exceeds the urban CBSA based increase in the wage index. Consistent with the transition policy adopted in FY 2006 (70 FR 47923 through 47927), we considered the appropriateness of applying a 3-year phase-out of the rural adjustment for IRFs located in rural counties that would become urban under the new OMB delineations, given the potentially significant payment impacts for these facilities. We continue to believe, as discussed in the FY 2006 IRF final rule (70 FR 47880), that the phase-out of the rural adjustment transition period for these facilities specifically is appropriate because, as a group, we expect these IRFs would experience a steeper and more abrupt reduction in their payments compared to other IRFs.

Therefore, in addition to the 1-year transition policy noted, we proposed using a budget-neutral 3-year phase-out of the rural adjustment for existing FY 2015 rural IRFs that will become urban in FY 2016 and that experience a loss in payments due to changes from the new CBSA delineations. Accordingly, the incremental steps needed to reduce the impact of the loss of the FY 2015 rural adjustment of 14.9 percent would be phased out over FYs 2016, 2017 and 2018. This policy would allow rural IRFs which would be classified as urban in FY 2016 to receive two-thirds of the 2015 rural adjustment for FY 2016, as well as the blended wage index. For FY 2017, these IRFs would receive the full FY 2017 wage index and one-third of the FY 2015 rural

adjustment. For FY 2018, these IRFs would receive the full FY 2018 wage index without a rural adjustment. We believe a 3-year budget-neutral phase-out of the rural adjustment for IRFs that transition from rural to urban status under the new CBSA delineations would best accomplish the goals of mitigating the loss of the rural adjustment for existing FY 2015 rural IRFs. The purpose of the gradual phase-out of the rural adjustment for these facilities is to alleviate the significant payment implications for existing rural IRFs that may need time to adjust to the loss of their FY 2015 rural payment adjustment or that experience a reduction in payments solely because of this redesignation. As stated, this policy is specifically for rural IRFs that become urban in FY 2016 and that experience a loss in payments due to changes from the new CBSA delineations. Thus we did not propose implementing a transition policy for urban facilities that become rural in FY 2016 because these IRFs would receive the full rural adjustment of 14.9 percent beginning October 1, 2015 in addition to the 1-year blended wage index using 50 percent of their FY 2016 wage index based on the proposed new OMB delineations and 50 percent of their FY 2016 wage index based on the OMB delineations used in FY 2105.

We received 4 comments on the proposed implementation of a 1-year transition with a blended wage index for all providers and a 3-year phase-out of the rural adjustment for a subset of providers in FY 2016 to assist those providers in adjusting to the new OMB delineations, which are summarized below.

Comment: Commenters were generally supportive of CMS' efforts to implement a 1-year blended wage index to mitigate potential negative impacts from the transition to the new OMB delineations. Two commenters requested that CMS expand the 1-year budget neutral 50/50 blended wage index for a longer period of time. One commenter requested that CMS implement

the new CBSA delineations over a three year transition period (rather than our proposed one year transition).

Response: We appreciate the support for our proposal to adopt the new CBSA delineations with a transition period. We explored multiple alternatives to the proposed 1-year 50/50 blended wage index. While we acknowledge that some providers will see negative impacts based upon the adoption of the new OMB delineations, we also point out that some providers will experience increases in their wage index values due to the new OMB delineations. We believe that a transition period longer than 1 year would reduce the accuracy of the overall labor market area wage index system. The wage index is a relative measure of the value of labor in prescribed labor market areas; therefore, we believe it is important to implement the new delineations with as minimal a transition as is reasonable. We do not believe it is appropriate to expand or extend the 1-year 50/50 blended transition wage index further than what was proposed, because doing so would only further delay what we believe are the more refined and accurate labor market areas, based on the recent 2010 Census.

Comment: Commenters were generally supportive of CMS' efforts to implement a 3-year phase-out of the rural adjustment for FY 2015 rural IRFs that are transitioning to urban status in FY 2016 due to the new OMB delineations. Four commenters requested that CMS extend the 3-year phase-out of the rural adjustment for rural IRFs transitioning to urban CBSAs. The commenters were supportive of implementing the phase-out of the rural adjustment gradually over a period of years but suggested we extend the transition timeframe to a 4-year period. One commenter suggested we implement a 5-year phase-out or allow the affected facilities to apply for reclassification back to rural status for a period of 3 years.

Response: We appreciate the commenters' support for a phase-out of the rural adjustment for FY 2015 rural IRFs that will be considered urban in FY 2016. The intent of the 3-year phase-out of the rural adjustment is to mitigate potential negative payment effects on rural facilities that will be redesignated as urban facilitates, effective FY 2016. As described in more detail in the FY 2006 IRF PPS final rule (70 FR 47880), our analysis determined a 3-year budget neutral transition policy would best accomplish the goals of mitigating the loss of the rural adjustment for existing rural IRFs that will become urban under the new CBSA designations. For a complete discussion of this policy, we refer readers to the FY 2006 IRF PPS final rule (70 FR 47880, 47921 through 47925). Based on similar concerns to those we expressed during the FY 2006 rulemaking cycle to the proposed adoption of the new CBSA definitions, we considered different multi-year transition policies to provide a sufficient buffer for rural IRFs that may experience a reduction in payments due to being designated as urban. However, fewer IRFs (19) will be impacted by the transition from rural to urban status than were affected in FY 2006 (34). Additionally, the FY 2016 rural adjustment of 14.9 percent is less than the FY 2006 rural adjustment of 21.3 percent; therefore we believe that a 3-year budget-neutral phase-out of the rural adjustment would appropriately mitigate the adverse payment impacts for these IRFs while also ensuring that payment rates for these facilities are set accurately and appropriately.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals for transitioning to the wage index associated with the new OMB delineations without modification. We are finalizing our proposal to provide a 1-year blended wage index for all IRF facilities and a 3-year phase-out of the rural adjustment for IRFs that were deemed rural in FY 2015 but are considered urban under the new delineations. All IRF

providers will receive a 1-year blended wage index using 50 percent of their FY 2016 wage index based on the proposed new OMB delineations and 50 percent of their FY 2016 wage index based on the OMB delineations used in FY 2015. We will apply this 1-year blended wage index in FY 2016 for all geographic areas to assist providers in adapting to these proposed changes. FY 2015 rural IRFs which will be classified as urban in FY 2016 will receive two-thirds of the FY 2015 rural adjustment in FY 2016, as well as the blended wage index. For FY 2017, these IRFs will receive the full FY 2017 wage index and one-third of the FY 2015 rural adjustment. For FY 2018, these IRFs will receive the full FY 2018 wage index without a rural adjustment.

The wage index applicable to FY 2016 is set forth in Table A available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html. Table A provides a crosswalk between the FY 2015 wage index for a provider using the current OMB delineations in effect in FY 2015 and the FY 2016 wage index using the revised OMB delineations, as well as the transition wage index values for FY 2016.

To calculate the wage-adjusted facility payment for the payment rates set forth in this final rule, we multiply the unadjusted federal payment rate for IRFs by the FY 2016 labor-related share based on the 2012-based IRF market basket (71.0 percent) to determine the labor-related portion of the standard payment amount. A full discussion of the calculation of the labor-related share can be found in section VI.E of this final rule. We then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this final rule. The table is available through the Internet on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html. The change from the proposed FY 2016 labor-related share of 69.6 percent to the final FY 2016 labor-related share of 71.0

percent results in a final FY 2016 budget-neutral wage adjustment factor of 1.0033 instead of the proposed FY 2016 budget-neutral wage adjustment factor of 1.0027.

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at §412.624(e)(1), as described in the steps below. We use the listed steps to ensure that the FY 2016 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2011 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Determine the total amount of the estimated FY 2015 IRF PPS rates, using the FY 2015 standard payment conversion factor and the labor-related share and the wage indexes from FY 2015 (as published in the FY 2015 IRF PPS final rule (79 FR 45871)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2016 standard payment conversion factor and the FY 2016 labor-related share and CBSA urban and rural wage indexes.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2016 budget-neutral wage adjustment factor of 1.0033.

Step 4. Apply the FY 2016 budget-neutral wage adjustment factor from step 3 to the FY 2015 IRF PPS standard payment conversion factor after the application of the adjusted market basket update to determine the FY 2016 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2016 in section VI.G of this final rule.

We received 4 comments on the proposed IRF wage adjustment for FY 2016, which are summarized below.

Comment: One commenter, while supportive of CMS' proposed IRF wage adjustment, effective for FY 2016, recommended that CMS institute a smoothing variable to lessen year-to-year volatility in the wage index experienced by some facilities. Three commenters requested that CMS align the timeframe for the IRF wage index with other post-acute and acute care settings. One commenter also recommended that we consider wage index policies under the current IPPS because IRFs compete in a similar labor pool as acute care hospitals. Four commenters requested that CMS grant IRFs the ability to request reclassification of their applicable CBSAs.

Response*:* Consistent with our previous responses to these comments (most recently published in our FY 2015 IRF PPS final rule (79 FR 45887)), we note that the IRF PPS does not account for geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act. Furthermore, as we do not have an IRF-specific wage index, we are unable to determine at this time the degree, if any, to which a geographic reclassification adjustment under the IRF PPS would be appropriate. The rationale for our current wage index policies is fully described in the FY 2006 IRF PPS final rule (70 FR 47880, 47926 through 47928).

Additionally, while some commenters recommended that we adopt IPPS reclassification, we note the MedPAC's June 2007 report to the Congress, titled "Report to Congress: Promoting Greater Efficiency in Medicare" (available at http://www.medpac.gov/documents/Jun07_EntireReport.pdf), recommends that Congress "repeal the existing hospital wage index statute, including reclassification and exceptions, and give the Secretary authority to establish new wage index systems." We continue to believe it would not be prudent at this time to adopt the IPPS wage index policies, such as reclassification, and will,

therefore, continue to use the CBSA labor market area definitions and the pre-reclassification and pre-floor hospital wage index data based on 2011 cost report data in this final rule.

With regard to issues mentioned about ensuring that the wage index minimizes fluctuations, matches the costs of labor in the market, and provides for a single wage index policy, section 3137(b) of the Affordable Care Act required us to submit a report to the Congress by December 31, 2011 that includes a plan to reform the hospital wage index system. The report that we submitted is available online at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html. However, we will continue to monitor the IPPS wage index to identify any policy changes that may be appropriate for IRFs. This is consistent with our previous responses to these recurring comments.

Final Decision: After careful consideration of the comments, we are finalizing use of the FY 2015 pre-floor, pre-reclassified hospital wage index data to derive the applicable IRF PPS wage index for FY 2016.

G. Description of the IRF Standard Payment Conversion Factor and Payment Rates for FY 2016

To calculate the standard payment conversion factor for FY 2016, as illustrated in Table 15, we begin by applying the adjusted market basket increase factor for FY 2016 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment conversion factor for FY 2015 ($15,198). Applying the 1.7 percent adjusted market basket increase for FY 2016 to the standard payment conversion factor for FY 2015 of $15,198 yields a standard payment amount of $15,456. Then, we apply the budget neutrality factor for the FY 2016 wage index and labor-related share of 1.0033, which results in a standard payment amount of $15,507. We next apply the budget neutrality factors for the revised CMG relative

weights of 0.9981, which results in the standard payment conversion factor of $15,478 for FY 2016.

TABLE 15: Calculations to Determine the FY 2016 Standard Payment Conversion Factor

Explanation for Adjustment	Calculations	
Standard Payment Conversion Factor for FY 2015		$15,198
Market Basket Increase Factor for FY 2016 (2.4 percent), reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.2 percentage point in accordance with paragraphs 1886(j)(3)(C) and (D) of the Act	x	1.017
Budget Neutrality Factor for the Wage Index and Labor-Related Share	x	1.0033
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	x	0.9981
FY 2016 Standard Payment Conversion Factor	=	$15,478

We received 1 comment on the proposed FY 2016 standard payment conversion factor, which is summarized below.

Comment: One commenter expressed support for the proposed budget neutrality factors used to adjust the FY 2016 standard payment conversion factor.

Response: We appreciate the commenter's support.

Final Decision: After consideration of the public comments, we are finalizing the IRF standard payment conversion factor of $15,478 for FY 2016.

After the application of the CMG relative weights described in section IV of this final rule to the FY 2016 standard payment conversion factor ($15,478), the resulting unadjusted IRF prospective payment rates for FY 2016 are shown in Table 16.

TABLE 16: FY 2016 Payment Rates

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0101	$ 12,506.22	$ 10,953.78	$ 10,198.45	$ 9,757.33
0102	$ 15,733.39	$ 13,781.61	$ 12,831.26	$ 12,275.60
0103	$ 17,688.26	$ 15,493.48	$ 14,425.50	$ 13,800.18
0104	$ 19,113.78	$ 16,742.55	$ 15,587.89	$ 14,913.05
0105	$ 22,433.81	$ 19,650.87	$ 18,295.00	$ 17,504.07

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0106	$ 25,012.45	$ 21,909.11	$ 20,398.46	$ 19,516.21
0107	$ 28,016.73	$ 24,540.37	$ 22,848.62	$ 21,858.03
0108	$ 35,565.35	$ 31,151.02	$ 29,004.22	$ 27,747.41
0109	$ 32,431.05	$ 28,406.77	$ 26,448.81	$ 25,303.43
0110	$ 42,722.38	$ 37,421.16	$ 34,842.53	$ 33,333.42
0201	$ 12,400.97	$ 10,190.72	$ 9,195.48	$ 8,687.80
0202	$ 16,306.07	$ 13,397.76	$ 12,091.41	$ 11,422.76
0203	$ 18,660.28	$ 15,332.51	$ 13,837.33	$ 13,071.17
0204	$ 20,573.36	$ 16,905.07	$ 15,255.12	$ 14,411.57
0205	$ 24,610.02	$ 20,220.46	$ 18,248.56	$ 17,239.40
0206	$ 29,349.38	$ 24,114.72	$ 21,762.07	$ 20,557.88
0207	$ 39,063.38	$ 32,096.73	$ 28,965.53	$ 27,363.56
0301	$ 17,290.47	$ 14,433.24	$ 13,235.24	$ 12,349.90
0302	$ 21,463.34	$ 17,917.33	$ 16,429.90	$ 15,332.51
0303	$ 25,010.90	$ 20,878.27	$ 19,146.29	$ 17,866.26
0304	$ 33,266.87	$ 27,770.63	$ 25,465.95	$ 23,763.37
0401	$ 15,007.47	$ 12,772.45	$ 11,696.72	$ 10,811.38
0402	$ 22,005.07	$ 18,728.38	$ 17,151.17	$ 15,852.57
0403	$ 35,110.30	$ 29,881.83	$ 27,363.56	$ 25,294.15
0404	$ 61,478.62	$ 52,323.38	$ 47,915.24	$ 44,290.30
0405	$ 54,815.34	$ 46,652.24	$ 42,722.38	$ 39,490.57
0501	$ 13,422.52	$ 10,696.85	$ 9,932.23	$ 9,116.54
0502	$ 17,634.09	$ 14,052.48	$ 13,047.95	$ 11,976.88
0503	$ 22,317.73	$ 17,785.77	$ 16,513.48	$ 15,159.15
0504	$ 25,623.83	$ 20,418.58	$ 18,959.00	$ 17,403.46
0505	$ 29,943.74	$ 23,862.43	$ 22,156.76	$ 20,338.09
0506	$ 42,095.52	$ 33,545.47	$ 31,146.38	$ 28,590.96
0601	$ 16,115.69	$ 12,716.72	$ 11,866.98	$ 10,723.16
0602	$ 20,646.10	$ 16,290.60	$ 15,202.49	$ 13,736.73
0603	$ 25,664.07	$ 20,249.87	$ 18,897.09	$ 17,073.78
0604	$ 33,690.96	$ 26,583.47	$ 24,808.14	$ 22,415.24
0701	$ 14,950.20	$ 12,518.61	$ 11,856.15	$ 10,769.59
0702	$ 19,392.39	$ 16,237.97	$ 15,378.94	$ 13,968.90
0703	$ 23,251.05	$ 19,469.78	$ 18,438.94	$ 16,748.74
0704	$ 30,234.73	$ 25,317.36	$ 23,978.52	$ 21,779.09
0801	$ 12,435.03	$ 9,794.48	$ 8,885.92	$ 8,206.44
0802	$ 16,346.32	$ 12,874.60	$ 11,681.25	$ 10,788.17

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0803	$ 22,048.41	$ 17,366.32	$ 15,756.60	$ 14,550.87
0804	$ 19,717.42	$ 15,529.08	$ 14,089.62	$ 13,012.35
0805	$ 23,766.47	$ 18,719.09	$ 16,984.01	$ 15,685.41
0806	$ 29,536.67	$ 23,264.98	$ 21,107.35	$ 19,492.99
0901	$ 14,801.61	$ 11,905.68	$ 10,911.99	$ 9,946.16
0902	$ 19,678.73	$ 15,827.80	$ 14,505.98	$ 13,224.40
0903	$ 24,572.87	$ 19,765.41	$ 18,115.45	$ 16,513.48
0904	$ 31,048.87	$ 24,973.75	$ 22,888.87	$ 20,864.34
1001	$ 16,536.70	$ 14,498.24	$ 12,910.20	$ 11,648.74
1002	$ 20,661.58	$ 18,115.45	$ 16,129.62	$ 14,555.51
1003	$ 29,655.85	$ 25,999.94	$ 23,151.99	$ 20,890.66
1101	$ 21,565.50	$ 21,565.50	$ 17,131.05	$ 16,097.12
1102	$ 28,044.59	$ 28,044.59	$ 22,277.49	$ 20,932.45
1201	$ 15,265.95	$ 14,821.73	$ 13,496.82	$ 12,591.35
1202	$ 18,739.21	$ 18,194.39	$ 16,567.65	$ 15,456.33
1203	$ 23,114.85	$ 22,443.10	$ 20,435.60	$ 19,065.80
1301	$ 18,250.11	$ 15,038.42	$ 14,179.40	$ 12,947.35
1302	$ 23,133.42	$ 19,061.16	$ 17,973.05	$ 16,411.32
1303	$ 30,375.58	$ 25,029.47	$ 23,600.85	$ 21,550.02
1401	$ 14,037.00	$ 11,535.75	$ 10,432.17	$ 9,387.41
1402	$ 18,601.46	$ 15,287.62	$ 13,824.95	$ 12,439.67
1403	$ 22,404.41	$ 18,412.63	$ 16,649.68	$ 14,982.70
1404	$ 28,434.63	$ 23,368.68	$ 21,132.11	$ 19,016.27
1501	$ 16,292.14	$ 13,123.80	$ 12,083.67	$ 11,627.07
1502	$ 20,661.58	$ 16,645.04	$ 15,324.77	$ 14,745.89
1503	$ 24,996.97	$ 20,136.88	$ 18,539.55	$ 17,839.94
1504	$ 31,053.51	$ 25,017.09	$ 23,032.81	$ 22,162.95
1601	$ 17,607.77	$ 12,947.35	$ 12,719.82	$ 11,695.18
1602	$ 23,124.13	$ 17,002.58	$ 16,703.86	$ 15,358.82
1603	$ 29,576.91	$ 21,746.59	$ 21,364.28	$ 19,644.68
1701	$ 16,569.20	$ 14,055.57	$ 12,825.07	$ 11,935.09
1702	$ 21,509.78	$ 18,245.47	$ 16,648.14	$ 15,493.48
1703	$ 24,630.14	$ 20,892.20	$ 19,064.25	$ 17,742.43
1704	$ 32,335.09	$ 27,428.56	$ 25,026.38	$ 23,291.29
1801	$ 19,785.53	$ 14,990.44	$ 13,696.48	$ 12,187.38
1802	$ 29,109.47	$ 22,053.05	$ 20,150.81	$ 17,929.72
1803	$ 47,878.10	$ 36,272.69	$ 33,143.04	$ 29,491.78

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
1901	$ 18,304.28	$ 15,912.93	$ 15,474.90	$ 13,529.32
1902	$ 34,683.10	$ 30,152.69	$ 29,323.07	$ 25,636.21
1903	$ 58,010.00	$ 50,431.97	$ 49,045.14	$ 42,878.70
2001	$ 14,320.25	$ 11,767.92	$ 10,854.72	$ 9,825.43
2002	$ 18,576.70	$ 15,265.95	$ 14,080.34	$ 12,744.59
2003	$ 23,128.78	$ 19,006.98	$ 17,531.93	$ 15,869.59
2004	$ 29,784.32	$ 24,476.91	$ 22,576.21	$ 20,435.60
2101	$ 26,546.32	$ 26,546.32	$ 20,605.86	$ 19,989.84
5001				$ 2,408.38
5101				$ 11,199.88
5102				$ 25,252.36
5103				$ 11,970.69
5104				$ 29,836.94

H. Example of the Methodology for Adjusting the Federal Prospective Payment Rates

Table 17 illustrates the methodology for adjusting the federal prospective payments (as described in sections VI.A. through VI.F. of this final rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 16.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8416, and a rural adjustment of 14.9 percent. Facility B, an urban teaching hospital, has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0454 percent), a wage index of 0.8599, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the federal prospective payment,

we begin by taking the unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) from Table 16. Then, we multiply the labor-related share for FY 2016 (71.0 percent) described in section VI.E. of this final rule by the unadjusted federal prospective payment rate. To determine the non-labor portion of the federal prospective payment rate, we subtract the labor portion of the federal payment from the unadjusted federal prospective payment.

To compute the wage-adjusted federal prospective payment, we multiply the labor portion of the federal payment by the appropriate transition wage index, which may be found in Table A. The table is available on CMS website at http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/. The resulting figure is the wage-adjusted labor amount. Next, we compute the wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the wage-adjusted federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted federal prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted federal prospective payment rates. Table 17 illustrates the components of the adjusted payment calculation.

TABLE 17: Example of Computing the IRF FY 2016 Federal Prospective Payment

Steps		Rural Facility A (Spencer Co., IN)	Urban Facility B (Harrison Co., IN)
1	Unadjusted Federal Prospective Payment	$ 33,333.42	$ 33,333.42

Steps		Rural Facility A (Spencer Co., IN)		Urban Facility B (Harrison Co., IN)	
2	Labor Share	X	0.71	X	0.71
3	Labor Portion of Federal Payment	=	$23,666.73	=	$23,666.73
4	CBSA-Based Wage Index (shown in the Addendum, Tables 1 and 2)	X	0.8416	X	0.8599
5	Wage-Adjusted Amount	=	$19,917.92	=	$20,351.02
6	Non-Labor Amount	+	$ 9,666.69	+	$9,666.69
7	Wage-Adjusted Federal Payment	=	$29,584.61	=	$30,017.71
8	Rural Adjustment	X	1.149	X	1.000
9	Wage- and Rural-Adjusted Federal Payment	=	$33,992.72	=	$30,017.71
10	LIP Adjustment	X	1.0156	X	1.0454
11	FY 2016 Wage-, Rural- and LIP-Adjusted Federal Prospective Payment Rate	=	$34,523.01	=	$31,380.51
12	FY 2016 Wage- and Rural-Adjusted Federal Prospective Payment		$33,992.72		$30,017.71
13	Teaching Status Adjustment	X	0	X	0.0784
14	Teaching Status Adjustment Amount	=	$0.00	=	$2,353.39
15	FY 2016 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+	$34,523.01	+	$31,380.51
16	Total FY 2016 Adjusted Federal Prospective Payment	=	$34,523.01	=	$33,733.90

Thus, the adjusted payment for Facility A would be $34,523.01, and the adjusted payment for Facility B would be $33,733.90.

VII. Update to Payments for High-Cost Outliers under the IRF PPS

A. Update to the Outlier Threshold Amount for FY 2016

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for

the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2015 IRF PPS final rules and the FY 2011 and FY 2013 notices (70 FR 47880, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 76 FR 47836, 76 FR 59256, and 77 FR 44618, 78 FR 47860, 79 FR 45872, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

In the FY 2016 IRF PPS proposed rule (80 FR 23332 at 23367), to update the IRF outlier threshold amount for FY 2016, we proposed to use FY 2014 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS

final rule (66 FR 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2015. Based on an analysis of the preliminary data used for the proposed rule, we estimated that IRF outlier payments as a percentage of total estimated payments would be approximately 3.2 percent in FY 2015. Therefore, we proposed to update the outlier threshold amount from $8,848 for FY 2015 to $9,698 for FY 2016, as described in the FY 2016 IRF PPS proposed rule (80 FR 23332 at 23367), to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2016.

We note that, as we typically do, we updated our data between the FY 2016 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. Based on our analysis using this updated data, we now estimate that IRF outlier payments as a percentage of total estimated payments are approximately 2.9 percent in FY 2015.

We received 4 comments on the proposed update to the FY 2016 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments, which are summarized below.

Comment: Several commenters expressed support for the proposed update to the outlier threshold amount to maintain estimated outlier payments for FY 2016 at 3 percent of total IRF PPS payments. However, some commenters expressed concern about the proposed increase in the outlier threshold and the potential financial impact this could have on IRFs with many high-cost outlier cases. One commenter suggested that CMS implement a two-year transition policy for changes to the FY 2016 outlier threshold to mitigate any financial impact on IRFs. Several commenters also expressed concerns about the distribution of outlier payments and questioned whether the IRF outlier policy is reimbursing IRFs appropriately for high-cost cases. One

commenter suggested that we ensure that Medicare pays out the full 3 percent to IRFs in FY 2016.

Response: We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs appropriately for treating unusually high-cost patients and, thereby, promote access to care for patients who are likely to require unusually high-cost care. We note that when we updated the IRF claims data between the proposed and final rules, as we do each year, our analysis of the most recent available data indicates that an outlier threshold decrease (from $8,848 in FY 2015 to $8,658 in FY 2016) is necessary to ensure that estimated outlier payments in FY 2016 equal 3 percent of total estimated IRF PPS payments. Thus, we do not estimate any negative financial impact of this update on IRFs with many high-cost outlier cases. Nevertheless, the annual updates to the outlier threshold amount are not substantial, and we do not believe the financial impact on individual IRFs would be large enough to warrant an extended transition period for the changes. We will continue to monitor trends in IRF outlier payments to ensure that they are working as intended to compensate IRFs for treating exceptionally high-cost IRF patients, and that the IRF outlier policy continues to result in IRF outlier payments that equal approximately 3 percent of total IRF PPS payments annually.

Final Decision: Having carefully considered the public comments received and also taking into account the most recent available data, we are finalizing the outlier threshold amount of $8,658 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2016. This update is effective October 1, 2015.

B. Update to the IRF Cost-to-Charge Ratio Ceiling and Urban/Rural Averages

In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we proposed to apply a ceiling to IRFs' CCRs. Using the

methodology described in that final rule, we proposed to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2016, based on analysis of the most recent data that is available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first Medicare cost report.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2016, as discussed below.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2016, we proposed to estimate a national average CCR of 0.562 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we proposed to estimate a national average CCR of 0.435 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher costs factor more heavily into the averages than the CCRs of IRFs with lower costs. For this final rule, we have used the most recent available cost report data (FY 2013). This includes all IRFs whose cost reporting periods begin on or after October 1, 2012, and before October 1, 2013. If, for any IRF, the FY 2013 cost report was missing or had an "as submitted" status, we used data from a previous fiscal year's (that is, FY 2004 through FY 2012) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care.

In accordance with past practice, we proposed to set the national CCR ceiling at

3 standard deviations above the mean CCR. Using this method, the national CCR ceiling would be 1.36 for FY 2016. This means that, if an individual IRF's CCR exceeds this proposed ceiling of 1.36 for FY 2016, we would replace the IRF's CCR with the appropriate national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as previously discussed) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

We did not receive any comments on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2016.

Final Decision: As we did not receive any comments on the proposed updates to the IRF CCR ceiling and the urban/rural averages for FY 2016, we are finalizing the national average urban CCR at 0.435, the national average rural CCR at 0.562, and the national CCR ceiling at 1.36 for FY 2016. These updates are effective October 1, 2015.

VIII. ICD-10-CM Implementation for IRF PPS

In the FY 2015 IRF PPS final rule (79 FR 45872), we finalized conversions from the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) to the

ICD-10-CM for the IRF PPS, which will be effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions. We remind providers of IRF services that the implementation date for ICD-10-CM is October 1, 2015. The ICD-10-CM lists are available for download from the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.

IX. Revisions and Updates to the IRF QRP

A. Background and Statutory Authority

Section 3004(b) of the Affordable Care Act amended section 1886(j)(7) of the Act, requiring the Secretary to establish the IRF QRP. This program applies to freestanding IRFs, as well as IRF units affiliated with either acute care facilities or critical access hospitals (CAHs). Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary.

The Act requires that for the FY 2014 payment determination and subsequent years, each IRF submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. The Secretary is required to specify quality measures that are endorsed by the entity that holds the contract with the Secretary under section 1890(a) of the Act. This entity is currently the NQF. Information regarding the NQF is available at http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx. The Act authorizes an exception under which the Secretary may specify non-endorsed quality measures for specified areas or medical topics determined appropriate by the Secretary for which a feasible

or practical measure has not been endorsed by the NQF, as long as due consideration is given to NQF-endorsed measures or measures adopted by a consensus organization identified by the Secretary.

Additionally, section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185, enacted on Oct. 6, 2014), amended title XVIII of the Act by adding section 1899B of the Act, titled Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment and Discharge Planning. Section 1899B(c)(1) of the Act requires that the Secretary specify not later than the applicable specified application date, as defined in section 1899B(a)(2)(E) of the Act, quality measures on which IRF providers are required to submit standardized patient assessment data described in section 1899B(b)(1) of the Act and other necessary data specified by the Secretary. Section 1899B(c)(2)(A) requires, to the extent possible, the submission of such quality measure data through the use of a PAC assessment instrument and the modification of such instrument as necessary to enable such use; for IRFs, this requirement refers to the IRF-PAI. In addition, section 1899B(d)(1) of the Act requires that the Secretary specify not later than the applicable specified application date, resource use and other measures on which IRF providers are required to submit any necessary data specified by the Secretary, which may include standardized assessment data in addition to claims data. Furthermore, section 2(c)(2) of the IMPACT Act amended section 1886(j)(7) of the Act by adding section 1886(j)(7)(F)(i), which requires IRF providers to submit to the Secretary data on the quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act. Additionally, section 1886(j)(7)(F)(ii) requires that, beginning in FY 2019 and for each subsequent year, providers submit standardized patient assessment data required under section 1899B(b)(1) of the Act. Under section 1886(j)(7)(F)(iii) of the Act, the required data

must be submitted in the form and manner, and at the time, specified by the Secretary.

Section 1899B(c)(1) and (d)(1) of the Act direct CMS to specify measures that relate to at least 5 stated quality domains and 3 stated resource use and other measure domains. The quality measures specified under section 1899B(c)(1) of the Act must address at least the following domains:

- Functional status, cognitive function, and changes in function and cognitive function;
- Skin integrity and changes in skin integrity;
- Medication reconciliation;
- Incidence of major falls; and
- Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual when the individual transitions (1) from a hospital or CAH to another applicable setting, including a PAC provider or the home of the individual, or (2) from a PAC provider to another applicable setting, including a different PAC provider, hospital, CAH, or the home of the individual.

The resource use and other measures specified under section 1899B(d)(1) of the Act must address at least the following domains:

- Resource use measures, including total estimated Medicare spending per beneficiary;
- Discharge to community; and
- Measures to reflect all-condition risk-adjusted potentially preventable hospital readmissions rates.

Sections 1899B(c) and (d) of the Act indicate that data satisfying the eight measure domains in the IMPACT Act is the minimum data reporting requirement. Therefore, we may

specify additional measures and additional domains.

Section 1899B(e)(2)(A) of the Act requires that each measure specified by the Secretary under that section be endorsed by the entity that holds the contract with the Secretary under section 1890(a) of the Act. This entity is currently the NQF. Information regarding the NQF is available at http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx. However, under section 1899B(e)(2)(B) of the Act, the Secretary may specify a measure that has not been so endorsed in the case of a specified area of medical topic determined appropriate by the Secretary for which a feasible or practical measure has not been endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Section 1899B(e)(3) of the Act mandates the use of the pre-rulemaking process of section 1890A with respect to the measures specified under sections 1899B(c) and (d) and provides that the Secretary may use expedited procedures, such as ad-hoc reviews, as necessary in the case of a measure required for data submissions during the 1-year period before the applicable specified application date. In addition, section 1899B(e)(3)(B)(ii) of the Act gives the Secretary the option to waive the pre-rulemaking process for a measure if the pre-rulemaking process (including through the use of expedited procedures) would result in the inability of the Secretary to satisfy any deadline specified in section 1899B of the Act with respect to the measure.

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making data submitted under the IRF QRP available to the public, and section 1899B(g) of the Act requires public reporting of the performance of individual providers on the quality, resource use, and other measures beginning not later than 2 years after the applicable specified application

date. The Secretary must ensure, including through a process consistent with the provisions of section 1886(b)(3)(B)(viii)(VII) of the Act, that each IRF is given the opportunity to review the data and information that is to be made public and to submit corrections prior to the publication or posting of this data. Public reporting of data and information under section 1899B(g)(1) of the Act must be consistent with the provisions of section 1886(j)(7)(E) of the Act. In addition, section 1899B(f)(1) of the Act, as added by the IMPACT Act, requires the Secretary to make confidential feedback reports available to post-acute providers on their performance on the measures required under section 1899B(c)(1) and (d)(1) of the Act, beginning 1 year after the applicable specified application date.

For more information on the statutory history of the IRF QRP, please refer to the FY 2015 IRF PPS final rule (79 FR 45908). More information on the IMPACT Act is available at https://www.govtrack.us/congress/bills/113/hr4994.

As previously stated, the IMPACT Act adds new section 1899B of the Act that imposes new data reporting requirements for certain post-acute care (PAC) providers, including IRFs. Sections 1899B(c)(1) and 1899B(d)(1) of the Act collectively require that the Secretary specify quality measures and resource use and other measures with respect to certain domains not later than the specified application date that applies to each measure domain and PAC provider setting. Section 1899B(a)(2)(E) of the Act delineates the specified application dates for each measure domain and PAC provider. The IMPACT Act also amends various sections of the Act, including section 1886(j)(7), to require the Secretary to reduce the otherwise applicable PPS payment to a PAC provider that does not report the new data in a form and manner, and at a time, specified by the Secretary. For IRFs, amended section 1886(j)(7)(A)(i) of the Act would require the Secretary to reduce the payment update for any IRF that does not satisfactorily

submit the new required data.

Under the current IRF QRP, the general timeline and sequencing of measure implementation occurs as follows: specification of measures; proposal and finalization of measures through rulemaking; IRF submission of data on the adopted measures; analysis and processing of the submitted data; notification to IRFs regarding their quality reporting compliance with respect to a particular FY; consideration of any reconsideration requests; and imposition of a payment reduction in a particular FY for failure to satisfactorily submit data with respect to that FY. Any payment reductions that are taken with respect to a FY begin approximately one year after the end of the data submission period for that fiscal year and approximately 2 years after we first adopt the measure.

To the extent that the IMPACT Act could be interpreted to shorten this timeline so as to require us to reduce an IRF's PPS payment for failure to satisfactorily submit data on a measure specified under section 1899B(c)(1) or (d)(1) of the Act beginning with the same FY as the specified application date for that measure, such a timeline would not be feasible. The current timeline previously discussed reflects operational and other practical constraints, including the time needed to specify and adopt valid and reliable measures, collect the data, and determine whether an IRF has complied with our quality reporting requirements. It also takes into consideration our desire to give IRFs enough notice of new data reporting obligations so that they are prepared to timely start reporting the data. Therefore, we intend to follow the same timing and sequence of events for measures specified under section 1899B(c)(1) and (d)(1) of the Act that we currently follow for other measures specified under the IRF QRP. We intend to specify each of these measures no later than the specified application dates set forth in section 1899B(a)(2)(E) of the Act and propose to adopt them consistent with the requirements in the Act

and Administrative Procedure Act. To the extent that we finalize a proposal to adopt a measure for the IRF QRP that satisfies an IMPACT Act measure domain, we intend to require IRFs to report data on the measure for the fiscal year that begins 2 years after the specified application date for that measure. Likewise, we intend to require IRFs to begin reporting any other data specifically required under the IMPACT Act for the FY that begins 2 years after we adopt requirements that would govern the submission of that data.

Comment: Several commenters requested the development of a comprehensive overall plan for implementation across all settings covered by the IMPACT Act. Commenters stated that a comprehensive implementation plan would give PAC providers an opportunity to plan for the potential impacts to their operations, and enable all stakeholders to understand CMS's approach in implementing the IMPACT Act across care settings. Commenters requested that CMS describe an overall strategy for identifying cross-cutting measures, timelines for data collection and timelines for reporting. One commenter requested that CMS plans be communicated as soon as possible and that CMS develop setting-specific communications to facilitate understanding of the IMPACT Act requirements.

Response: We appreciate the request for a comprehensive plan to allow PAC providers to plan for implementation of the IMPACT Act, as well as the need for stakeholder input, the development of reliable, accurate measures, clarity on the level of standardization of items and measures, and avoidance of unnecessary burden on PAC providers. Our intent has been to comply with these principles in the implementation and rollout of QRPs in the various care settings, and we will continue to adhere to these principles as the agency moves forward with implementing IMPACT Act requirements.

In addition, in implementing the IMPACT Act requirements, we will follow the strategy

for identifying cross-cutting measures, timelines for data collection and timelines for reporting as outlined in the IMPACT Act. As described above, the IMPACT Act requires us to specify measures that relate to at least five stated quality domains and three stated resource use and other measure domains. The IMPACT Act also outlines timelines for data collection and timelines for reporting. We intend to adopt measures that comply with the IMPACT Act in a manner that is consistent with the sequence we follow in other quality reporting programs. We agree that outreach and education are invaluable, and we intend to continue to provide easy reference information to the public, such as a high-level walk-through of information.),.

In addition to the Special Open Door Forum (SODF), we hosted on the topic of the IMPACT Act, we have created a post-acute care quality initiatives website, which pertains primarily to the IMPACT Act required quality measures/assessment instrument domains, and allows access to a mail box for IMPACT Act provider related questions. We note that the slides used for the SODF are accessible on the IMPACT Act/Post-Acute Care Quality Initiatives website http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html, and that they provide high-level background and information, including timelines as they pertain to the assessment domains required under the IMPACT Act. Further, we are in the midst of developing plans for providing additional and ongoing education and outreach (to include timelines) in the near future, as suggested by commenters. For further information and future postings of such documents and information, please continue to check the Post-Acute Care Quality Initiatives website (listed above), as well as the IRF Quality Reporting website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/.

We also refer the public to the following website for updates: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html.

Comment: Several commenters asked for more opportunities for stakeholder input into various aspects of the measure development process. The commenters requested opportunities to provide input early and throughout the measure development process. One commenter requested stakeholder input on and reaction to an IMPACT Act implementation plan. Two commenters requested that CMS hold meetings with PAC providers on a frequent and regular basis to provide feedback on implementation and resolve any perceived inconsistencies in the FY 2016 IRF PPS proposed rule. One commenter specifically noted an appreciation for the listening sessions held by CMS thus far, yet requested opportunities for more extensive collaboration. Finally, one commenter suggested that CMS prioritize patient and their families as important stakeholders in the development and implementation of quality of care measures, particularly with regard to measures assessing the transfer of health information and patient care preferences.

Response: We plan to implement the IMPACT Act in a manner that is transparent and includes input from and collaboration with the PAC provider community. It is of the utmost importance to us to continue to engage stakeholders, including patients and their families, throughout the measure development process through participation in technical expert panels (TEPs), listening sessions, and public comments. We have provided multiple opportunities for stakeholder input, which include the following activities to date: our measure development contractor(s) convened a TEP that included stakeholder experts on February 3, 2015; we convened listening sessions on February 10 and March 24, 2015; we heard stakeholder input during the February 9th 2015 ad hoc MAP meeting convened for the sole purpose of reviewing

measures we had developed to comply with the IMPACT Act. Additionally, we implemented a public mail box for the submission of comments in January 2015, PACQualityInitiative@cms.hhs.gov, which is listed on our post-acute care quality initiatives website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html, and we held a Special Open Door Forum to seek input on the measures on February 25, 2015. The slides from the Special Open Door Forum are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html.

Comment: One commenter noted that it would be important for CMS to include in the FY 2016 IRF PPS final rule the aspects of IMPACT Act implementation relating to the timeline and sequencing of standardization of patient assessment data. One commenter suggested that CMS move quickly to reduce the burden of reporting duplicative data and to allow for better cross-setting comparisons, as well as the evolution of better quality measures.

Response: We believe that the commenter is requesting information pertaining to specific milestones related to our efforts to meet the statutory timelines which are specified within the IMPACT Act. We intend to use the rulemaking process to establish and communicate timelines for implementation. In addition, we will continue to provide ongoing education and outreach to stakeholders through Special Open Door Forums and periodic training sessions. We will also provide information about the measures at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html.

Also, we have made additional details regarding standardization of patient assessment

data and the cross-setting measure specifications available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html. We plan to continue to update this information as additional measures are specified.

Comment: Several commenters supported the use of NQF-endorsed measures, while one commenter expressed concern that two of the measures proposed for FY 2018 lacked NQF endorsement. A few commenters requested that CMS only use measures that have been endorsed by NQF. Some commenters suggested that CMS use only NQF-endorsed measures that were specified for the exact setting in which they would be used and that were fully supported by the Measures Application Partnership (MAP).

Response: We will continue to propose and adopt measures that have been appropriately tested and, when possible, that have been endorsed by the NQF. However, when this is not feasible, and where, as here, due consideration has been given to measures that are endorsed or adopted by a consensus organization, the exception authority given to the Secretary in sections 1899B(e)(2)(B) and 1886(j)(7)(D)(ii) of the Act permit the Secretary to adopt a measure for the IRF QRP that is not NQF-endorsed. Additionally, when selecting cross-setting measures and assessment items, we take into consideration the variations in patient populations treated in different PAC settings. Finally, we appreciate the comment regarding using only measures that are fully supported by the MAP. We recognize and support the importance of this multi-stakeholder partnership that provides invaluable feedback to the federal government on the selection of performance measures and consider the MAP's recommendations regarding all quality measures under consideration for use in the IRF QRP.

Comment: Several commenters identified the need to have as much standardization of

measures and data collection across PAC settings as possible, while recognizing that some variations among settings may be necessary. Some commenters cautioned that complete standardization among PAC settings may not be possible and suggested that CMS consider standardization around topics or domains but allow different settings to use assessment instruments that are most appropriate for the patient populations assessed.

Response: We agree that standardization is important, but would like to clarify that while the IMPACT Act requires that certain data be standardized in order to allow for interoperability and the exchange and use of such data among and by PAC providers, there will be instances in which providers in some PAC settings may need somewhat different items that are unique to their patient population. We will, however, ensure that a core set of standardized items is collected across each PAC setting.

Comment: Several commenters requested that CMS consider minimizing the burden for PAC providers when available and avoid duplication in data collection efforts.

Response: We appreciate the importance of avoiding undue burden and will continue to evaluate and consider any burden the IRF QRP places on IRFs.

B. General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the IRF QRP

We refer readers to the FY 2015 IRF PPS final rule (79 FR 45911) for a detailed discussion of the considerations we use for the selection of IRF QRP quality measures. In this final rule, we apply the same considerations to the selection of quality, resource use, and other measures required under section 1899B of the Act for the IRF QRP, in addition to the considerations discussed below.

The quality measures we are adopting address the measure domains that the Secretary is

required to specify under sections 1899B(c)(1) and (d)(1) of the Act. The totality of the measures considered to meet the requirements of the IMPACT Act will evolve, and additional measures will be proposed over time as they become available.

To meet the first specified application date applicable to IRFs under section 1899B(a)(2)(E) of the Act, which is October 1, 2016, we have focused on measures that:

- Correspond to a measure domain in sections 1899B(c)(1) or (d)(1) of the Act and are setting-agnostic: for example, falls with major injury and the incidence of pressure ulcers;
- Are currently adopted for 1 or more of our PAC quality reporting programs, are already either NQF-endorsed and in use or finalized for use, or already previewed by the Measure Applications Partnership (MAP) with support;
- Minimize added burden on IRFs;
- Minimize or avoid, to the extent feasible, revisions to the existing items in assessment tools currently in use (for example, the IRF-PAI); and
- Where possible, the avoidance of duplication of existing assessment items.

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. This process is based on a private-public partnership, and it occurs via the MAP. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890 of the Act, to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. The NQF must convene these stakeholders and provide us with the stakeholders' input on the selection of such measures. We, in turn, must take this input into consideration in selecting such measures. In addition, the Secretary must make available to the

public by December 1 of each year a list of such measures that the Secretary is considering under Title XVIII of the Act.

As discussed in section IX.A. of this final rule, section 1899B(e)(3) of the Act provides that the pre-rulemaking process required by section 1890A of the Act applies to the measures required under section 1899B of the Act, subject to certain exceptions for expedited procedures or, alternatively, waiver of section 1890A.

We initiated an ad hoc MAP process for the review of the quality measures under consideration for proposal, in preparation for adoption of those quality measures into the IRF QRP that are required by the IMPACT Act, and that must be implemented by October 1, 2016. The List of Measures under Consideration (MUC List) under the IMPACT Act was made public on February 5, 2015. Under the IMPACT Act, these measures must be standardized so they can be applied across PAC settings and must correspond to measure domains specified in sections 1899B(c)(1) and (d)(1) of the Act. The MAP reviewed the IMPACT Act-related quality measures adopted in this final rule for the IRF QRP, in light of their intended cross-setting uses. We refer to sections IX.F. and IX.G. of this final rule for more information on the MAP's recommendations. The MAP's final report, MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report is available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

As discussed in section IX.A. of this final rule, section 1899B(j) of the Act requires that we allow for stakeholder input, such as through town halls, open door forums, and mailbox submissions, before the initial rulemaking process to implement section 1899B of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: our measure development contractor(s) convened a TEP that included stakeholder experts and

patient representatives on February 3, 2015; we provided 2 separate listening sessions on February 10 and March 24, 2015; we sought public input during the February 9th 2015 ad hoc MAP process provided for the sole purpose of reviewing the measures adopted in response to the IMPACT Act. Additionally, we implemented a public mail box for the submission of comments in January 2015, PACQualityInitiative@cms.hhs.gov, which is listed on our post-acute care quality initiatives website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html, and held a National Stakeholder Special Open Door Forum to seek input on the measures on February 25, 2015. The slides from the SODF are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html.

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for the IRF QRP, we are adopting these measures for the IRF QRP for the purposes of satisfying the measure domains required under the IMPACT Act that most closely align with the national priorities identified in the National Quality Strategy (http://www.ahrq.gov/workingforquality/) and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these measures in the IRF setting is included under each quality measure proposal in this final rule. In addition, for measures not endorsed by the NQF, we have sought, to the extent practicable, to adopt measures that have been endorsed or adopted by a national consensus organization, recommended by multi-stakeholder organizations, and/or developed with the input of providers, purchasers/payers, and other stakeholders.

C. Policy for Retention of IRF QRP Measures Adopted for Previous Payment Determinations

In the CY 2013 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Payment Systems and Quality Reporting Programs final rule (77 FR 68500 through 68507), we adopted a policy that would allow any quality measure adopted for use in the IRF QRP to remain in effect until the measure was actively removed, suspended, or replaced. For the purpose of streamlining the rulemaking process, when we initially adopt a measure for the IRF QRP for a payment determination, this measure will also be adopted for all subsequent years or until we propose to remove, suspend, or replace the measure. For further information on how measures are considered for removal, suspension, or replacement, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507).

We did not propose any changes to this policy for retaining IRF QRP measures adopted for previous payment determinations.

D. Policy for Adopting Changes to IRF QRP Measures

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted a subregulatory process to incorporate NQF updates to IRF quality measure specifications that do not substantively change the nature of the measure. Substantive changes will be proposed and finalized through rulemaking. Regarding what constitutes a substantive versus a nonsubstantive change, we expect to make this determination on a measure-by-measure basis. Examples of such nonsubstantive changes might include updated diagnosis or procedure codes; medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. The subregulatory process for nonsubstantive changes will include revision of the IRF PAI Manual and posting of updates at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/InpatientRehabFacPPS/IRFPAI.html.

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, such as changes in acceptable timing of medication, procedure/process, test administration, or expansion of the measure to a new setting.

We did not propose any changes to this policy for adopting changes to IRF QRP measures. However, we received a public comment, which is discussed below.

Comment: One commenter recommended that CMS more clearly define the sub-regulatory process criteria for determining what constitutes a non-substantive change, and stated that they appreciated the need for a sub-regulatory process in order for CMS to have some flexibility in updating measures that need non-substantive changes. This commenter also recommended that CMS consider any changes to numerator definitions for measures and not just denominator changes (for example, exclusions) as substantive.

Response: We will take these recommendations into account as we further examine what constitutes a substantive versus a non-substantive change. We will propose any changes to our policy for adopting changes to IRF QRP measures in future rulemaking.

E. Quality Measures Previously Finalized for and Currently Used in the IRF QRP

1. Measures Finalized in the FY 2012 IRF PPS Final Rule

In the FY 2012 IRF PPS final rule (76 FR 47874 through 47878), we adopted applications of 2 quality measures for use in the first data reporting cycle of the IRF QRP: (1) an application of Catheter-Associated Urinary Tract Infection (CAUTI) for Intensive Care Unit Patients (NQF#0138); and (2) an application of Percent of Residents or Patients with Pressure

Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). We adopted applications of these 2 measures because neither of them, at the time, was endorsed by the NQF for the IRF setting. We also discussed our plans to propose a 30-Day All-Cause Risk-Standardized Post-IRF Discharge Hospital Readmission Measure.

2. Measures Finalized in the CY 2013 OPPS/ASC Final Rule

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted the following measures:

a. National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)

In the CY 2013 OPPS/ASC final rule, we adopted the NHSN CAUTI Outcome Measure (NQF #0138) (replacing an application of this measure that we initially adopted in the FY 2012 IRF PPS (76 FR 47874 through 47886)). Data submission for the NQF-endorsed measure applies to the FY 2015 adjustments to the IRF PPS annual increase factor and all subsequent annual increase factors (77 FR 68504 through 68505). Additional information about this measure can be found at http://www.qualityforum.org/QPS/0138. IRFs submit their CAUTI measure data to the Centers for Disease Control and Prevention (CDC) NHSN. Details regarding submission of IRF CAUTI data to the NHSN can be found at the NHSN website at http://www.cdc.gov/nhsn/inpatient-rehab/index.html.

b. Application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted a non-risk-adjusted application of this measure.

3. Measures Finalized in the FY 2014 IRF/PPS Final Rule

For the FY 2016 adjustments to the IRF PPS annual increase factor, we finalized the adoption of one additional measure: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (78 FR 47902 through 47921). In addition, for the FY 2017 adjustments to the IRF PPS annual increase factor, we finalized the adoption of 3 additional quality measures: (1) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities; (2) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (3) the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). In the FY 2014 IRF PPS final rule (78 FR 47912 through 47916), we also adopted a revised version of the IRF-PAI (Version 1.2), which providers began using as of October 1, 2014, for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year annual increase factors.

a. Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)

In the FY 2014 IRF PPS final rule (78 FR 47905 through 47906), we adopted the CDC-developed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) quality measure that is collected by the CDC via the NHSN. We finalized that the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1 (or when the vaccine becomes available) through March 31. We further finalized that IRFs submit their data for this measure to the NHSN (http://www.cdc.gov/nhsn/). We also finalized that for the FY 2016 adjustments to the IRF PPS annual increase factor, data collection will cover the period from October 1, 2014 (or when the vaccine becomes available) through March 31, 2015.

Details related to the use of 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/inpatient-rehab/hcp-vacc/index.html and at http://www.qualityforum.org/QPS/0431. While IRFs can enter information in NHSN at any point during the influenza vaccination season for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure, data submission is only required once per influenza vaccination season. We finalized that the final deadline for data submission associated with this quality measure is May 15th of each year.

b. All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities (NQF #2502)

In the FY 2014 IRF PPS final rule (78 FR 47906 through 47910), we adopted an All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs. This quality measure estimates the risk-standardized rate of unplanned, all-cause hospital readmissions for cases discharged from an IRF who were readmitted to a short-stay acute care hospital or LTCH, within 30 days of an IRF discharge. We noted that this is a claims-based measure that will not require reporting of new data by IRFs and thus will not be used to determine IRF reporting compliance for the IRF QRP.

c. Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

In the FY 2014 IRF PPS final rule (78 FR 47906 through 47911), we adopted the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) measure for the IRF QRP.

We added the data elements needed for this measure to the "Quality Indicator" section of the IRF-PAI Version 1.2, which became effective on October 1, 2014. These data elements are harmonized with data elements (O0250: Influenza Vaccination Status) from the Minimum Data Set (MDS) 3.0 and the LTCH CARE Data Set Version 2.01, and the specifications and data elements for this measure are available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html and at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

For purposes of this quality measure, the influenza vaccination season is October 1 (or when the vaccine becomes available) through March 31 each year. We also finalized that for the FY 2017 adjustments to the IRF PPS annual increase factor, data collection covers the period from October 1, 2014 (or when the vaccine becomes available) through March 31, 2015.

The measure specifications for this measure can be found on the NQF and CMS websites at http://www.qualityforum.org/QPS/0680 and at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

d. Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)

In the FY 2014 IRF PPS final rule (78 FR 47911 through 47912), we adopted the NQF-endorsed version of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), with data collection beginning October 1, 2014, using the IRF-PAI Version 1.2, for quality reporting affecting the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year annual increase factors. The measure specifications

for this measure can be found on the NQF and CMS websites at http://www.qualityforum.org/QPS/0678 and at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

4. Measures Finalized in the FY 2015 IRF-PPS Final Rule

In the FY 2015 IRF-PPS final rule, we adopted 2 additional quality measures:

a. National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)

In the FY 2015 IRF PPS final rule (79 FR 45911 through 45913), we adopted the NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716), a measure of hospital-onset unique blood source MRSA laboratory-identified events among all patients in the inpatient rehabilitation facility. This measure was developed by the CDC and is NQF-endorsed. We finalized that data submission would start on January 1, 2015, and that adjustments to the IRF PPS annual increase factor would begin with FY 2017. Data are submitted via the CDC's NHSN. 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 NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) can be found at http://www.qualityforum.org/QPS/1716 and http://www.cdc.gov/nhsn/inpatient-rehab/mdro-cdi/index.html.

b. National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

In the FY 2015 IRF PPS final rule (79 FR 45913 through 45914), we adopted the NHSN

Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717), a measure of hospital-onset CDI laboratory-identified events among all inpatients in the facility. This measure was developed by the CDC and is NQF-endorsed. We finalized that data would be submitted starting January 1, 2015, and that adjustments to the IRF PPS annual increase factor would begin with FY 2017. Providers will use the CDC/NHSN data collection and submission framework for reporting of the NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717). 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 NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717) can be found at http://www.qualityforum.org/QPS/1717 and http://www.cdc.gov/nhsn/inpatient-rehab/mdro-cdi/index.html.

TABLE 18: Quality Measures Previously Finalized for and Currently Used in the IRF Quality Reporting Program

NQF Measure ID	Quality Measure Title	Data Submission Mechanism
NQF #0138	National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	CDC NHSN
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel	CDC NHSN
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)	IRF-PAI
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)	IRF-PAI
NQF #2502	All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities*	Claims-based
NQF #1716	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	CDC NHSN
NQF #1717	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure	CDC NHSN

* Claims-based measure; no additional data submission required by IRFs

5. Continuation of Previously Adopted IRF QRP Quality Measures for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 adjustments to the IRF PPS annual increase factor, we are retaining the previously discussed measures: (1) NHSN CAUTI Outcome Measure (NQF #0138); (2) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); (3) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678); (4) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502); (5) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431); (6) NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716), (7) and NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717) quality measures.

We received several comments on Quality Measures Previously Finalized for and Currently Used in the IRF QRP, which are summarized below.

Comment: MedPAC commented in support of outcome measures, such as avoiding preventable readmissions and hospital-acquired infections in the Quality Reporting Programs.

Response: We appreciate MedPAC for their support of outcome measures such as hospital readmissions and episodes of healthcare-acquired infections. We believe that outcomes-based measures are important in ascertaining quality and intend to continue to implement outcomes-based measures throughout the life of the IRF QRP. For example, we proposed IRF functional outcomes as part of this rulemaking cycle and we intend to propose outcomes-based measures to satisfy the IMPACT Act domains, such as Discharge to Community and Potentially Preventable Hospital Readmissions.

Comment: Two commenters did not support the measure Percentage of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680), stating that it is not an outcome measure, not related to the specific rehabilitative care provided to the patient, and that the majority of patients admitted to the IRFs have already been vaccinated. One commenter did not support the NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus Aureus Bacteremia Outcome Measure (NQF #1716) or the NHSN Facility-Wide Inpatient Hospital-Onset Clostridium Difficile Infection Outcome Measure (NQF #1717), stating that they are not related to the specific rehabilitative care provided to the patient.

Response: We thank the commenters for their comments. While the main focus of IRFs is improving the functional status of the patient, it is not the sole focus. We maintain that prevention and tracking of infectious disease is the responsibility of every care setting, regardless

of where they fall within the continuum of care. For a broader discussion on the importance of each of the above listed measures, we refer you to the FY 2015 IRF PPS Final Rule (79 FR 45872).

Comment: One commenter had concerns about measures that are collected via the CDC's NHSN system, noting that more data is collected through NHSN than is required for the quality measure, and that those reporting processes are not subject to rulemaking and may add additional reporting burdens.

Response: When we propose to adopt a quality measure that is collected and submitted to CMS via the CDC's NHSN, we make certain that the proposed rule provides a detailed description of the measure, and we address and respond to public comments on the reporting burden related to the measure. In addition, we make certain that the measure specifications and protocols for the measure are posted on the CDC's NHSN website, the CMS website, and the NQF website, as applicable, and available for public scrutiny and comment, including details related to the procedures for using NHSN for data submission and information on definitions, numerator data, denominator data, data analysis, and measure specifications for the proposed measure. Because of this, we believe that the substantive aspects of the reporting processes are subject to rulemaking.

Comment: Two commenters supported the current healthcare-associated infection (HAI) measures, reported through the CDC's NHSN.

Response: We thank the commenters for their support; we have considered all public comments submitted on the healthcare-associated infection measures previously finalized. The measures, as listed above, will continue to be part of the IRF QRP unless we propose to remove them through future rulemaking.

F. Quality Measures Previously Adopted for IRF QRP for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 payment determination and subsequent years, we proposed to adopt 2 quality measures to reflect NQF endorsement or to meet the requirements of the IMPACT Act: (1) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502); and (2) an application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678). These quality measures are as follows:

1. Quality Measure to Reflect NQF Endorsement: All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502)

The All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) measure was adopted for use in the IRF QRP in the FY 2014 IRF PPS final rule (78 FR 47906 through 47910). We proposed to adopt this measure for the FY 2018 payment determination and subsequent years to reflect that it is NQF-endorsed for use in the IRF setting as of December 2014. For current specifications of this measure, please visit http://www.qualityforum.org/QPS/2502.

As adopted through the FY 2014 IRF PPS final rule, All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) is a Medicare Fee-For-Service (FFS) claims-based measure. IRFs would not be required to report any additional data to us because we would calculate this measure based on claims data that are already reported to the Medicare program for payment purposes. We believe there would be no additional data collection burden on providers resulting from our implementation of All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) as part of the IRF QRP. In the FY 2014 IRF PPS final rule, we stated that we would provide initial feedback to

providers, prior to public reporting of this measure, based on Medicare FFS claims data from CY 2013 and CY 2014.

The description of this measure provided in the FY 2014 IRF PPS final rule (78 FR 47906 through 47910) noted this measure was the ratio of the number of risk-adjusted predicted unplanned readmissions for each individual IRF to the average number of risk-adjusted predicted unplanned readmissions for the same patients treated at the average IRF. This ratio is referred to as the standardized risk ratio (SRR). However, the measure specifications compute the risk-standardized readmission rate (RSRR) for this measure. The RSRR is the SRR multiplied by the overall national raw readmission rate for all IRF stays. The outcome is expressed as a percentage rate rather than a ratio.

This measure, which harmonizes with the Hospital-Wide All-Cause Readmission Measure (NQF #1789) currently in use in the Hospital Inpatient Quality Reporting (HIQR) Program, continues to use the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. This algorithm was refined in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50211 through 50216). The All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) measure for the IRF QRP will utilize the most recently updated version of the algorithm. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on CMS website (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html). The additional post-acute care planned readmission procedures specified for All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) remain the same as when first adopted through FY 2014 IRF PPS final rule. Documentation on the additional post-acute care planned

readmissions for this measure is available at http://www.qualityforum.org/QPS/2502. http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73619.

We sought public comments on our proposal to adopt the NQF-endorsed version of All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) for the IRF QRP for the FY 2018 payment determination and subsequent years. The responses to public comments on this measure are discussed in this section of the final rule.

Comment: Several commenters supported the adoption of this measure. One commenter noted that many hospital readmissions are preventable and that readmissions are costly and associated with increased morbidity and mortality. Another commenter supported the measure proposal, noting that NQF endorsement by a consensus-building entity is an important prerequisite designed to ensure the measure has been appropriately reviewed by stakeholders.

Response: We agree that readmissions are preventable and associated with increased morbidity, mortality, and costs. We also appreciate the commenters' support on the measure's NQF endorsement.

Comment: Several commenters expressed concern over this measure's use of claims data which are not accessible to IRFs in real time for quality improvement. Commenters noted concerns over their ability to track patients' post-IRF discharge to know whether patients were readmitted and the reason for the readmission. These commenters noted that a facility's readmission rate alone does not provide them with the specific patient information they would need for quality improvement and suggested that CMS share data with IRFs. Specifically, commenters indicated that they would need information on whether a patient was readmitted, as well as information on demographics and diagnosis. One commenter who also noted that the claims data are outdated and not reflective of IRFs' more recent quality improvement efforts

suggested that CMS work with the industry to develop a standardized mechanism to track patients after IRF discharge in "real time."

Response*:* We appreciate the commenters' concern pertaining to quality improvement and the readmissions of patients following an IRF discharge. We support the intent to seek information that will drive improved quality; however, we are currently unable to provide information pertaining to a patient's readmission episode. As part of their quality improvement and care coordination efforts, IRFs are encouraged to monitor hospital readmissions and follow up with patients post-discharge. Although this measure will not provide specific information at the patient level on a real-time basis, we believe that IRFs will be able to monitor their overall hospital readmission rates, assess their performance, and improve quality.

Comment*:* Several commenters expressed concern over the lack of risk adjustment for sociodemographic status factors among IRF patients, such as community factors including access to primary care, medications, and appropriate food. One commenter recommended using proxy data on these factors such as Census-derived data on income and the proportion of facilities' patients that are dually eligible for Medicare and Medicaid.

Response*:* While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding providers to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance reviews will be assessed to determine if risk-adjusting for

sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act in section (2)(d)(1). We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment*:* One commenter expressed concern that the measure does not adequately adjust for differences in functional status.

Response*:* To clarify, this measure does adjust for differences in functional status by including risk adjusters based on the IRF PPS case mix groups, which incorporate patients' motor function, and in some cases cognitive function, at admission.

Comment*:* One commenter noted that there is inconsistency in reporting periods with the pressure ulcer and CAUTI measures; specifically, the reporting periods for the pressure ulcer and CAUTI measures is calendar year 2015 whereas the readmission measure is based on calendar years 2013-2014.

Response*:* With regard to the inconsistency of reporting periods with other proposed IRF QRP measures, we appreciate this feedback. To clarify, the All-Cause Unplanned Readmission

Measure for 30 Days Post-Discharge from IRFs (NQF #2502) was previously adopted in the FY 2014 IRF PPS final rule (78 FR 47906 through 47910) as part of the IRF QRP and was proposed in the FY 2016 IRF PPS proposed rule (80 FR 23373) to reflect NQF endorsement. The dates associated with this measure were based on data analysis and have not changed. The readmissions measure is a claims-based measure, and we therefore must rely on the submission of claims to CMS, and the time it takes to ensure all associated claims have been submitted to CMS. The other IRF QRP required measures are simply based on the calendar year, with quarterly submission deadlines. There is not a way to align the two types of measures, as claims for the same timeframe take an additional 6 to 9 months to mature.

Comment: Two commenters noted that this measure does not harmonize with hospital readmission measures used in other settings, such as the SNF measure (NQF #2510) and the LTCH measure (NQF #2512). Specifically, one commenter noted that the SNF measure is based on 12 months of data and the IRF measure is based on 24 months of data.

Response: We appreciate this comment regarding alignment of the PAC readmission measures. Though this measure is not identical to the hospital readmission measures being proposed for SNFs and LTCHs, it was developed to harmonize with those measures. As noted in the SNF PPS proposed rule (80 FR 22044 at 22059 through 22061), the SNF readmission measure (NQF #2510) is based on 12 months of data as this ensures an accurate sample size for calculating the RSRR. However, 24 months of data were needed in order to ensure sufficient sample sizes to reliably calculate this measure for IRFs due to the substantially lower number of IRF stays in comparison with SNF stays.

Comment: One commenter expressed concern that PAC facilities should not be penalized for readmissions that are unrelated to the patient's initial reason for admission.

Response*:* In the FY 2016 IRF PPS proposed rule (80 FR 23373), we proposed a measure of all-cause unplanned readmissions for the IRF QRP. The issue of all-cause readmissions as opposed to a more focused set of readmission types has been raised in other contexts such as the Hospital-Wide Readmission Inpatient Quality Reporting (HWR IQR) measure finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51476). As we explained in the FY 2014 IRF PPS final rule (78 FR 47906 through 47910), discussions with technical experts have led us to prefer using an all-cause measure rather than a condition-specific readmissions measure. A measure of avoidable or related readmissions is possible when the population being measured is narrowly defined and certain complications are being targeted. For broader measures, a narrow set of readmission types is not practical. In addition, readmissions may be clinically related even if they are not diagnostically related. A patient may have comorbid conditions that are unrelated to the reason for rehabilitation. If not properly dealt with in discharge planning, a readmission for such a condition may become more likely. One of the primary purposes of a readmission measure is to encourage improved transitions at discharge, a choice among discharge destinations and care coordination. A readmission can occur that is less related to the primary condition being treated in the IRF than to the coordination of care post-discharge. That said, we have chosen to reduce the all-cause readmission set by excluding readmissions that are normally for planned or expected diagnosis and procedures. We augmented the research for the Hospital IQR set of planned readmissions for the IRF setting with recommendations and input from a TEP in the field of post-acute care (including IRFs). In the case where the readmission is due to a random event, such as a car accident, we expect these events to be randomly distributed across IRFs.

Comment*:* One commenter did not support a potentially preventable hospital

readmission rate because this would be based on data not accessible to all IRFs and that there are factors outside the control of an IRF that result in readmission that could not be predicted during the IRF stay.

Response*:* We appreciate this feedback; however, we would like to clarify that the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) was not proposed to meet the requirements of the IMPACT Act and is not a measure of potentially preventable hospital readmissions. This measure was adopted for use in the IRF QRP in the FY 2014 IRF PPS final rule (78 FR 47906 through 47910), and was proposed in the FY 2016 IRF PPS final rule (80 FR 23373) to reflect NQF endorsement for the IRF setting.

Final Decision: Having carefully considered the comments we received on the NQF-endorsed version of All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), we are finalizing the adoption of this measure for use in the IRF QRP for the FY 2018 payment determination and subsequent years.

2. Quality Measure Addressing the Domain of Skin Integrity and Changes in Skin Integrity: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)

Section 1899B(c)(1) of the Act directs the Secretary to specify quality measures on which PAC providers are required under the applicable reporting provisions to submit standardized patient assessment data and other necessary data specified by the Secretary to 5 quality domains, one of which is skin integrity and changes in skin integrity. The specified application date by which the Secretary must specify quality measures to address this domain for IRFs, SNFs, and LTCHs is October 1, 2016, and for HHAs is January 1, 2017. To satisfy these requirements, we proposed to adopt the measure Percent of Residents or Patients with Pressure Ulcers that are

New or Worsened (Short-Stay) (NQF #0678) that we have already adopted for the IRF QRP as a cross-setting quality measure that satisfies the domain of skin integrity and changes in skin integrity (80 FR 23373 through 23375). The reporting of data for this measure would affect the payment determination for FY 2018 and subsequent years. For the IRF setting, the measure assesses the percent of patients with stage 2 through stage 4 pressure ulcers that are new or worsened since admission.

As described in the FY 2012 IRF PPS final rule (76 FR 47876 through 47878), pressure ulcers are high-cost adverse events and are an important measure of quality. For information on the history and rationale for the relevance, importance, and applicability of this measure in the IRF QRP, we refer readers to the FY 2012 IRF PPS final rule and the FY 2014 IRF PPS final rule (78 FR 47911 through 47912). Details regarding the specifications for this measure are available on the NQF website at http://www.qualityforum.org/QPS/0678.

The IMPACT Act requires the implementation of quality measures and resource use and other measures that are standardized in order to enable interoperability across PAC settings, as well as the reporting of standardized patient assessment data and other necessary data specified by the Secretary. This requirement is in line with the NQF Steering Committee report, which stated: "to understand the impact of pressure ulcers across providers, quality measures addressing prevention, incidence, and prevalence of pressure ulcers must be harmonized and aligned."[4] The Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) measure is NQF-endorsed for the IRF setting and has been successfully implemented using a harmonized set of data elements in three PAC settings (IRF,

[4] National Quality Forum. National voluntary consensus standards for developing a framework for measuring quality for prevention and management of pressure ulcers. April 2008. Available from http://www.qualityforum.org/Projects/Pressure_Ulcers.aspx.

LTCH and SNF). As discussed in section IX.E. of this final rule, an application of this measure was adopted for the IRF QRP in the FY 2012 IRF PPS final rule (76 FR 47876 through 47878) for the FY 2014 payment determination and subsequent years, and the current NQF-endorsed version of the measure was finalized in the FY 2014 IRF PPS final rule (78 FR 47911 through 47912) for the FY 2017 payment determination and subsequent years. The measure has been in use in the IRF QRP since October 1, 2012, and currently, IRFs are submitting data for this measure using the IRF-PAI.

The Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) measure was adopted for use in the LTCH QRP in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51756) for the FY 2014 payment determination and subsequent years, and has been successfully submitted by LTCHs using the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set since October 2012. It has also been implemented in CMS' Nursing Home Quality Initiative, using the MDS 3.0 since 2011, and is currently reported on CMS' Nursing Home Compare at http://www.medicare.gov/nursinghomecompare/search.html.

A TEP convened by our measure development contractor in February 2015 provided input on the measure specifications and the feasibility and clinical appropriateness of implementing the measure as a cross-setting quality measure under the IMPACT Act of 2014, for use across PAC settings, including the IRF setting. The TEP supported the implementation of this measure across PAC providers and also supported our efforts to standardize this measure for cross-provider development. Additionally, the MAP, convened by the NQF, met on February 9, 2015 and provided input to CMS. The MAP supported the use of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF

#0678) in the IRF QRP as a cross-setting quality measure to be specified in accordance with the IMPACT Act of 2014. MAP noted that this measure addresses one of its previously identified PAC/LTC core concepts as well as an IMPACT Act domain. More information about the MAP's recommendations for this measure is available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

We proposed that that data collection for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) would continue to occur through the quality indicator section of the IRF-PAI submitted through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system. IRFs have been submitting data on the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) measure (NQF #0678) through the quality indicator section of the IRF-PAI since October 2012. For more information on IRF reporting using the QIES ASAP system refer to http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html and http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html.

In an effort to further harmonize the data elements across PAC providers, we proposed an update to the IRF-PAI items used to calculate the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) measure (NQF #0678) to align with the items included in the LTCH CARE Data Set and the MDS 3.0. The proposed modified IRF-PAI items used to identify new or worsened pressure ulcers consist of: M0800A: Worsening in Pressure Ulcer Status Since Admission, Stage 2; M0800B: Worsening in Pressure Ulcer Status Since Admission, Stage 3; and M0800C: Worsening in Pressure Ulcer Status Since Admission, Stage 4. We did not propose a change to the IRF-PAI items used to risk adjust this quality

measure. These items consist of: FIM® Item 39I (Transfers: Bed, Chair, and Wheelchair), FIM® Item 32 (Bowel Frequency of Accidents), I0900A (Peripheral Vascular Disease (PVD)), I0900B (Peripheral Arterial Disease (PAD)), I2900A (Diabetes Mellitus), 25A (Height), and 26A (Weight). More information about the IRF-PAI items is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html. For more information about the changes to the IRF-PAI, see http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html.

The specifications and data elements for the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), are available in the IRF-PAI training manual at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html, as well as at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

We sought public comment on our proposal to specify and adopt the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) measure for the IRF QRP for the FY 2018 payment determination and subsequent years to fulfill the requirements in the IMPACT Act. The responses to public comments on this measure are discussed below.

Comment: Several comments supported our proposal to implement Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) to fulfill the requirements of the IMPACT Act. The commenters stated that this measure is NQF-endorsed and has been supported by the MAP for use in the IRF QRP. One commenter

highlighted that this measure has also been adopted for use in quality reporting programs in other PAC settings, specifically pointing to the use of this measure in the LTCH QRP and the Nursing Home Quality Initiative.

Response*:* We agree that this measure fulfills the requirements of the IMPACT Act to implement quality measures that are standardized to enable interoperability across PAC settings. As the commenters stated, this measure is NQF-endorsed, is supported by the MAP for use in the IRF QRP, and has been endorsed for quality reporting programs in the nursing home, LTCH and IRF settings.

Comment*:* One commenter supported CMS's proposal to adopt the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) measure in the IRF QRP. However, the commenter noted that the measure only focuses on Stage 2 through Stage 4 pressure ulcers and recommended that IRFs monitor all stages of pressure ulcers.

Response: We agree with the commenter that it is important for all healthcare providers to monitor all stages of pressure ulcers and implement clinically appropriate practices to maintain skin integrity to prevent and manage all changes to skin integrity. However, our review of the relevant literature and feedback from our TEP and clinical advisors suggest that providers have difficulty objectively identifying and measuring Stage 1 pressure ulcers. Therefore, Stage 1 pressure ulcers have been excluded from the measure. Although we do not include Stage 1 pressure ulcers in the measure calculation, the proposed IRF-PAI version 1.4 tracks Stage 1 pressure ulcers at the time of admission and discharge for preventative purposes and to assist providers in care planning. The National Pressure Ulcer Advisory Panel (NPUAP) classifies unstageable or unclassified pressure ulcers as an additional category or stage of pressure ulcer in

the United States. As currently specified, unstageable pressure ulcers are also excluded from the proposed quality measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). However, we invited comment on our proposal for future measure development to include unstageable pressure ulcers, including suspected deep tissue ulcers, in the numerator of the quality measure. We appreciate the commenter's feedback and support of including unstageable pressure ulcers in the numerator of this proposed quality measure as new or worsened pressure ulcers. We would like to note that the proposed IRF-PAI version 1.4 includes reporting of unstageable pressure ulcers at the time of admission and discharge.

Comment*:* Commenters expressed concerns about the measure not being standardized across PAC settings, for example, specifically noting differences in the payers that are required to report patient/resident data for this measure resulting in differences in the denominators for each setting. The commenter suggested measures include all patients, regardless of payer.

Response: We appreciate the comments pertaining to the differences in the pressure ulcer quality measure denominators by payer type across the IRF, SNF and LTCH settings. Additionally, we appreciate the commenters' suggested expansion of the population used to calculate all measures to include payer sources beyond Medicare Part A and agree that quality measures that include all persons treated in a facility are better able to capture the health outcomes of that facility's patients or residents, and that quality reporting on all patients or residents is a worthy goal. ,,Although we had not proposed all payer data collection through this current rulemaking, we will take this recommendation into consideration for future rulemaking.

Comment: Several commenters were concerned that the pressure ulcer measure is not standardized across PAC settings. The commenters stated that although the measure appears to

meet the goals and the intent of the IMPACT Act, it does not use a single data assessment tool.

One commenter specifically mentioned the frequency of assessments, highlighting the fact that the LTCH and IRF versions of the measure are calculated using assessments at two points in time (admission and discharge), while the SNF version uses assessments at more than two points in time. The commenter expressed concern that the higher frequency of assessments for the MDS could potentially result in higher rates of pressure ulcer counts for SNFs. Another commenter expressed particular concerns regarding differences in the look-back periods for the items used on the IRF, SNF and LTCH assessments (MDS=7 day assessment period, IRF=3 day assessment period, LTCH = 3 day assessment period) and suggested that this would result in different rates of detection of new or worsened ulcers. Commenters encouraged CMS to address all of these discrepancies, and suggested that we should switch to using only an admission and discharge assessment in the SNF version of the measure.

Response: While the IMPACT Act requires the modification of PAC assessment instruments to revise or replace certain existing patient assessment data with standardized patient assessment data as soon as practicable, it does not require a single data collection tool. We intend to modify the existing PAC assessment instruments as soon as practicable to ensure the collection of standardized data. While we agree that it is possible that within the PAC assessment instruments certain sections could incorporate a standardized assessment data collection tool, for example, the Brief Interview for Mental Status (BIMS), we have not yet concluded whether this kind of modification of the PAC assessment instruments is necessary.

As to the concern that the pressure ulcer measure calculation is based on more frequent assessments in the SNF setting than in the LTCH and IRF settings, we wish to clarify that the result of the measure calculation for all three PAC providers is the same. For all three PAC

(SNF, LTCH, and IRF) providers, the measure calculation ultimately shows the difference between the number of pressure ulcers present on admission and the number of new or worsened pressure ulcers present on discharge. While the SNF measure calculation arrives at that number differently than does the measure calculation in the IRF and LTCH settings, ultimately all three settings report the same result – as noted, the difference between the number of pressure ulcers present on admission and the new or worsened pressure ulcers at discharge. To explain, in IRFs and LTCHs, pressure ulcer assessment data is obtained only at 2 points in time – on admission and on discharge. Therefore, the calculation of the measure includes all new or worsened pressure ulcers since admission. In contrast, in SNFs pressure ulcer assessment data is obtained on admission, at intervals during the stay (referred to as "interim assessments"), and at discharge. Each interim assessment and the discharge assessment only look back to whether there were new or worsened pressure ulcers since the last interim assessment. The sum of the number of new or worsened pressure ulcers identified at each interim assessment and at the time of discharge yields the total number of new or worsened pressure ulcers that occurred during the SNF stay and that were present on discharge. In other words, the collection of pressure ulcer data in LTCHs and IRFs is cumulative, whereas in SNFs, data collection is sequential. In all cases the calculation for SNFS, IRFs and LTCHs reaches the same result – the total number of new or worsened pressured ulcers between admission and discharge. With respect to the commenter's concern that the use of interim assessment periods on the MDS will result in a higher frequency of pressure ulcers for SNF residents, we clarify that pressure ulcers found during interim assessments that heal before discharge are not included in the measure calculation.

In regards to the commenter's concern about different look-back periods, we acknowledge that although the LTCH CARE Data Set and IRF-PAI allow up to the third day

starting on the day of admission as the assessment period and the MDS allows for an assessment period of admission up to day 7, we note that the training manuals for SNFs, LTCHs and IRFs provide specific and equivalent-coding instructions related to the items used to calculate this measure (found in Section M - skin conditions for all three assessments). These instructions ensure that the assessment of skin integrity occurs at the initiation of patients' or residents' PAC stays regardless of setting. All three manuals direct providers to complete the skin assessment for pressure ulcers present on admission as close to admission as possible, ensuring a harmonized approach to the timing of the initial skin assessment. Regardless of differences in the allowed assessment periods, providers across PAC settings should adhere to best clinical practices, established standards of care, and the instructions in their respective training manuals, to ensure that skin integrity information is collected as close to admission as possible. Although the manual instructions are harmonized to ensure assessment at the beginning of the stay, based on the commenter's feedback, we will take into consideration the incorporation of uniform assessment periods for this section of the assessments.

Comment: Several commenters stated that collection of data for the proposed quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), is burdensome for IRFs. Commenters expressed that the transitions needed to meet the proposed changes to the IRF-PAI items used to calculate this measure will be financially burdensome for IRFs and will require a significant investment of time and updates to electronic medical records (EMRs). Commenters noted that even small changes to the data set can result in significant changes in the logic and flow of the data collection and require re-training of staff to complete the new items. The commenters also pointed out that the possible future addition of unstageable pressure ulcers in the numerator of the measure represents an

additional potential change and additional added burden for IRFs.

Response*:* We recognize the commenter's concern pertaining to burden due to data set revisions, data collection, or training of staff due to the revisions in the proposed quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). We recognize the importance of education and will continue to disseminate information on assessment or quality measure revisions by means of training sessions, training manuals, webinars, open door forums, and help desk support. It should be noted that standard clinical practice requires providers to conduct thorough skin assessments, comprehensively document and track skin integrity, including pressure ulcers, and to adhere to pressure ulcer prevention and management guidelines. Thus, the documentation of pressure ulcer status as required by the IRF-PAI aligns with standard clinical practice, which we expect all PAC providers to adhere to. Although we recognize that the items have changed, pressure ulcer data has been collected in IRFs since October 2012, and the new items measure the same concepts as the pressure ulcer items in the current version of the IRF-PAI. In addition, in an effort to minimize burden of these items, we continue to include a gateway question and have a skip pattern. If the answer is [0-No] to IRF-PAI version 1.4 item number M0210: Unhealed Pressure Ulcer(s) - Does this patient have one or more unhealed pressure ulcer(s) at Stage 1 or higher?, the IRF staff will be able to skip several items in section M, including the M0300 and M0800 items. The skip pattern means that for many patients, IRF staff will not be required to complete the M0300 and M0800 items.

While we applaud the use of EMRs, we do not require that providers use EMRs to populate assessment data. It should be noted that with each assessment release, we provide free software to our providers that allows for the completion and submission of any required

assessment data. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html. Whether to take further steps than required to submit the assessment data—for example, the use of a vendor to design software that extracts data from a provider's EMR to populate the CMS quality assessment—is a business decision that is made solely by the provider. We only require that assessment data be submitted via the QIES ASAP system in a specific compatible format. To submit the required assessment data, providers can choose to use our free software, or the data submission specifications we provide that allow providers and their vendors to develop their own software, while ensuring compatibility with the QIES ASAP system.

Implementing quality measures and data collection tools that are consistent with standard clinical practice, support positive outcomes, and are standardized across PAC settings are key objectives in our quality initiatives. It should be noted that the changes to the IRF-PAI were proposed in an effort to further standardize the data elements across PAC providers. Feedback relating to provider burden will be taken into account as we consider future updates to the quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), including the consideration to add unstageable pressure ulcers, which includes suspected deep tissue injuries (sDTIs), in the numerator. In an effort to minimize provider burden, we will make every effort to utilize items that will already be in the IRF-PAI for this possible future change.

Comment: Several commenters questioned whether the pressure ulcer measure is representative of the quality of care provided by IRFs. Some commenters shared that based on analysis of IRF-PAI data in the Uniform Data System for Medical Rehabilitation database, less

than 1 percent of Medicare IRF cases are identified with a new or worsened pressure ulcer at discharge and questioned if improvement below 1 percent would be a meaningful indication of quality to consumers. One commenter suggested that pressure ulcer history would be a more appropriate measure of outcomes, compared to the proposed measure, because history is not taken at a single point in time.

Response*:* We believe that pressure ulcer development and the worsening of pressure ulcers is an issue that is highly relevant to the IRF setting, as well as all post-acute care settings. Pressure ulcers are high-cost adverse events across the spectrum of health care settings from acute hospitals to home health. Specifically, patients in an IRF setting may have medically complex conditions and severe functional limitations and are, therefore, at high risk for the development, or worsening, of pressure ulcers. Pressure ulcers are serious medical conditions and an important measure of quality. Pressure ulcers can lead to severe, life-threatening infections, which substantially increase the total cost of care. Even if the proportion of patients in IRFs with new or worsening pressure ulcers is small, any such cases are particularly troubling. The National Quality Strategy identifies patient safety one of six priorities for quality measurement and assessment.[5] In addition, section 1899B(c)(1)(B) of the Act directs CMS to specify measures that relate to skin integrity and changes in skin integrity, and section 1899B(g) of the Act requires public reporting of PAC provider performance on these measures. Therefore, we proposed the quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). The proposed quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF

[5] US Department of Health and Health Services. *National Strategy for Quality Improvement in Health Care 2014 Annual Progress Report to Congress*. September 2014. Accessed July 2015. http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2014annlrpt.pdf

#0678), considers pressure ulcers that developed or worsened during the entire stay, holding PAC facilities accountable for the entirety of pressure ulcer care provided rather than looking at a snapshot or prevalence measure (that is, a measure of the proportion of a population who have, or had, a specific characteristic in a given time period) of pressure ulcers on a given date or time. We are open to stakeholder feedback on measure development and encourage all stakeholders to submit comments via email at PACQualityInitiative@cms.hhs.gov.

Comment: Several commenters supported the intent of the measure, but had concerns regarding the risk adjustment of this measure. One commenter recommended the inclusion of pressure ulcer history, rather than the presence of severe pressure ulcers at admission, as a risk factor for pressure ulcer outcomes. Another commenter was concerned that the measure is limited to only high risk patients or residents, and that the denominator size is decreased by excluding individuals who are low risk. The commenter indicated that pressure ulcers do develop in low risk individuals and that this exclusion will impact each PAC setting differently because the prevalence of low risk individuals varies across settings. The commenter recommended that CMS use a logistic regression model for risk adjustment to allow for an increase in the measure sample size by including all admissions, take into consideration low-volume providers, and capture the development of pressure ulcers in low-risk individuals. The commenter stated that a patient's or resident's risk is not dichotomous (for example, high-risk vs. low-risk) and recommended that CMS grade risk using an ordinal scale related to an increasing number and severity of risk factors. The commenter also expressed that the populations and types of risk for pressure ulcers varies significantly across PAC settings, and that using a logistic regression model would be a more robust way to include a wide range of risk factors to better reflect the population across PAC settings. The commenter noted that the cross-setting pressure

ulcer TEP also recommended that CMS consider modifying the risk adjustment model and discussed excluding or risk adjusting for hospice patients and those at the end of life.

Response: We appreciate the commenters' recommendations regarding risk adjustment for this measure.

In regards to the recommendation that we risk adjust using a logistic regression model and incorporate low risk patients into the measure, we believe that this comment may have been submitted on the wrong quality measure. The comments apply to the quality measure Percent of High Risk Residents with Pressure Ulcers (Long Stay) (NQF #0679), which is not the measure that we proposed for the IRF QRP. The proposed measure is Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (NQF #0678). This measure is currently risk adjusted using a logistic regression that includes low-risk patients or residents. In the model, patients or residents are categorized as either high- or low-risk for four risk factors: functional limitation; bowel incontinence; diabetes or peripheral vascular disease/peripheral arterial disease; and low body mass index (BMI). The measure is not risk adjusted for severe pressure ulcers at admission. An expected score is calculated for each patient or resident using that patient or resident's risk level on the four risk factors described above. The patient/resident-level expected scores are then averaged to calculate the facility-level expected score, which is compared to the facility-level observed score to calculate the adjusted score for each facility. Additional detail regarding risk adjustment for this measure is available in the measure specifications, available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html. We have determined that risk adjustment is appropriate for this measure and we have carefully developed and implemented the risk adjustment model previously described. When developing the risk

adjustment model for this measure, we reviewed the relevant medical and scientific literature, conducted analyses to test additional risk factors, convened technical expert panels to seek stakeholder input, and obtained clinical guidance from subject matter experts and other stakeholders to identify additional risk factors. We will continue to analyze this measure as more data is collected and will consider changing the risk adjustment model, expanding the risk stratifications, and testing the inclusion of other risk factors as additional risk adjustors for future iterations of the measure. We will also take into consideration the TEP discussion and this commenter's feedback regarding the exclusion or risk adjustment for hospice patients and those at the end of life. As we transition to standardized data collection across PAC settings to meet the mandate of the IMPACT Act, we intend to continue our ongoing measure development and refinement activities to inform the ongoing evaluation of risk adjustment models and methodology. This continued refinement of the risk adjustment models will ensure that the measure remains valid and reliable to inform quality improvement within and across each PAC setting, and to fulfill the public reporting goals of quality reporting programs, including the IRF QRP. We remain committed to conducting ongoing testing and measure development activities in an effort to improve the risk adjustment of quality measures implemented through the quality reporting programs.

Comment: A few commenters expressed concern regarding the reliability and validity of this measure across different PAC settings. The commenters were concerned that the reliability and validity testing for this measure was only conducted in the SNF setting.

Response: We appreciate the commenters' concern that the SNF, LTCH and IRF populations are not identical and that some differences may exist in the reliability and validity of the measure across settings. However, the NQF has expanded its endorsement of this measure to

include the IRF and LTCH settings, and has agreed that the similarities between the facilities and the potential overlap in patients, along with nonclinical factors that affect where a patient is treated, suggest that research regarding SNF/nursing home residents and the use of the MDS assessment is applicable to the use of the IRF-PAI in IRFs and LTCH CARE Data Set in LTCHs.

All NQF-endorsed measures must meet strict reliability and validity criteria at regular intervals, in order to maintain NQF endorsement. Our measure development contractor is currently conducting measure and item level testing for this measure across PAC settings in preparation for NQF Endorsement Maintenance Review. Initial findings reviewed in 2014 suggest that the measure is both valid and reliable in the SNF, LTCH, and IRF settings. Details regarding this testing will be made available to stakeholders once testing is complete, as part of the NQF maintenance and review process. We agree that it is important to conduct ongoing evaluations of the measure across PAC settings, and we remain committed to conducting ongoing measure testing to inform future measure development. It should be noted that we are working towards the development of a more fully standardized data set for this measure. As such, we continue to conduct measure development and testing to explore differences to determine the best way to standardize quality measurement, while ensuring measure reliability and validity and appropriately accounting for unique differences in populations across different PAC settings.

Comment: A few commenters expressed concerns that although the MAP supports cross-setting use of this measure, it is only NQF-endorsed for the SNF setting and suggested that CMS delay implementing the cross-setting measure until it is NQF-endorsed across all PAC settings. One commenter also pointed out that the specifications available on the NQF website are dated October 2013.

Response*:* Although the proposed measure was originally developed for the SNF/nursing home resident population, it has been re-specified for the LTCH and IRF settings and received NQF endorsement for expansion to the LTCH and IRF settings by the NQF Consensus Standards Approval Committee (CSAC) on July 11, 2012[6] and was subsequently ratified by the NQF Board of Directors for expansion to the LTCH and IRF settings on August 1, 2012.[7] As reflected on the NQF website, the endorsed settings for this measure include Post-Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility.[8] NQF endorsement of this measure indicates that NQF supports the use of this measure in the LTCH and IRF settings, as well as in the SNF setting. In addition, this measure was fully supported by the MAP for cross-setting use at its meeting on February 9, 2015. With regard to the measure specifications posted on the NQF website, the most up-to-date version of the measure specifications were posted for stakeholder review at the time of the proposed rule on the CMS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Inpatient-Rehabilitation-Facility-Quality-Reporting-Program-Specifications-for-the-Quality-Measures-Proposed-Through-the-Fiscal-Year-2016-Notice-of-Proposed-Rulemaking-report.pdf. The specifications currently posted on the NQF website are computationally equivalent and have the same measure components as those posted on the CMS website at the time of the proposed rule. However, we provided more

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[7] National Quality Forum. NQF Removes Time-Limited Endorsement for 13 Measures; Measures Now Have Endorsed Status. August 1, 2012. Available; http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_13_Measures;_Measures_Now_Have_Endorsed_Status.aspx

[8] National Quality Forum. Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short -Stay). Available: http://www.qualityforum.org/QPS/0678

detail in the specifications posted with the proposed rule, in an effort to more clearly explain aspects of the measure that were not as clear in the NQF specifications. Additionally, we clarified language to make phrasing more parallel across settings, and updated item numbers and labels to match the 2016 data sets (MDS 3.0, LTCH CARE Data Sets, and IRF-PAI). We are working closely with NQF to make updates and ensure that the most current language and clearest version of the specifications are available on the NQF website.

Comment: Multiple commenters expressed concern or requested clarification regarding changes to Section M of the IRF-PAI. Commenters were concerned that changes in pressure ulcer documentation, definitions, and guidance in the IRF-PAI and relevant training materials, may lead to increased confusion for clinicians, ultimately resulting in decreased data consistency and validity. These changes also make it difficult to compare data over time, or to use historic data for benchmarking purposes. Commenters noted the importance of providing clear guidance in manuals and training materials. One commenter did not object to the proposed changes, but requested that CMS clarify any minor changes to the IRF-PAI items and instructions through the final rule and sub-regulatory mechanisms (for example, the IRF-PPAI Training Manual) and noted that there are several modifications that need clarification.

One commenter was concerned that the NPUAP staging system should not be used as the sole determinant of wound severity status and pointed out that there are many important pieces of information to consider, including wound size, worst tissue type and if a wound is open to the environment. The commenter also encouraged CMS to consider tools beyond the IRF-PAI to determine wound status and encouraged CMS to implement new tools for wound image documentation. They highlighted the fact that there is new technology available that would make it easier for CMS to standardize across facilities to ensure quality, transparency and accuracy in

pressure ulcer prevention and care. The commenter also recommended several changes to the IRF-PAI, aimed at ensuring that all pressure ulcers are tracked from the beginning to the end of the stay.

Response*:* We are committed to providing information and support that will allow providers to accurately interpret and complete quality reporting items. To increase provider understanding, we intend to provide comprehensive training, as we do each time the assessment items change for the IRF-PAI. In addition, we understand the importance of education and will continue to disseminate information on assessment or quality measure revisions through training sessions, training manuals, webinars, open door forums, and help desk support. It should be noted that the changes to the IRF-PAI were proposed in an effort to further standardize the data elements across PAC providers. Additionally, the new items measure the same concepts as the pressure ulcer items in the current version of the IRF-PAI and the quality measure has not changed. We believe that the standard CMS training activities, along with increased public outreach, will increase the accuracy of coding of the assessments, which will increase the reliability of the data submitted to us. As noted, the new IRF-PAI items measure the same concepts as the pressure ulcer items in the current version of the IRF-PAI, and the quality measure specifications, measure calculations, and scoring have not changed. This consistency will facilitate accurate and reliable data collection and reporting over time.

The measure utilizes NPUAP staging, an important indicator of the severity of pressure ulcers, to identify new or worsened pressure ulcers. However, the purpose of the measure is not to capture all details regarding pressure ulcer severity, prevention, management, or documentation. We encourage all providers to engage in best practices to manage and track pressure ulcers within each facility, and we applaud the use of advanced technologies to facilitate

improved quality and accuracy in pressure ulcer management and documentation. We will take all recommendations into consideration when updating future quality measures and the IRF-PAI assessment instrument. We appreciate stakeholder feedback on measure development and encourage everyone to submit comments to our comment email: PACQualityInitiative@cms.hhs.gov.

Final Decision: Having carefully considered the comments we received on the measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), we are finalizing the adoption of this measure for use in the IRF QRP as proposed.

As part of our ongoing measure development efforts, we are considering a future update to the numerator of the quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). This update would hold providers accountable for the development of unstageable pressure ulcers, including suspected deep tissue injuries (sDTIs). Under this possible future change, the numerator of the quality measure would be updated to include unstageable pressure ulcers, including sDTIs, that are new or developed in the facility, as well as Stage 1 or 2 pressure ulcers that become unstageable due to slough or eschar (indicating progression to a Stage 3 or 4 pressure ulcer) after admission. In the FY 2016 IRF PPS proposed rule, we did not propose the implementation of this change (that is, including unstageable pressure ulcers, including sDTIs, in the numerator) in the IRF QRP, but sought public comment on this potential area of measure development.

Our measure development contractor convened a cross-setting pressure ulcer TEP that strongly recommended that we hold providers accountable for the development of new unstageable pressure ulcers by including these pressure ulcers in the numerator of the quality measure. Although the TEP acknowledged that unstageable pressure ulcers, including sDTIs,

cannot and should not be assigned a numeric stage, panel members recommended that these be included in the numerator of the quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), as a new pressure ulcer if it developed in the facility. The TEP also recommended that a Stage 1 or 2 pressure ulcer that becomes unstageable due to slough or eschar should be considered worsened, because the presence of slough or eschar indicates a full thickness (equivalent to Stage 3 or 4) wound.[9,10] These recommendations were supported by technical and clinical advisors and the NPUAP.[11] Furthermore, exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including sDTIs, would increase the observed incidence of new or worsened pressure ulcers at the facility level and may improve the ability of the quality measure to discriminate between poor- and high-performing facilities.

We sought public comment to inform our future measure development efforts to include unstageable pressure ulcers, including sDTIs, in the numerator of the quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). The responses to public comments on future development of the measure, Percent

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[9] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf.

[10] Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf.

[11] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf.

of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), are discussed below in this section of the final rule.

Comment: Several commenters were supportive of our proposal to include unstageable pressure ulcers (we understand their comments to be referring to unstageable pressure ulcers due to slough or eschar and due to non-removable dressing/device) in the numerator of the quality measure as an area for future measure development, but expressed reservations about the possible future inclusion of suspected deep tissue injuries (sDTIs) in the numerator of the quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). One commenter cited literature suggesting that sDTIs can take between 72 hours and seven days to become visible, indicating that there is no reliable and consistent way to determine whether an sDTI at admission is facility-acquired or not. Another commenter indicated that providers should not be penalized for sDTIs because much is still unknown about sDTIs, including if there is an actual deep tissue injury. Additionally, many sDTIs heal without opening. One commenter requested more information regarding the way this change would be incorporated into the measure specification, the impact the change would have on the reliability and validity of the measure, and how the change may impact the risk adjustment methodology. Finally, the commenter encouraged CMS to submit any proposed changes through NQF review and specify all details in future rulemaking.

Response: We thank the commenters for their support of the proposal to include unstageable pressure ulcers and for providing input regarding this proposed area for measure development. We also appreciate the recommendations regarding the approach to future implementation. At this time we are only soliciting feedback on this concept for possible measure development and will continue to conduct analyses and solicit input before making any

final decisions. We intend to continue monitoring the literature, conduct reliability and validity testing, seek input from subject matter experts and stakeholders, and participate in ongoing refinement activities to inform this measure before proposing to adopt any changes. Should we move forward with the addition of unstageable pressure ulcers, including sDTIs, to the measure numerator, we will provide more details regarding the specifications for this change prior to implementation. We intend to submit any changes for NQF review and will seek public comment on future measure concepts or revisions.

With regard to the commenters' concerns regarding sDTIs, we believe that it is important to do a thorough admission assessment on each patient who is admitted to an IRF, including a thorough skin assessment documenting the presence of any pressure ulcers of any kind, including sDTIs. When considering the addition of sDTIs to the measure numerator, we convened cross-setting TEPs in June and November 2013, and obtained input from clinicians, experts, and other stakeholders. While we agree that ongoing research and exploration of the clinical evidence is needed, sDTIs are a serious medical condition. Given their potential impact on mortality, morbidity, and quality of life, it may be detrimental to the quality of care to exclude sDTIs from future quality measures. Currently, we are only considering including sDTIs in the measure numerator, and will continue to conduct analyses, monitor the literature and clinical evidence, and solicit input before making any final decisions. We thank the commenters and will take all comments into account as we consider potential measure development and revisions.

Comment*:* One commenter does not support the addition of unstageable pressure ulcers in the numerator of the quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). Although the commenter supports the collection of new or worsened pressure ulcer data in the IRF-PAI, they stated that some sDTIs

and unstageable pressure ulcers due to non-removable dressing or devices may not be identifiable on admission, and expressed concern that these may then be incorrectly assigned as "new or worsened." As CMS considers this future possible update, the commenter emphasizes the importance of ensuring that any clinical or coding guidance provided is reflective of the most recent evidence-based processes for recording pressure ulcers and sDTIs as detection methodology is updated continuously to reflect current medical evidence.

Response*:* We thank the commenter for their input regarding this proposed area for future measure development, their support of the inclusion of these items in the IRF-PAI, and their recommendations regarding implementation. As noted, at this time we are only soliciting feedback on this concept for possible measure development. Should we move forward with the addition of unstageable pressure ulcers, including sDTIs, to the measure numerator, we will submit any changes for NQF review and seek public comment on future measure concepts or revisions.

We thank the commenters and will take all comments into account as we consider potential measure development and revisions.

G. Additional IRF QRP Quality Measures for the FY 2018 Payment Determination and Subsequent Years

We proposed to adopt 6 additional quality measures beginning with the FY 2018 payment determination. These new quality measures are: (1) an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674); (2) an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015); (3) IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation

Patients (NQF #2633; under review); (4) IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review); (5) IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015); and (6) IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015).

1. Quality Measure Addressing the Domain of the Incidence of Major Falls: An Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674)

Section 1899B(c)(1) of the Act directs the Secretary to specify quality measures on which PAC providers are required, under the applicable reporting provisions, to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is the incidence of major falls. The specified application date by which the Secretary must specify quality measures to address this domain for IRFs, SNFs, and LTCHs is October 1, 2016, and for HHAs is January 1, 2019. To satisfy these requirements, we proposed to adopt an Application of Percent of Residents Experiencing One of More Falls with Major Injury (Long-Stay) (NQF #0674) in the IRF QRP as a cross-setting quality measure that addresses the IMPACT Act domain of incidence of major falls. Data collection would start on October 1, 2016. The reporting of data for this measure would affect the payment determination for FY 2018 and subsequent years. As described in more detail in section IX.I.2. of this final rule, the first data collection period is 3 months (October 1, 2016 to December 31, 2016), and the subsequent data collection periods are 12 months in length and follow the calendar year (that is, January 1 to December 31). For the IRF setting, this measure would report the percentage of patients who experienced 1 or more falls with major injury during the IRF stay. This measure

was developed by us and is NQF-endorsed for long-stay residents of nursing facilities.

Research indicates that fall-related injuries are the most common cause of accidental death in people aged 65 and older, responsible for approximately 41 percent of accidental deaths annually.[12] Rates increase to 70 percent of accidental deaths among individuals aged 75 and older.[13] In addition to death, falls can lead to fracture, soft tissue or head injury, fear of falling, anxiety, and depression.[14] It is estimated that 10 percent to 25 percent of nursing facility resident falls result in fractures and/or hospitalization.[15] For IRFs, a study of 5,062 patients found that 367 patients (7.25 percent) had 438 falls. Among these 438 falls, 129 (29.5 percent of the falls) resulted in an injury, of which 25 (5.7 percent of all falls and 19 percent of all falls with injury) were serious.[16] A separate study of 754 stroke patients in an IRF reported 117 patients (15.5 percent) experienced 159 falls. Among these 159 falls, 13 (8 percent of falls) resulted in a minor injury, and 3 (2 percent of falls) resulted in a serious injury.[17]

Falls also represent a significant cost burden to the entire health care system, with injurious falls accounting for 6 percent of medical expenses among those age 65 and older.[18] In their 2006 work, Sorensen et al., estimate the costs associated with falls of varying severity among nursing home residents. Their work suggests that acute-care costs range from $979 for a

[12] Currie LM. Fall and injury prevention. Annu Rev Nurs Res. 2006;24:39–74.
[13] Fuller GF. Falls in the elderly. Am Fam Physician. Apr 1 2000;61(7):2159–2168, 2173–2154.
[14] Love K, Allen J. Falls: why they matter and what you can do. Geriatr Nurs, 2011; 32(3): 206-208
[15] Vu MQ, Weintraub N, Rubenstein LZ. Falls in the nursing home: are they preventable? J Am Med Dir Assoc. 2004 Nov-Dec; 5(6):401-6. Review.
[16] Frisina PG, Guellnitz R, Alverzo J. A time series analysis of falls and injury in the inpatient rehabilitation setting. Rehab Nurs. 2010; 35(4):141-146.
[17] Rabadi MH, Rabadi FM, Peterson M. An analysis of falls occurring in patients with stroke on an acute rehabilitation unit. Rehab Nurs. 2008; 33(3):104-109.
[18] Tinetti ME, Williams CS. The effect of falls and fall injuries on functioning in community-dwelling older persons. J Gerontol A Biol Sci Med Sci. 1998 Mar;53(2):M112-9.

typical case with a simple fracture to $14,716 for a typical case with multiple injuries.[19] A similar study of hospitalizations of nursing home residents due to serious fall-related injuries (intracranial bleed, hip fracture, other fracture) found an average cost of $23,723.[20]

According to Morse,[21] 78 percent of falls are anticipated physiological falls. Anticipated physiological falls are falls among individuals who scored high on a risk assessment scale, meaning their risk could have been identified in advance of the fall. To date, studies have identified a number of risk factors for falls.[22,23,24,25,26,27,28,29,30] The identification of such risk factors suggests the potential for health care facilities to reduce and prevent the incidence of falls with injuries for their patients. In light of the evidence previously discussed, we proposed to adopt the quality measure, an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), for the IRF QRP, with data collection starting

[19] Sorensen SV, de Lissovoy G, Kunaprayoon D, Resnick B, Rupnow MF, Studenski S. A taxonomy and economic consequence of nursing home falls. Drugs Aging. 2006;23(3):251-62.
[20] Quigley PA, Campbell RR, Bulat T, Olney RL, Buerhaus P, Needleman J. Incidence and cost of serious fall-related injuries in nursing homes. Clin Nurs Res. Feb 2012;21(1):10-23.
[21] Morse, J. M. (2002) Enhancing the safety of hospitalization by reducing patient falls. Am J Infect Control 2002; 30(6): 376–80.
[22] Rothschild JM, Bates DW, Leape LL. Preventable medical injuries in older patients. Arch Intern Med. 2000 Oct 9; 160(18):2717–28.
[23] Morris JN, Moore T, Jones R, et al. Validation of long-term and post-acute care quality indicators. CMS Contract No: 500–95–0062/T.O. #4. Cambridge, MA: Abt Associates, Inc., June 2003.
[24] Avidan AY, Fries BE, James ML, Szafara KL, Wright GT, Chervin RD. Insomnia and hypnotic use, recorded in the minimum data set, as predictors of falls and hip fractures in Michigan nursing homes. J Am Geriatr Soc. 2005 Jun; 53(6):955–62.
[25] Fonad E, Wahlin TB, Winblad B, Emami A, Sandmark H. Falls and fall risk among nursing home residents. J Clin Nurs. 2008 Jan; 17(1):126– 34.
[26] Currie LM. Fall and injury prevention. Annu Rev Nurs Res. 2006;24:39–74.
[27] Ellis AA, Trent RB. Do the risks and consequences of hospitalized fall injuries among older adults in California vary by type of fall? J Gerontol A Biol Sci Med Sci. Nov 2001;56(11):M686–692.
[28] Chen XL, Liu YH, Chan DK, Shen Q, Van Nguyen H. Chin Med J (Engl). Characteristics associated with falls among the elderly within aged care wards in a tertiary hospital: a retrospective. 2010 Jul;123(13):1668–72.
[29] Frisina PG, Guellnitz R, Alverzo J. A time series analysis of falls and injury in the inpatient rehabilitation setting. Rehabil Nurs. 2010 JulAug;35(4):141–6, 166.
[30] Lee JE, Stokic DS. Risk factors for falls during inpatient rehabilitant Am J Phys Med Rehabil. 2008 May;87(5):341–50; quiz 351, 422.

on October 1, 2016 and affecting the payment determination for FY 2018 and subsequent years.

The IMPACT Act requires the specification of quality measures and resource use and other measures that are standardized and interoperable across PAC settings, as well as the reporting of standardized patient assessment data and other necessary data specified by the Secretary. The Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) quality measure is NQF-endorsed for long-stay residents in nursing homes and has been successfully implemented in nursing facilities for long-stay residents. The NQF-endorsed measure has been in use as part of CMS' Nursing Home Quality Initiative since 2011. In addition, the measure is currently reported on CMS' Nursing Home Compare website at http://www.medicare.gov/nursinghomecompare/search.html. Further, the measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290), we revised the data collection period for this measure with data collection to begin starting April 1, 2016.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures focused on falls with a major injury. We are unaware of any other cross-setting quality measures for falls with major injury that have been endorsed or adopted by another consensus organization. Therefore, we proposed the quality measure, an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), under the Secretary's authority to select non-NQF-endorsed measures.

A TEP convened by our measure development contractor provided input on the measure specifications, including the feasibility and clinical appropriateness of implementing the measure across PAC settings, which include the IRF setting. The TEP supported the implementation of

this measure across PAC settings, including the IRF setting, and also supported our efforts to standardize this measure for cross-setting development. Additionally, the NQF-convened MAP met on February 9, 2015 and provided input to us on this measure. The MAP conditionally supported the use of the quality measure, an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), in the IRF QRP as a cross-setting quality measure. More information about the MAP's recommendations for this measure is available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

More information on the quality measure, Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), is located at the NQF website at http://www.qualityforum.org/QPS/0674. Details regarding the changes made to modify the quality measure, Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), and updated specifications are located at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

We proposed that data for this quality measure would be collected using the IRF-PAI with submission through the QIES ASAP system. More information on IRF reporting using the QIES ASAP system is located at the website http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html and http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html.

Data collected through a revised IRF-PAI would be used to calculate this quality measure. Consistent with the IRF-PAI reporting requirements, the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), will apply to all

Medicare patients discharged from IRFs. Data items in the revised IRF-PAI would include: J1800: Any Falls Since Admission, and J1900: Number of Falls Since Admission.

The calculation of the proposed quality measure would be based on item J1900C: Number of Falls with Major Injury since Admission. The specifications and data elements for the quality measure, the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html. For more information on the proposed data collection and submission timeline for the proposed quality measure, please see section IX.I.2 of this final rule.

We sought public comment on our proposal to adopt the quality measure, an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), with data collection beginning on October 1, 2016, for the IRF QRP for FY 2018 payment determination and subsequent years to fulfill the requirements in the IMPACT Act. The responses to public comments on this measure are discussed below in this section of the final rule.

Comment: One commenter supported measuring falls in IRFs, but believed that all falls should be documented, not just those with major injury.

Response: We appreciate the commenter's position that all falls should be measured. The proposed quality measure, an Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), assesses falls with major injuries, satisfying the domain delineated in the IMPACT Act, Incidence of Major Falls. We believe this domain mandates a quality measure related to major falls. However, the data elements included in the

IRF-PAI version 1.4 do enable IRFs to track all falls, regardless of injury. As part of best clinical practice, we agree that IRFs should track falls for multiple purposes, such as those that satisfy regulatory requirements, quality improvement, risk assessment, and clinical decisions support.

Comment: Several commenters supported the proposed quality measure, an Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), but believed that the measure should be risk-adjusted. One commenter noted that quality of care is not the only determinant of risk of falls; a variety of other clinical factors that are not within the control of the provider may increase the risk for falls. Commenters asserted that risk adjustment creates a "level playing field" that allows for fair comparisons. Some commenters recommended risk adjustment as a strategy for minimizing disincentives to IRFs to accept cognitively impaired patients. Several commenters suggested risk adjustment for populations that are at a higher risk for falls, such as IRF patients with nervous system disorders (for example, stroke and spinal cord injury or brain injury), low FIM® scores, and patients with amputations. Commenters pointed out that the TEP convened in February 2015 recommended risk adjustment for cognitive impairment, which several commenters also supported. One commenter asked whether the TEP was presented the current specification of the cross-setting falls measure. One commenter provided support for risk adjustment by pointing out that the references cited in the rule indicate that risk for falls varies by patient characteristics. That commenter asserted that the PAC-PRD research indicated that the risk of falls with injury differs across post-acute settings. Several commenters also noted that the measure should be risk adjusted, claiming that risk adjustment is required by the IMPACT Act and that the MAP suggested that the measure should be risk adjusted.

Response: To clarify, the proposed quality measure pertains to falls with a major injury,

satisfying the IMPACT Act domain, Incidence of Major Falls. Thus, falls with no injury, such as those that may be considered near-falls, are not included in the measure. The application of risk adjustment for this measure as required by the IMPACT Act is "as determined appropriate by the Secretary," as stated in section 1899B(c)(3)(B) of the Act.

While we acknowledge that patient characteristics that elevate risk for falls with major injury vary across the IRF population, a short-stay and long-stay Nursing Home TEP, convened in 2009 by our measurement development contractor, concluded that risk adjustment for this quality measure concept was inappropriate because it is each facility's responsibility to take steps to reduce the rate of injurious falls, especially since such events are considered to be "never events" (see http://psnet.ahrq.gov/primer.aspx?primerID=3 for further details on the origins and use of the term "never event").

We note that the PAC-PRD did not assess falls with major injury, as falls with major injury was not an item that was tested. However, as the commenter pointed out, the prevalence of a *history of falls* prior to the PAC admission did vary across post-acute settings (as assessed by item B7 from the PAC-PRD CARE tool: "History of Falls. Has the patient had two or more falls in the past year or any fall with injury in the past year?"). Nonetheless, as part of best clinical practice, IRFs should assess patients for falls risk and take steps to prevent future falls and falls with major injury. In the most recent TEP (2015) that discussed falls as a cross-setting measure aligned with the IMPACT Act, the numerator, denominator, and exclusion definitions provided are virtually identical to the specifications we proposed to adopt for this measure and did not include risk adjustment. Although 2 out of 11 TEP members supported risk adjustment of the falls measure for cognitive impairment, that was not the majority position. More information about the specifications and the convening of the TEP is available at

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/SUMMARY-OF-FEEDBACK-FROM-THE-TECHNICAL-EXPERT-PANEL-TEP-REGARDING-CROSS-SETTING-MEASURES-ALIGNED-WITH-THE-IMPACT-ACT-OF-2014-Report.pdf.

Factors that increase the risk of falling, such as cognitive impairment, should be included by facilities in their risk assessment to support proper care planning. Although it is possible that risk adjusting for cognitive impairment would reduce disincentives for caring for such patients in IRFs, it could also have the unintended consequence of leading to insufficient risk prevention efforts by the provider.

We do not pay hospitals for the higher costs associated with treating patients for hospital-acquired conditions, including falls resulting in intracranial injuries, fractures and dislocations, and these payment reductions are not risk adjusted. More specifically, for Medicare FFS patients discharged from a hospital on or after October 1, 2008, under the Deficit Reduction Act: Hospital-Acquired Conditions-Present on Admission Indicator Program (please see http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html and http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/wPOAFactSheet.pdf), hospitals do not receive additional payment for treating injuries (fracture, dislocation, intracranial injury, crushing injury, burns, or other injuries) resulting from falls and trauma when these injuries were deemed to be a hospital-acquired condition (that is, when the injuries resulting from falls were not present on admission and were acquired during the hospital stay). The MAP feedback regarding risk adjustment for

this quality measure applied to the home health setting, not IRFs.[31] We note that a more recent Cochrane review by Cameron et al., [32] which included 9 randomized controlled trials of multifactorial interventions in care facilities, found mixed evidence but did note that within care facilities, multifactorial interventions have the potential to reduce rates of falls and risk of falls. Specifically, two studies showed a statistically significant reduction in the rate of falls, 2 found statistically significant reductions in the risk of falling, 1 showed a statistically significant increase in the rate of falls, and the remainder did not find a significant result.

Comment: Several commenters supported the measure in concept, but suggested changes to the specifications, including mentioning "patients" (as opposed to residents), clarifying the list of major injuries covered under the measure, and providing the full specifications of the numerator, denominator, and exclusions. One commenter suggested that the measure be specified across settings, using the same assessment tool at admission and discharge, and the same numerator and denominator definitions, noting that there are differences between settings in terms of the payers. One commenter asserted that the item used in the IRF specification asks about the occurrence of two or more falls in the past year and whether a patient had major surgery, and that the exclusions listed in the specification were different in different settings, when they are the same.

Response: The occurrence of 2 or more falls in the past year, and major surgery prior to admission, are not risk adjustors for this proposed quality measure. However, the occurrence of

[31] Measure Applications Partnership. MAP Off-Cycle Deliberations 2015: Measures Under Consideration to Implement Provisions of the IMPACT Act. March 2015. Available at: http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Off-Cycle_Deliberations_2015_-_Final_Report.aspx

[32] Cameron ID, Gillespie LD, Robertson MC, Murray GR, Hill KD, Cumming RG, Kerse N. Interventions for preventing falls in older people in care facilities and hospitals. Cochrane Database of Systematic Reviews 2012, Issue 12. Art. No.: CD005465. DOI: 10.1002/14651858.CD005465.pub3.

two or more falls in the past year, and major surgery prior to admission, are risk adjusters for the function outcomes measures, IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review) and IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015), which were also proposed in the FY 2016 IRF PPS Proposed Rule (80 FR 23368). For the proposed quality measure, an Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), the single exclusion criterion (patients/residents with missing data) is standardized across the IRF, LTCH, and SNF settings.

The term "resident" is in the title of the measure because the proposed quality measure, an Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF# 0674), is an application of the existing NQF-endorsed quality measure, Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), which is a long-stay nursing home quality measure that uses the term "resident." However, as the measure is harmonized across settings, we are using both patient and resident in the descriptions of the measure specifications.

The complete list of major injuries in the quality measure is: bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma.

Although the measure is calculated using only J1900C (number of falls with major injury), the measure was developed using all three categories (no injury, minor injury, and major injury) to ensure that major injuries are accurately assessed. During item development, testing revealed that to obtain accurate data, different types of falls had to be assessed separately. Thus, the measure was designed this way because psychometric item development testing showed it

was imperative to stratify the types of falls. To omit the other two categories of falls would be inconsistent with how the measure was designed and could disable the ability to calculate the data in a way that the information has been evaluated to be usable.

Comment: Commenters expressed concerns about the measure not being standardized across PAC settings, for example, specifically noting differences in the payers that are required to report patient/resident data for this measure resulting in differences in the denominators for each setting. Several commenters suggested that CMS standardize numerator and denominator definitions across settings.

Response: The general issue raised by commenter with respect to standardization of the cross setting measures has been addressed under the comments and responses to the finalization of the measure Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF #0678) above.

Comment: Several commenters expressed concern that the measures do not comply with the IMPACT Act requirements for standardization and discussed the frequency of assessments as one area where there is lack of standardization. Commenters recommended that measures be "consistently stated (same wording, same timeframe, and same item set) and measured across all PAC settings to meet the requirements of the IMPACT Act."

Response: The quality measure, an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), and the data collection items used to calculate this measure are harmonized across settings and assessment instruments, (that is, use of only admission and discharge assessments in IRFs and LTCHs versus admission/re-entry, interim, and discharge assessments in SNFs). As to the concern that the falls with major injury measure calculation is based on more frequent assessments in the SNF setting than in the

LTCH and IRF settings, we wish to clarify that result of the measure calculation for all three PAC providers is the same. For all three PAC (SNF, LTCH, and IRF) providers, the measure calculation ultimately shows the total number of falls during the stay. While the SNF measure calculation arrives at that number differently than does the measure calculation in the IRF and LTCH settings, ultimately all three settings report the same result – as noted, the total number of falls during the stay. To explain, in IRFs and LTCHs, falls data is obtained only at discharge and looks back to admission. Therefore, the calculation of the measure includes all falls since admission. In contrast, in SNFs, falls data is obtained on admission, at intervals during the stay (referred to as "interim assessments"), and at discharge. Each interim assessment and the discharge assessment only look back to whether there were falls since the last interim assessment. The sum of the number of falls identified at each interim assessment and at the time of discharge yields the total number of falls that occurred during the stay. In other words, the collection of falls data in LTCHs and IRFs is cumulative, whereas in SNFs, data collection is sequential. In all cases the calculation for SNFs, IRFs and LTCHs reaches the same result – the total number of falls between admission and discharge.

We made additional details regarding the measure specifications for the quality measure, an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

Comment: One commenter that suggested CMS should use one standard assessment tool that asks questions in a consistent manner across all PAC settings in order to meet the requirements of the IMPACT Act.

Response: We intend to modify the existing PAC assessment instruments as soon as practicable to ensure the collection of standardized data. While we agree that it is possible that within the PAC assessment instruments certain sections could incorporate a standardized assessment data collection tool, for example, the Brief Interview for Mental Status (BIMS), we have not yet concluded whether this kind of modification of the PAC assessment instruments is necessary.

Comment: Several commenters supported this measure in concept, but stated their position that the measure should be validated and endorsed by NQF prior to implementing the measure in the IRF setting. Several commenters expressed concerns about the measure not having been adequately tested in the IRF population.

Response: We appreciate the commenters' position that the cross-setting falls measure should be tested in the short-stay IRF population prior to adoption. We also appreciate the commenters' concerns pertaining to the reliability and validity of the proposed measure, an Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) across PAC settings. We note that the TEP convened by the measurement development contractor in 2011 supported measuring falls with major injury in IRFs, and agreed that falls with major injury is a "never event." The TEP also concurred that facilities need to take responsibility to not only prevent falls, but to ensure that if they do occur, protections are in place so that the fall does not result in injury.

With regard to the adequacy of the measure's testing for use in the short-stay nursing home population, the item-level testing during the development of the MDS 3.0 showed near-perfect inter-rater reliability for the MDS item (J1900C) used to identify falls with major injury. The NQF measure evaluation criteria do not require measure-level reliability if item reliability is

high. However, we believe that, given the overlap in the IRF and SNF populations and item-level testing results, the application of this measure for IRF patients will be reliable. That said, we intend to continue to test the measure once data collection begins and as part of ongoing maintenance of the measure. We appreciate the commenters' recommendations regarding NQF endorsement in the IRF setting and recognize that it is an important step in the measure development process. However, falls with major injury is an important patient safety concern in IRFs, and given the lack of availability of NQF-endorsed measures for the IRF setting or measures endorsed by any other consensus organizations, we proposed to adopt this measure under the exception authority given to the Secretary.

Comment*:* One commenter noted that there are many risk factors for falls, including different diagnoses (such as cognitive impairment), and that rehabilitation hospitals tend to have a higher incidence of falls than acute-care settings. The commenter requested that CMS only review fall rates in IRFs in comparison to other IRFs.

Response*:* We thank the commenter for their comment, and appreciate the commenter's position that fall rates in IRFs should only be compared to rates in other IRFs. The intent of the IRF quality reporting program is, in part, to support such comparisons – so that providers receive important feedback on how they are performing relative to similar providers. In addition, the IMPACT Act requires the Secretary to standardize the domain, Incidence of Major Falls, across PAC settings. Therefore, fall rates data must be collected in order to allow for comparison across PAC settings. Also, NQF strongly suggests a coordinated strategy among PAC settings that includes prevention of falls. Reporting falls with major injury across PAC settings will inform providers, policymakers, and researchers in the post-acute care field on collaborating to improve rates of falls. As we continue to develop and test constructs pertaining to falls, we will

consider these factors.

Comment*:* Several commenters suggested that IRFs should not be required to collect data on all falls. Some noted that it seemed to be inappropriate because the measure is focused on falls with major injury. Others stated that it seemed inappropriate because patients in IRFs are encouraged to exert themselves to meet their functional goals, which inevitably leads to unintended falls. Moreover, IRFs may need to teach patients how to fall. Commenters noted that because of the rehabilitation needs of their patients, some providers may have a higher proportion of "assisted" falls.

Response*:* We agree that the rehabilitation process requires that patients be allowed to be as mobile and independent as possible, and some patients may need to learn how to fall safely. However, this measure is focused on falls with major injury. In proposing this measure to satisfy the IMPACT Act domain, Incidence of Major Falls, we are encouraging IRFs to balance the need to foster patient mobility and independence with the need to avoid major injuries (bone fractures, joint dislocations, closed head injuries with altered consciousness, and subdural hematoma), which are considered "never events."

Collecting data on all falls can be useful in informing providers about falls in general, as a considerable proportion of falls are preventable. Persons who have a history of falls, regardless of injury status, have a greater likelihood of falling again; thus, gathering data on all falls is a way to collect important and relevant data on risk factors. As part of best clinical practice, IRFs should track falls for multiple purposes, such as those that satisfy regulatory requirements, quality improvement, risk assessment, and clinical decisions support, including those that are assisted/non-assisted and preventable/non-preventable. For the purposes of this quality measure, the assessment instrument includes an item about whether any fall took place (J1800) as a

gateway item. If there were any falls, the assessor then completes the next set of items (J1900) indicating the number of falls by injury status. As discussed previously, facilities must report the data associated with all these items to avoid issues with missing data and as a way to ensure accurate data collection, but only the data on falls with major injury are used in calculating the quality measure.

Comment: One commenter pointed out that the proposed rule included a statement that could be misinterpreted as stating that 19 percent of falls in IRFs are serious.

Response: In the FY 2016 IRF PPS proposed rule (80 FR 23375), the original sentences read as follows: "For IRFs, a study of 5,062 patients found 367 patients (7.25 percent) had 438 falls. Among these 438 falls, 129 (29.5 percent of the falls) resulted in an injury, of which 25 (19 percent of falls) were serious." To clarify, the second sentence in question should have read: "Among these 438 falls, 129 (29.5 percent of the falls) resulted in an injury, of which 25 (5.7 percent of all falls and 19 percent of all falls with injury) were serious." The commenter correctly pointed out that 25 seriously injurious falls out of 438 total falls equals a 5.7 percent incidence of seriously injurious falls in the cited study of 5,062 IRF patients.[33]

Final Decision: Having carefully considered the comments we received on the application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674), we are finalizing the adoption of this measure for use in the IRF QRP as proposed.

2. Quality Measure Addressing the Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of Long-Term Care

[33] Frisina PG, Guellnitz R, Alverzo J. A time series analysis of falls and injury in the inpatient rehabilitation setting. Rehab Nurs. 2010; 35(4):141-146.

Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015)

Section 1899B(c)(1) of the Act directs the Secretary to specify quality measures on which PAC providers are required under the applicable reporting provisions to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to 5 quality domains, one of which is functional status, cognitive function, and changes in function and cognitive function. To satisfy these requirements, we proposed to specify and adopt an application of the quality measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), in the IRF QRP as a cross-setting quality measure that addresses the domain of functional status, cognitive function, and changes in function and cognitive function. The reporting of data for this measure would affect the payment determination for FY 2018 and subsequent years. This quality measure reports the percent of patients with both an admission and a discharge functional assessment and a goal that addresses function.

The National Committee on Vital and Health Statistics, Subcommittee on Health[34], noted: "[i]information on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations, that is, their functional status." This statement is supported by research showing that patient functioning is associated with important patient outcomes such as discharge destination and length of stay in

[34] Subcommittee on Health National Committee on Vital and Health Statistics, "Classifying and Reporting Functional Status" (2001).

inpatient settings,[35] as well as the risk of nursing home placement and hospitalization of older adults living the in community.[36] Functioning is important to patients and their family members.[37, 38, 39]

The majority of patients and residents who receive PAC services, such as care provided by SNFs, HHAs, IRFs and LTCHs, have functional limitations, and many of these patients are at risk for further decline in function due to limited mobility and ambulation.[40] The patient populations treated by SNFs, HHAs, IRFs and LTCHs vary in terms of their functional abilities at the time of the PAC admission and their goals of care. For IRF patients and many SNF residents, treatment goals may include fostering the patient's ability to manage his or her daily activities so that the patient can complete self-care and/or mobility activities as independently as possible, and if feasible, return to a safe, active, and productive life in a community-based setting. For HHA patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other HHA patients, the goal of care may be to slow the rate of functional decline to allow the person to remain at home and avoid institutionalization.[41] Lastly, in addition to having complex medical care needs for an extended period of time, LTCH patients often have limitations in functioning because of the nature of their

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[35] Reistetter TA, Graham JE, Granger CV, Deutsch A, Ottenbacher KJ. Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. Archives of Physical Medicine and Rehabilitation, 2010; 91:345-350.

[36] Miller EA, Weissert WG. Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259-297.

[37] Kurz, A. E., Saint-Louis, N., Burke, J. P., & Stineman, M. G. (2008). Exploring the personal reality of disability and recovery: a tool for empowering the rehabilitation process. *Qual Health Res, 18*(1), 90-105.

[38] Kramer, A. M. (1997). Rehabilitation care and outcomes from the patient's perspective. *Med Care, 35*(6 Suppl), JS48-57.

[39] Stineman, M. G., Rist, P. M., Kurichi, J. E., & Maislin, G. (2009). Disability meanings according to patients and clinicians: imagined recovery choice pathways. Quality of Life Research, *18*(3), 389-398.

[40] Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ. Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772-4.

[41] Ellenbecker CH, Samia L, Cushman MJ, Alster K. Patient safety and quality in home health care. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Vol 1.

conditions, as well as deconditioning due to prolonged bed rest and treatment requirements (for example, ventilator use). The clinical practice guideline Assessment of Physical Function[42] recommends that clinicians should document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan (that is, treatment plan) is an important aspect of patient and resident care in all of these PAC providers.

Given the variation in patient and resident populations across the PAC providers, the functional activities that are typically assessed by clinicians for each type of PAC provider may vary. For example, the activity of rolling left and right in bed is an example of a functional activity that may be most relevant for low-functioning patients or residents who are chronically critically ill. However, certain functional activities, such as eating, oral hygiene, lying to sitting on the side of the bed, toilet transfers, and walking or wheelchair mobility, are important activities for patients and residents in each PAC provider.

Although functional assessment data are currently collected in SNFs, HHAs, IRFs and LTCHs, this data collection has employed different assessment instruments, scales, and item definitions. The data collected cover similar topics, but are not standardized across PAC settings. Further, the different sets of functional assessment items are coupled with different rating scales, making communication about patient functioning challenging when patients transition from one type of provider to another. Collection of standardized functional assessment data across SNFs, HHAs, IRFs and LTCHs, using common data items, would establish a common language for patient functioning, which may facilitate communication and care

[42] Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89-103. Retrieved from http://www.guideline.gov/content.aspx?id=43918

coordination as patients transition from one type of provider to another. The collection of standardized functional status data may also help improve patient or resident functioning during an episode of care by ensuring that basic daily activities are assessed at the start and end of each episode of care with the aim of determining whether at least one functional goal is established.

The functional assessment items included in the proposed functional status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration (PAC-PRD) version of the CARE Item Set, which was designed to standardize assessment of patients' status across acute and post-acute providers, including SNFs, HHAs, IRFs and LTCHs. The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge to determine a patient's or resident's needs, evaluate patient or resident progress, and prepare a patient or resident and the patient's/resident's family for a transition to home or to another provider.

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3."[43] Reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled "The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability

[43] Barbara Gage et al., "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set " (RTI International, 2012).

Testing: Volume 2 of 3"[44] and the report entitled "The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3."[45] The reports are available on CMS' Post-Acute Care Quality Initiatives webpage at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.

The cross-setting function quality measure we proposed to adopt for the FY 2018 payment determination and subsequent years is a process measure that is an application of the quality measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). This quality measure was developed by the CMS. It reports the percent of patients with both an admission and a discharge functional assessment and a treatment goal that addresses function. The treatment goal provides documentation that a care plan with a goal has been established for the patient.

This process measure requires the collection of admission and discharge functional status data using standardized clinical assessment items, or data elements that assess specific functional activities, that is, self-care and mobility activities. The self-care and mobility function activities are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. For this quality measure, documentation of a goal for one of the function items reflects that the patient's care plan addresses function. The function goal is recorded at admission for at least one of the standardized self-care or mobility

[44] Ibid.
[45] Ibid.

function items using the 6-level rating scale.

To the extent that a patient has an incomplete stay (for example, for the purpose of being admitted to an acute care facility), collection of discharge functional status data might not be feasible. Therefore, for patients with incomplete stays, admission functional status data and at least one treatment goal would be required, and discharge functional status data would not be required to be reported.

A TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, including the feasibility of implementing the measure across PAC settings, which included the IRF setting. The TEP supported the implementation of this measure across PAC providers and also supported our efforts to standardize this measure for cross-setting use. Additionally, the MAP met on February 9, 2015 and provided input to us on the quality measure. The MAP conditionally supported the specification of an application of the quality measure, Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015) for use in the IRF QRP as a cross-setting measure. The MAP conditionally supported this measure pending NQF-endorsement and resolution of concerns about the use of two different functional status scales for quality reporting and payment purposes. The MAP reiterated its support for adding measures addressing function, noting the group's special interest in this PAC/LTC core concept. More information about the MAPs recommendations for this measure is available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

This quality measure was developed by CMS. The specifications are available for review at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-

Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures focused on assessment of function for PAC patients. We are also unaware of any other cross-setting quality measures for functional assessment that have been endorsed or adopted by another consensus organization. Therefore, we proposed to specify and adopt this functional assessment measure for use in the IRF QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures. As described in more detail in section IX.I.2, of this final rule, the first data collection period is 3 months (October 1, 2016 to December 31, 2016), and the subsequent data collection periods are 12-months in length and follow the calendar year (that is, January 1 to December 31).

We proposed that data for this proposed quality measure be collected using the IRF-PAI, with submission through the QIES ASAP system. For more information on IRF QRP reporting through the QIES ASAP system, we refer readers to http://cms.gov/ Medicare/Quality-Initiatives-PatientAssessment-Instruments/IRF-QualityReporting/index.html and http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html.

The measure calculation algorithm are: (1) for each IRF stay, the records of Medicare patients discharged during the 12-month target time period are identified and counted; this count is the denominator; (2) the records of Medicare patients with complete stays are identified, and the number of these patient stays with complete admission functional assessment data and at least one self-care or mobility activity goal and complete discharge functional assessment data is counted; (3) the records of Medicare patients with incomplete stays are identified, and the

number of these patient records with complete admission functional status data and at least one self-care or mobility goal is counted; (4) the counts from step 2 (complete IRF stays) and step 3 (incomplete IRF stays) are summed; the sum is the numerator count; and (5) the numerator count is divided by the denominator count and multiplied by 100 to calculate this quality measure. (Please note that part of step 5, the conversion to a percent value, was accidentally omitted from the FY 2016 IRF PPS proposed rule).

For purposes of assessment data collection, we proposed to add a new section into the IRF-PAI. The new proposed section will include new functional status data items that will be used to calculate the quality measure, the Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), should this proposed measure be adopted. The items to be added to the IRF-PAI, which assess specific self-care and mobility activities, would be based on functional items included in the PAC-PRD version of the CARE Item Set.

The specifications and data elements for the quality measure are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

The proposed function items to be included within the IRF-PAI do not duplicate existing items currently used for data collection within the IRF-PAI. While many of the items to be included have labels that are similar to existing items on the IRF-PAI, there are several key differences between the two assessment item sets that may result in variation in the patient assessment results. Key differences include: (1) the data collection and associated data collection instructions; (2) the rating scales used to score a patient's level of independence; and (3) the item definitions. A description of these differences is provided with the measure

specifications on CMS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

This measure is calculated using data from two points in time, at admission and discharge (see Section IX.I: Form, Manner, and Timing of Quality Data Submission of this final rule). The items would assess specific self-care and mobility activities, and would be based on functional items included in the PAC-PRD version of the CARE Item Set. The items have been developed and tested for reliability and validity in SNFs, HHAs, IRFs, and LTCHs. More information pertaining to item testing is available on our Post-Acute Care Quality Initiatives webpage at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.

For more information on the data collection and submission timeline for the adopted quality measure, refer to section IX.I.2 of this final rule. Additional information regarding the items to be added to the IRF-PAI may be found on CMS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

Lastly, in alignment with the requirements of the IMPACT Act to develop quality measures and standardize data for comparative purposes, we believe that evaluating outcomes across the post-acute settings using standardized data is an important priority. Therefore, in addition to proposing a process-based measure for the domain in the IMPACT Act of "[f]unctional status, cognitive function, and changes in function and cognitive function," which is included in this year's final rule, we also intend to develop outcomes-based quality measures, including functional status and other quality outcome measures to further satisfy this domain.

These measures will be proposed in future rulemaking to assess functional change for each care setting as well as across care settings.

We sought public comments on our proposal to adopt the application of the quality measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015) for the IRF QRP, with data collection starting on October 1, 2016, for the FY 2018 payment determination and subsequent years. The responses to public comments on this measure are discussed below in this section of the final rule. We note that we received many comments about the standardized (that is CARE) items that pertain to several of the 5 proposed function quality measures. Many of these comments are provided in this final rule as part of review of comments about this quality measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015).

Comment*:* MedPAC did not support the adoption of the function process measure in the IRF QRP and urged CMS to adopt outcomes measures focused on changes in patient physical and cognitive functioning while under a provider's care.

Response*:* We appreciate MedPAC's preference for moving toward the use of functional outcome measures to assess the patient's physical and cognitive functioning under a provider's care, and we believe that using this process measure at this time will give us the data we need to develop a more robust outcome-based quality measure on this topic in the future. The proposed function quality measure, the Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), has attributes to enable outcomes-based evaluation by the provider.

Such attributes include the assessment of functional status at two points in time, admission and discharge, enabling the provider to identify, in real time, changes, improvement or decline, as well as maintenance. Additionally, the proposed quality measure requires that the provider indicate at least one functional goal associated with a functional activity, and the provider can calculate the percent of patients who meet goals. Such real time use enables providers to engage in person-centered goal setting and the ability to use the data for quality improvement efforts. With regard to burden, we would like to note that this process measure primarily uses the same data elements as the functional outcome measures that were also proposed for the IRF QRP. IRF providers only need respond to each data item once on admission and discharge in order to inform multiple measures. The reporting of at least one functional assessment goal and the wheelchair mobility items are the only data required for this measure that are unique to this measure.

Comment*:* Several commenters expressed their support for cross-setting quality measure data because they facilitate their goal of providing high-quality care and conforming to best practices, and conveyed their request that CMS ensure the implementation of cross setting measures using standardized data and common definitions. Some of these commenters questioned whether the proposed function items were standardized and interoperable. One commenter noted that the four functional outcome measures were not proposed for SNFs or LTCHs, nor was there a time frame discussed for including them in the future.

Response*:* We agree with the importance of cross-setting standardization and we agree that assessment items and quality measure should promote best practices. The quality measure, an Application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015),

which is being proposed as a cross-setting measure for SNFs, IRFs and LTCHs is an application of a measure that was NQF-endorsed on July 23, 2015 (http:www.qualityforum.org/QPS/2631). The specifications for this cross-setting measure are available on the IRF QRP webpage at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html. The IMPACT Act requires interoperability through the use of such standardized data. There will be instances in which some provider types may need more or less standardized items than other provider types—but where required by the IMPACT Act we will work to ensure that such core items are standardized. For example, we proposed functional outcome measures for IRFs and are currently developing functional outcome measures, including self-care and mobility quality measures for use in the SNF setting. These outcome function quality measures are intentionally being designed to use the same standardized functional assessment items that are included in the proposed function process measure, which will result in a limited additional reporting burden. To clarify which function items are included in each function measure for each QRP, we added a table to the document entitled, Inpatient Rehabilitation Facility Quality Reporting Program: Specifications of Quality Measures Adopted in the FY 2016 Final Rule, which clearly identifies which functional assessment items are used in the cross-setting process measure, as well as the setting-specific IRF outcome measures. The document is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

Comment*:* One commenter supported the concept of measuring function and monitoring the percentage of patients with completed functional assessments. This commenter was pleased that the quality measure, an Application of Percent of LTCH Patients with an Admission and

Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631, endorsed on July 23, 2015), was proposed for multiple PAC settings in accordance with the IMPACT Act. This commenter noted that the proposed quality measure is an application of the LTCH measure under review at NQF, and that fewer functional assessment items are in the proposed measure when compared to the LTCH process quality measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. For example, the commenter noted that the Confusion Assessment Method (CAM©) items and the Bladder Continence items are not included in the proposed application of the quality measure. Several commenters questioned why the CARE function items on the proposed IRF-PAI, MDS 3.0 and LTCH CARE Data Set are not the same set of items and believed the measure, an Application of The Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015), should be the same set of items.

Response*:* The proposed function process measure, specified as a cross-setting quality measure, is an application of the measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed July 23, 2015). The application includes only selected function items from the measure, and thus is not exactly the same. The application of the measure is standardized across multiple settings. We believe that standardization of assessment items across the spectrum of post-acute care is an important goal. In the cross-setting process quality measure, there is a common core subset of function items that will allow tracking of patients' functional status across settings. We recognize that there are some differences in patients' clinical characteristics, including medical acuity, across the LTCH, SNF and IRF settings, and that certain functional

items may be more relevant for certain patients. Decisions regarding item selection for each quality measure were based on our review of the literature, input from a TEP convened by our measure contractor, our experiences and review of data in each setting from the PAC-PRD, and public comments.

As to the comments regarding the PAC assessment instruments, a core set of mobility and self-care items are proposed for IRFs, SNFs, and LTCHs, and are nested in the proposed Section GG of the IRF-PAI. Additional function items are included on the IRF-PAI and LTCH CARE Data Set due to the proposal or adoption of various other outcome-based quality measures in those specific settings. Therefore, we believe that the core set of items in the proposed Section GG are standardized to one another by item and through the use of the standardized 6-level rating scale. We will work to harmonize the assessment instructions that better guide the coding of the assessment(s) as we believe that this will lead to accurate and reliable data, allowing us to compare the data within each setting. To clarify which function items are included in each function measure for each QRP, we added a table to the document entitled, Inpatient Rehabilitation Facility Quality Reporting Program: Specifications of Quality Measures Adopted in the FY 2016 Final Rule, which clearly identifies which functional assessment items are used in the cross-setting process measure, as well as the setting-specific IRF outcome quality measures. The document is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

Comment: One commenter noted that the reason for standardized assessment items "would establish a common language for patient and resident functioning, which may facilitate communication and care coordination as patients and residents transition from one type of

provider to another," and asked CMS to provide data on the number of percent of patients/residents that transition from one type of provider to another. The commenter further requested information about why the current measures fail to provide clinicians with the information needed.

Response: Several studies have documented patient/resident transition patterns following discharge from the hospital and continuing for 30, 60, or 90 days.[46,47, 48] While the exact proportions discharging to each type of care vary slightly across the years, the proportion of acute hospital admissions being discharged to PAC has grown from 35 percent in 2006 to 43 percent in more recent years (MedPAC, 2014). Among those discharged to PAC, the majority are discharged to SNFs or HHAs, and a much smaller proportion is discharged to IRFs and LTCHs. Further, many individuals in PAC settings continue to transition to subsequent sites of care. Common discharge patterns from the IRF, for example, include over 75 percent of cases continuing into HHA or outpatient therapy services. SNF cases are commonly discharged home with either outpatient therapy or home health services. A 2009 report outlining these issues http://aspe.hhs.gov/health/reports/09/pacihs/report.pdf includes a summary of the most common PAC transition patterns for Medicare FFS Beneficiaries in 2006[49.] This report shows that over

[46] Gage, B., Morley, M., Ingber, M., & Smith, L. (2011). Post-Acute Care Episodes Expanded Analytic File: RTI International. Prepared for the Assistant Secretary for Planning and Evaluation. Retrieved from http://aspe.hhs.gov/health/reports/09/pacihs/report.pdf

[47] Gage, B., Morley, M., Constantine, R., Spain, P., Allpress, J., Garrity, M., & Ingber, M. (2008). Examining Relationships in an Integrated Hospital System: RTI International. Prepared for the Assistant Secretary for Planning and Evaluation. Retrieved from http://aspe.hhs.gov/health/reports/08/examine/report.html

[48] Gage, B., Pilkauskas, N., Dalton, K., Constantine, R., Leung, M., Hoover, S., & Green, J. (2007). Long-Term Care Hospital (LTCH) Payment System Monitoring and Evaluation Phase II Report RTI International. Prepared for the Centers for Medicare & Medicaid Services. Retrieved from http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/downloads/rti_ltchpps_final_rpt.pdf

49 Gage, B., Morley, M., Spain, P., & Ingber, M. (2009) Examining Post Acute Care

20 percent of all hospital admissions in 2008 were discharged to a SNF, IRF, or LTCH. Among those 3 settings, over two-thirds of each were discharged from a SNF to another PAC setting or readmitted directly to the acute hospital. Specifically, 66 percent of all SNF FFS admissions, 91 percent of IRF post-acute admissions, and 73 percent of LTCH post-acute admissions continued on to additional post-care. These materials document the various patterns of care for Medicare beneficiaries using PAC. The episode trajectories underscore the importance of using standardized language to measure patient/resident complexity across all settings.

Comment*:* One commenter noted that the proposed function measure includes reporting of a function goal as a way to document that patients have a care plan that addresses function, and that this reporting of function goals was not part of the original PAC-PRD. This commenter further noted that reporting of only one goal was not ideal, because many patients have goals for multiple functional limitations and the number of standardized functional assessment items is limited compared to the full set of function items tested as part of the PAC-PRD. Finally, this commenter indicated that goals of care may be to improve function, or may be focused on maintenance of a patient's function.

Response*:* The proposed function process measure requires a minimum of 1 goal per patient stay; however, clinicians can report goals for every self-care and mobility item included in the proposed Section GG of the IRF-PAI. The IMPACT Act specifically mentions goals of care as an important aspect of the use of standardized assessment data, quality measures, and resource use to inform discharge planning and incorporate patient preference. We agree that for many PAC patients, the goal of therapy is to improve function and we also recognize that, for example, for a PAC patient with a progressive neurologic condition, delaying decline may be the

Relationships in an Integrated Hospital System. Prepared for the Assistant Secretary for Planning and Evaluation. Retrieved from http://aspe.hhs.gov/health/reports/09/pacihs/report.pdf

goal. We believe that individual, person-centered goals exist in relation to individual preferences and needs. We will provide instructions about reporting of goals in a training manual and in training sessions to clarify that goals set at admission may be focused on improvement of function or maintenance of function.

Comment*:* Several commenters suggested that CMS, in lieu of collecting the proposed five functional measures, conduct a study of a nationally-representative sample of IRFs to collect data on both the FIM® and CARE Tool items. Some commenters suggest that the CARE data could be used to develop a FIM®/CARE crosswalk, and a new case mix classification system. Other commenters discouraged CMS from developing a FIM®/CARE crosswalk.

Response*:* We recognize the potential contribution of developing a crosswalk to transform the FIM® data to CARE data and will take this recommendation under advisement.

Comment*:* One commenter suggested that CMS conduct additional testing of the CARE function items with specific patient subpopulations. This commenter also suggested research studies that compare CARE items with other instruments across diverse PAC populations. They suggested this data be used to improve the CARE items or replace them with other items to address any potential floor or ceiling effects. This commenter also suggested studies that compare models of care for subpopulations so as to elicit best practices related to complex conditions.

Response*:* We agree that adoption of the proposed function quality measures would offer many opportunities to examine best practices for caring for IRF patients. Examining the data for any floor and ceiling effects in special populations is also a very worthy research idea. With regard to examining the CARE data against other functional assessment instrument data, as part of the PAC-PRD analyses, we compared data from the existing items (that is MDS, OASIS and

the FIM® instrument) with data from the analogous CARE items. More specifically, we ran cross tabulations of FIM® scores and CARE scores for the patients in the PAC-PRD to compare scores. A full description of the analyses and the results are provided in the report, The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set and Current Assessment Comparisons Volume 3 of 3, and the report is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.

Comment: Two commenters suggested further reliability and validity testing of the function items. Some commenters noted concerns that the CARE item inter-rater reliability does not exhibit satisfactory inter-rater reliability among clinicians in IRFs, and suggested CMS utilize existing items until further modifications can be made to the CARE functional scale. Another commenter was concerned that no external reliability or validity testing of the CARE tool items had been done to assess its applicability across sites and provider types, outside of the inter-rater reliability assessed for the PAC-PRD.

Response: The reliability testing results mentioned by these commenters was only one of several reliability analyses conducted on these items as part of the PAC–PRD, which can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Reporton-Reliability-Testing-Volume-2-of- 3.pdf. That particular result was a reflection of the small sample size available for analysis. In addition to the inter-rater reliability study mentioned by these commenters, we examined inter-rater reliability of the CARE items using videotaped case studies, which included

550 assessments from 28 facilities, of which 237 assessments were from 8 IRFs. We also conducted analyses of the internal consistency of the function data. The results of these analyses indicate moderate to substantial agreement, which suggests sufficient reliability for the CARE items. In addition to the PAC-PRD analyses, as part of the NQF application process, we conducted additional analyses focused on the 6 submitted IRF and LTCH function quality measures, including item-level, scale-level and facility-level analyses testing the reliability and validity of the CARE function data. A description of the analyses and the results are available on the NQF website's Person- and Family-Centered Care project at http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867. Therefore, given the overall findings of the reliability analyses, we believe that the proposed function measure is sufficiently reliable for the IRF QRP.

We understand the importance of education in assisting providers to collect accurate data and we worked in the past with public outreach including training sessions, training manuals, webinars, open door forums and help desk support. Further, we note that as part of the IRF QRP, we intend to evaluate the national-level data for this quality measure submitted by IRFs to CMS. These data will inform ongoing measure development and maintenance efforts, including further analysis of reliability and validity of the data elements and the quality measure. Finally, we agree that ongoing reliability and validity testing is critical for all items used to calculate quality measures. For external reliability and validity, we encourage stakeholders to design and conduct reliability testing. We are aware that 1 external entity conducted CARE function data reliability testing on the SNF population and reported the testing procedures and results in NQF measure documents which can be found on the NQF's Person- and Family-Centered Care project at http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867.

Comment*:* Several commenters were concerned that the measure, an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015) was not NQF-endorsed.

Response*:* We agree that the NQF endorsement process is an important part of measure development. We have proposed *an applicatio*n of the quality measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. This quality measure was ratified by the NQF Board of Directors on July 22, 2015, and has been endorsed by NQF effective July 23, 2015.

Comment*:* One commenter noted that IRFs are already required to develop a care plan and this commenter did not support requiring additional documentation of the care plan as part of the measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015).

Response*:* To clarify, the proposed function measure requires reporting of a minimum of one self-care or mobility goal. We are ensuring that a minimum of one goal is represented in the plan of care, which is a best practice.

Comment*:* Several commenters were concerned that the measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631, endorsed on July 23, 2015), does not guarantee that the patient's plan of care will be reflective of the functional assessment or contain goals associated with the assessment. Several commenters expressed concerns regarding the lack of benchmarks for goal-setting for the CARE function items. One commenter expressed concerns regarding the requirement to document a functional goal in the quality measure in the absence of

data to guide goal-setting. One commenter noted that this process measure does not have a process to ensure a patient's plan of care includes a functional goal; this commenter noted a preference for outcome measures.

Response*:* We appreciate the commenter's concern about establishing function goals for IRF patients. The proposed quality measure requires a minimum of 1 self-care or mobility goal per patient stay. The documentation of a functional goal requires a valid numeric score indicating the patient's expected level of independence at discharge. With regard to benchmarks and having data to guide goal-setting, licensed clinicians can establish a patient's discharge goal(s) based on the admission assessment, discussions with the patient and family, by using their professional judgment and the professionals' standard of practice. For example, a patient may require the assistance of 2 helpers to get from a sitting to standing position on admission (Level 1 for Sit to Stand) and the goal is for the patient to progress to requiring supervision for the same activity by discharge (level 4 for Sit to Stand). National benchmarks could be developed over time based on national data.

Comment: One commenter was concerned that no data was provided clearly linking improved outcomes to this process measure.

Response*:* We believe that there is evidence that conducting functional assessments is a best practice for improving functional outcomes. The NQF requirement for endorsing process measures is that the process should be evidence-based, such as processes that are recommended in clinical practice guidelines. As part of the NQF process, we submitted several such clinical practice guidelines[50,51,52] to support this measure, and referenced another cross-cutting clinical

50 Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89-103. Retrieved from http://www.guideline.gov/content.aspx?id=43918

practice guideline in the proposed rule. The clinical practice guideline Assessment of Physical Function[53] recommends that clinicians should document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan (that is, treatment plan) is an important aspect of patient/resident care for all PAC providers.

Comment: Several commenters expressed concern that the proposed function process measure, an Application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), does not meet the requirements of the IMPACT Act because measures must be outcome based. One commenter asserted that the proposed measure did not satisfy the specified IMPACT Act domain, as the measure is not able to report on changes in function, and another commenter claimed that the measure does not satisfy the reporting of data on functional status. Finally, a comment stated that the measure does not have an appropriate numerator, denominator, or exclusions, lacks NQF endorsement, fails to be based on a common standardized assessment tool, is not risk adjusted, and lacks evidence that associates the measure with improved outcomes. One commenter claims that because the specifications for the proposed measure are inconsistent with the measure specifications posted by NQF for the measure that is

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51 Centre for Clinical Practice at NICE (UK). (2009). Rehabilitation after critical illness (NICE Clinical Guidelines No. 83). Retrieved from http://www.nice.org.uk/guidance/CG83

52 Balas MC, Casey CM, Happ MB. Comprehensive assessment and management of the critically ill. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 600-27. Retrieved from http://www.guideline.gov/content.aspx?id=43919

Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89-103. Retrieved from http://www.guideline.gov/content.aspx?id=43918.

under endorsement review, we failed to meet the requirements under the IMPACT Act to provide measure specifications to the public, and further asserts that one cannot determine the specifications that are associated with the proposed measure, which is an application of the NQF version of the measure.

Response: We believe that the proposed function measure meets the requirements of the IMPACT Act. Although we have specified this measure as a process measure, the measure itself has attributes that enable outcomes-based evaluation by the provider. Such attributes include the assessment of functional status at two points in time, admission and discharge, enabling the provider to identify, in real time, changes, improvement or decline, as well as maintenance. Additionally, the proposed quality measure requires that the provider indicate at least one functional goal associated with a functional activity, and providers can calculate the percent of patients who meet and exceed goals. Such real time use enables providers to engage in person-centered goal setting and the ability to use the data for quality improvement efforts. Therefore, we disagree with the observation that the proposed process quality measure does not satisfy the domain requirements specified in the IMPACT Act associated with functional status and functional change.

We also intend to use the data we collect on this measure to better inform our development of a better outcome-based cross-setting function measure. To the extent that commenters are concerned that the proposed function measure is not outcome-based because it is not risk adjusted, the TEP that reviewed this measure considered, but did not recommend, that the measure be risk-adjusted because completion of a functional assessment is not affected by the medical and functional complexity of the resident/patient. Rather, clinicians are able to report that an activity was not attempted due to the resident's or patient's medical condition or a safety

concern (including patient or clinician safety), and clinicians take this complexity into account when setting goals.

We disagree with the commenter that we failed to meet the requirements under the IMPACT Act to provide measure specifications to the public. . The specifications were identified in the FY 2016 IRF PPS proposed rule (80 FR 23332) as being posted at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html. Also, we would like to clarify that the proposed function process quality measure is an application of the measure posted on the NQF website, which is the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed July 23, 2015). The measure, NQF #2631, which was developed for LTCHs was proposed and finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298) for adoption in the LTCH QRP. An application of this measure, the cross-setting measure, was proposed in the FY 2016 IRF PPS proposed rule (80 FR 23376 through 23379), and similarly it was proposed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24602 through 24605) and the FY 2016 SNF QRP proposed rule (80 FR 22073through 22075). This cross-setting version, *an application* of the LTCH QRP quality measure, was proposed based on guidance from multiple TEPs convened by our measure contractor, RTI International.

Finally, we have addressed the comment regarding modifying the various PAC setting patient assessment instruments to use a single standardized assessment tool in response to similar comments above.

Comment: Several commenters noted the significance of adequate training, stressing the importance of appropriate coding of the new items used to calculate the proposed measures, and

one commenter specifically asked for clarification on which health care professional would be responsible for performing the assessment, while another asked that the IRF-PAI Training Manual be provided with the necessary coding and assessment instructions for the provider's reference in a timely manner. One commenter suggested transparency with regard to how CMS will implement the new quality measures and stated that training for all providers, including instructions for the revised IRF-PAI Training Manual, would be needed. The commenter suggested open door forums and training webinars for providers. One commenter recommended that training be available at least 5 months prior to implementation, as both national and local training would be needed.

Response*:* We agree with the importance of thorough and comprehensive training, and we intend to provide such training in the near future for all updates to the IRF-PAI and assessment requirements. In addition to the manual and training sessions, we will provide training materials through the CMS webinars, open door forums, and help desk support. We welcome ongoing input from stakeholders on key implementation and training considerations, which can be submitted via email: PACQualityInitiative@cms.hhs.gov .

Comment*:* Several commenters noted that the items included in the IRF-PAI differ from those tested during the PAC-PRD and represented a limited set of items from the original CARE Tool. One of these commenter suggested that the contributions of occupational therapy may not be measureable with the limited set of items. Another commenter suggested that the assessment time frame used in the PAC-PRD is different than the assessment time frame for the proposed items and noted that the definition of level 1 was modified to include the assistance of 2 or more helpers.

Response*:* The PAC-PRD tested a range of items, some of which were duplicative, to

identify the best performing items in each domain. Select items were removed from the item set where testing results and clinician feedback suggested the need for fewer items to be included in a particular measure or scale. We also received feedback on the items proposed for inclusion on the process quality measure from a cross-setting TEP convened by our measure development contractor, RTI International during this year's pre-rulemaking process. The proposed measure was based on these analyses and input. Other changes from the original PAC-PRD items included incorporating instructional detail from the manual and training materials directly into the data collection form and updating skip patterns to minimize burden. We agree that the contribution of occupational therapy, as well as other clinical disciplines, should be reflected in all item and measure development. During the PAC-PRD, clinicians from many different disciplines collected CARE data, including occupational therapists (OTs). In addition, the items were developed with the input from those individuals who would be performing the assessments, including OTs.

With regard to the assessment time frame for the CARE function items, we instructed clinicians during the PAC-PRD to use a 2-day time frame if the patients were admitted before 12 PM (noon) or 3 calendar days if the patients were admitted after 12 p.m. (noon). Our exit interviews revealed that most patients were admitted to the IRF after 12 p.m. and that clinicians used 3 calendar days. Therefore, we proposed to use the assessment time frame that most clinicians used during the PAC-PRD. With regard to the definition of level 1 to include the assistance of 2 or more helpers, this instruction was provided in the CARE Training Manual, but was not on the CARE Tool assessment form. User feedback included a suggestion to add this phrase onto the data set itself so that clinicians were aware of this scoring example.

Comment: Several commenters were concerned about the potential for confusion

between the FIM® and the CARE rating scales.

Response*:* During the PAC-PRD, our training included a discussion of CARE functional items and scales, as well as differences between the FIM® and CARE items and rating scale. We share the commenters' concerns related to ensuring data accuracy. We intend to conduct comprehensive training prior to implementation of the CARE function items, as well as develop comprehensive training materials. Further, to ensure data accuracy, we intend to propose through future rulemaking a process and program surrounding data validation and accuracy analysis.

Comment: Several commenters were concerned that historical FIM® data for benchmarking will be lost if the FIM® instrument is replaced by CARE items in the future.

Response*:* We appreciate the commenters' concerns about the historical availability of FIM® data. When the IRF-PAI was implemented in 2002, researchers examined differences in IRF data prior to and after 2002 to better understand adjustments that would be needed to make fair comparisons of IRF data across these years[54, 55]

Comment*:* A few commenters stated that FIM® instrument functional data should satisfy measure requirements, because the NQF measure requires valid function scores.

Response*:* To clarify, the proposed function quality measure, an Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), reports standardized functional assessment (that is, CARE) data at admission and discharge as well as at least one functional

[54] Granger, C. V., Deutsch, A., Russell, C., Black, T., & Ottenbacher, K. J. Modifications of the FIM instrument under the inpatient rehabilitation facility prospective payment system. American Journal of Physical Medicine & Rehabilitation, 2007; 86(11), 883-892.

[55] Deutsch, A., Granger, C. V., Russell, C., Heinemann, A. W., & Ottenbacher, K. J. Apparent changes in inpatient rehabilitation facility outcomes due to a change in the definition of program interruption. Archives of physical medicine and rehabilitation, 2008; 89(12), 2274-2277.

status discharge goal. This description is consistent with the technical description submitted to NQF for the measure, Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan (NQF #2631; endorsed on July 23, 2015), which is available on the Patient- and Family-Centered Care Project Measures website at http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867. In our NQF Measure Information Form, we defined the valid scores using the CARE 6-level rating scale, along with activity not attempted codes, and we listed the names of the CARE function items (see Numerator Statement Detail - Section 5.6 of the NQF Measure Information Form). The commenter's description of the use of "valid codes" for the measure seems to refer to the Numerator Statement (section 5.4) on the NQF Measure Information Form, which is intended to be a brief narrative of the description of the numerator. The Numerator Statement Detail (Section 5.6) includes the following details: Valid scores/codes for the self-care items are: 06 – Independent, 05 - Setup or clean-up assistance, 04 - Supervision or touching assistance, 03 - Partial/moderate, assistance, 02 - Substantial/maximal assistance, 01 – Dependent, 07 - Patient Refused, 09 - Not applicable, 88 - Not attempted due to medical condition or safety concerns. Valid scores/codes for the mobility items are: 06 – Independent, 05 - Setup or clean-up assistance, 04 - Supervision or touching assistance, 03 - Partial/moderate assistance, 02 - Substantial/maximal assistance, 01 – Dependent, 07 - Patient Refused, 09 - Not applicable, 88 - Not attempted due to medical condition or safety concerns. Therefore, we disagree that other function items or rating scales could be used to calculate this measure. The calculation of this measure is based on the CARE scores/codes and labels and stem as a result of item testing conducted and provided in the NQF application materials, which are available at http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867.

Comment*:* One commenter expressed concerns regarding the CARE function rating scale and clinician safety. The commenter expressed concern over the CARE coding that uses the patient's "usual performance" versus use of "most dependent performance" to determine functional status coding and the effect on discharge planning. The commenter expressed concerns regarding clinician difficulty in using the CARE function rating scale during pilot testing of CARE function items and makes suggestions regarding rating scale modification. The commenter also considered the definition of the Substantial/Maximal Assistance to be too broad and insufficiently precise.

Response*:* We share the commenters' commitment to ensuring patient and clinician safety, and this is of utmost importance to us. With regard to the assessment of usual versus the most dependent performance, consistent with current clinical practices, we would encourage IRF clinicians to monitor for variation in patient functioning at different times of the day or in different environment (that is, therapy gym and the patient's room). We agree that clinicians' observation of any variation should be shared with the patient and family member at the time of discharge, including the amount of variation and the time of day or environment. For example, 1 patient who has a co-existing condition of osteoarthritis may require more assistance with toilet transfers in the morning than the evening, while a patient after a stroke may require more assistance with toilet transfers in the evening compared to the morning due to fatigue. A single function score alone does not convey all the information that should be shared with the patient and family. In addition, variations in patient functioning should also be documented in the patient's medical record. With regard to using the concerns about the CARE rating scale, we would like to note that we conducted exit interviews as part of the PAC-PRD, and that clinical coordinators "commented positively about the coding approach of determining whether a patient

could do at least half the task or not, and if they could, whether they could safely leave the patient to complete the task without supervision. For the definition of Substantial/maximal assistance, the LTCH staff appreciated being able to note small changes from complete dependence to being able to complete a task with much assistance (over half the task was completed by the helper), particularly for the most impaired populations." (March 2012 - Post-Acute Care Payment Reform Demonstration: Final Report Volume 1 of 4, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/PAC-PRD_FinalRpt_Vol1of4.pdf.)

We intend to provide training that would include descriptions and examples of the CARE rating scale in order to clarify any concerns about the rating levels. The development of the CARE function items, including the definitions for each activity, were selected based on a review of all existing items used by LTCHs, IRFs, SNFs and HHAs, a review of the relevant literature, and input from stakeholders such as clinicians and researchers. The items were designed to focus on a single activity rather than multiple activities, so that clinicians completing assessments did not have to determine a person's level of independence with multiple activities to then compute a composite score based on different levels of independence in these component activities. For example, the FIM® includes an item called "Grooming" that addresses washing hands and face, combing hair, brushing teeth, shaving, applying makeup. To score this item, the clinician needs to consider how much help was needed for each of these component activities and then derive a composite overall assessment of the patient's status for the activities as a whole for the FIM® score. For the CARE item, one activity is considered, oral hygiene, and there is one score reported that reflects the person's overall level of help needed for that activity. The CARE function rating scale was also developed based on input from the clinical communities

and research that used the existing rating scales. During PAC-PRD on-site training, when we explained differences between the existing and CARE rating scales, we received positive feedback about the CARE rating scale. We additionally conducted alpha and beta testing of the items before the PAC-PRD began in order to select rating scale, items and definitions that made sense to clinicians and were consistent with clinical logic. We also maintained a help desk and had frequent phone calls with site coordinators to ensure that we clarified any coding issues or item definitions. We also conducted extensive exit interviews with participating sites. This feedback was incorporated into the CARE items that we have proposed for the cross-setting function measure. Based on our experiences, we believe that the CARE items and associated rating scale represent a simple, but comprehensive method of documenting functional abilities at admission and discharge.

Comment: One commenter stated that the CARE items duplicate the existing IRF-PAI Items. This commenter indicated that CMS' description of the differences between the CARE items and the existing IRF-PAI items are not actually differences.

Response: As noted in the proposed rule, the key differences between the IRF-PAI and the CARE function items include: (1) The data collection and associated data collection instructions; (2) the rating scales used to score a patient's level of independence; and (3) the item definitions. We believe that the proposed standardized (that is, CARE) function items do not duplicate existing items currently used for data collection within the IRF–PAI. While many of the items to be included have labels that are similar to existing items on the IRF–PAI, there are several key differences between the assessment item sets that may result in variation in the patient assessment results. For example, the standardized CARE items are scored using a 6-level rating scale, while the existing IRF-PAI items are scored using a 7-level rating scale. The CARE

items include 4 items focused on the activity or walking and 2 items focused on wheelchair mobility. The walking items are Walking 10 feet (even surfaces), walking 50 feet with two turns, Walking 150 feet and Walking 10 feet on uneven surfaces, and the wheelchair mobility items are Wheel 50 feet with 2 turns and Wheel 150 feet. The FIM® includes 1 item that is scored based on either walking, wheelchair mobility, or both.

Comment: One commenter disagreed with the CMS's statement in the proposed rule that "[w]e are not aware of any other quality measures for functional assessment that have been endorsed or adopted by another consensus organization for the IRF setting." The commenter notes that the FIM® tool is endorsed by the American Academy of Physical Medicine and Rehabilitation and the American Congress of Rehabilitation Medicine, and that both of these organizations are considered consensus organizations in the IRF industry. The commenter also noted that a recent NQF meeting included discussions of the FIM® instrument and the CARE function items.

Response: The FIM is an assessment tool, and we believe that such a tool is different from a quality measure. A quality measure can be developed using an instrument or a set of items, but a quality measure has defined specifications beyond the instrument or items. For this reason, we believe our statement in the proposed rule is accurate.

Comment: One commenter questioned the utility of the data collected under this process measure Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function" (NQF #2631; endorsed on July 23, 2015).

Response: We believe that monitoring facility and provider activities using process measures initially will allow for the development of more robust outcome-based quality measures. By using the data collected with this quality measure, the IRF staff can calculate the

percent of patients who meet or exceed their discharge functional status goals, which were established at admission with the patient and family. The function goal is established at admission by the IRF clinicians with input from the patient and family, demonstrating person and family-centered care. It should be noted, we proposed functional outcome measures, specifically self-care and mobility quality measures, in addition to this proposed cross-setting process measure. These outcome function quality measures are intentionally being designed to use the same standardized functional assessment items that are included in the proposed cross-setting process measure in order to capitalize on the data collected using the currently proposed process measure, which will inform further development while allowing for the consideration of limited additional burden.

Comment*:* Several commenters requested specific guidance on scoring IRF-PAI items, such as the cognitive patterns items and the self-care and mobility items.

Response: We provide scoring guidance in training manuals, training sessions, and through the help desks. We intend to provide comprehensive training as they do each time the assessment items change, and we will address these types of inquiries as part of our training efforts.

Comment*:* Many commenters expressed concerns regarding the burden associated with the addition of the standardized (that is, CARE) function items to the IRF-PAI for quality reporting purposes. Many of these commenters indicated they support outcomes-based quality measures focused on function, but did not support the proposed cross-setting process measure. Several commenters noted their lack of support was due to the burden of collecting overlapping items for function, but with different scales. Many commenters stated that adding the CARE function items to the IRF-PAI would result in data duplication, because the IRF-PAI includes

FIM® function items, which are used for payment. Commenters expressed concerns regarding the subtle differences between the 6-level rating scale for the CARE function items and the 7-level rating scale for the FIM® function items, indicating that simultaneous use of the 2 scales could result in clinician confusion, potential risk to accuracy of clinical communication and data, potential risk to patient and clinician safety, and questionable validity and reliability of both scales. Several noted the importance of minimizing administrative burden on providers to limit duplication of effort and the risk of error associated with dual data entry. Additional comments included the increased length of the IRF-PAI from 8 to 18 pages; cost burden, as many IRFs may need to hire additional full-time clinical staff; potential for inconsistency associated with clinicians collecting and completing risk adjustment data for the function quality measures; time and cost burden and resources associated with training clinicians in use of the CARE function items, in addition to the usual training clinicians have to undergo to learn the FIM® instrument; costs associated with updating electronic medical records; and potential for data collection requirements to take away from direct patient care time. One commenter suggested CMS to consider the effect of the cost of compliance with the new data collection requirements on smaller-sized IRF units, including cost implications and their ability to provide quality care to beneficiaries. One commenter suggested adopting only one function measure to reduce burden. Several commenters recommended using the FIM® for quality reporting, including FIM® change and length of stay efficiency measures in IRFs, LTCHs and SNFs. One commenter noted that Medicare has a goal of improving the quality or care, but was concerned that the proposed regulations would be burdensome and require additional clerical staff. One commenter recommended that CMS suspend any measure not required by the IMPACT Act and those that are not critical to the mission of IRFs. The commenter also suggested adopting the minimum

number of quality measures necessary to meet the IMPACT Act to minimize burden on IRFs.

Response*:* We believe that the 6-level scale and the additional items in section GG allow us to better distinguish change at the highest and lowest levels of patient functioning by documenting minimal change from no change at the low end of the scale. [56] This is important for measuring progress in some of the most complex cases treated in PAC. The items in section GG were developed with input from the clinical therapy communities to better measure the change in function, regardless of the severity of the individual's impairment. We do not agree with the commenters' assertions that the inclusion of items that inform 2 different rating scales will cause issues of patient safety.

To reduce potential burden associated with collecting additional items, we have included several mechanisms in the new section GG to reduce the number of items that apply to any one patient. First, in section GG, there are gateway questions pertaining to walking and wheelchair mobility that allow the clinician to skip items that ask if the patient does not walk or does not use a wheelchair, respectively. For example, in Section GG, there is an item that asks whether or not the patient walks. If the resident does not walk, items in Section GG related to walking ability are skipped. Second, Section GG items will only be collected at admission and discharge. The gateway questions and skip patterns mean that only a subset of items are needed for most patients. However, by including all of them in the form, the standardized versions are available when appropriate for an individual patient.

We would like to clarify an issue related to the expected burden of collecting the additional items. At least one commenter had estimated that the additional staff needed to

[56] Barbara Gage et al., "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set" (RTI International, 2012)

complete the additional items was estimated to be 280 hours per year and would require over 4 additional FTE to collect this data. Using an estimate of 2080 hours per FTE, the additional time for data collection of these items should add 0.10 percent additional FTE per year.

We appreciate the comments pertaining to EMRs. While we applaud the use of EMRs, we do not require that providers use EMRs to populate assessment data. It should be noted that with each assessment release, we provide free software to our providers that allows for the completion and submission of any required assessment data. The use of a vendor to design software that extracts data from a provider's EMR to populate our quality assessments, is a business decision that is made solely by the provider. We only require that assessment data be submitted via the QIES ASAP system in a specific compatible format. Providers can choose to use our free software (the Inpatient Rehabilitation Validation and Entry (IRVEN) software product are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service Payment/InpatientRehabFacPPS/Software.html.), or the data submission specifications we provide that allow providers and their vendors to develop their own software, while ensuring compatibility with the QIES ASAP system.

Comment*:* One commenter stated that the CARE item set in the proposed IRF-PAI Version 1.4 does not assess eating, bladder, or bowel control at discharge. The commenters expressed concerns that eating and bladder outcomes cannot be assessed using the CARE function items.

Response*:* We would like to clarify that the CARE self-care item set on the proposed IRF-PAI Version 1.4 does include the item "eating" at both admission and discharge, allowing monitoring of eating outcomes. Additionally, clinicians have the opportunity to establish a discharge goal for eating, if relevant for the patient. Bladder and bowel continence are only

assessed at admission on the proposed IRF-PAI Version 1.4 because these data will only be used for risk adjustment for the IRF self-care and mobility quality measures. We are interested in developing quality measures focused on bladder and bowel function and management. Bladder and bowel functioning have been shown to be an independent construct from motor activities, such as self-care and mobility. While some functional assessment instruments analyses include bladder or bowel function as motor activities, Rasch analysis has shown that these items "misfit," suggesting they do not measure the same constructs as the motor items. [57] Quality measures that focus uniquely on bladder and bowel function would allow collection of data specific to bladder and bowel management, and would be more actionable for providers to improve quality of care and patient outcomes.

Comment: One commenter expressed concern regarding the burden of collecting both the existing as well as new proposed function items, suggesting that CMS address duplication with a gradual removal of the current function items and replacing them with the new function items across the item sets for all of the post-acute settings, expressing that achieving such standardization and exchangeable patient data will enable cross-setting data comparison and improved quality measures with consistent risk adjustment so as to achieve the intent of the IMPACT Act.

Response: We interpret the comment to mean that IRFs already collect functional assessment data that is setting-specific. We intend to work with providers as we implement the requirements of reporting standardized data as part of the IMPACT Act. We would like to clarify that while the IMPACT Act requires the enablement of interoperability through the use of

[57] Linacre JM, Heinemann AW, Wright BD, Granger CV and Hamilton. The Structure and Stability of the Functioning Independence Measure. Arch of Phys Med and Rehab 75(2):127-132, 1994

standardized data, there will be instances in which some provider types may need more or less standardized items than other provider types.

With regard to risk-adjustment, as noted in our previous response, the TEP that reviewed this measure did not recommend that the measure be risk-adjusted, because completion of a functional assessment is not affected by the medical and functional complexity of the resident/patient. Rather, clinicians are able to report that an activity was not attempted due to a medical condition or a safety concern, and clinicians take this complexity into account when setting goals. Further, we are aware that patients/resident may have acute events that trigger unplanned discharges, and this measure does not require a functional assessment to be completed in these circumstances. For medically acute patients, functional assessment data are not required. This specification is clearly noted in our specifications document. Finally, we have included skip patterns on the assessment instrument that take into account patient complexity. For example, we have a gateway question that asks if the patients walk. If the patient/resident does not walk, then several walking and stairs items are not required to be completed.

Comment*:* One commenter focused on the need to measure cognitive functioning and link functional assessment, care planning and goals to address patient functioning. This commenter noted that such a measure would be important for achieving the best outcomes and for discharge planning

Response*:* We would like to clarify that the Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631, endorsed on July 23, 2015) is for use as a cross-setting quality measure that includes self-care and mobility activities that are primarily focused on motor function. The quality measure does not include items that are focused on cognitive functioning. We do plan to

develop quality measures focused on cognitive functioning. We are always open to stakeholder feedback on measure development and encourage everyone to submit comments to our comment email: PACQualityInitiative@cms.hhs.gov.

Comment: Several commenters noted additional areas of function that are key to patients, including cognition, communication, and swallowing. One commenter encouraged CMS to consider cognition and expressive and receptive language and swallowing as items of function and not exclusively as risk adjustors, and offered their expertise to CMS for discussions and to develop goals. Another commenter examined the SNF, IRF, HHA and LTCH assessment instruments and noted that cognitive function is measured differently across the settings in terms of content, scoring process, and intended calibration of each tool, and encouraged CMS to align items and quality measurement of cognition.

Response: We are working toward developing quality measures that assess areas of cognition and expression, recognizing that these quality topic domains are intrinsically linked or associated to the domain of function and cognitive function. We appreciate the commenter's suggestion to align cognition items across the PAC settings. We appreciate the commenter's offer for assistance and encourage the submission of comments and measure specification details to our comment email: PACQualityInitiative@cms.hhs.gov.

Comment: Two commenters requested that CMS continue engaging with stakeholders, and one requested increased engagement with regard to the IMPACT Act and measures that CMS considers. One of the commenters criticized CMS, expressing that although CMS engaged with stakeholders, the proposals were rushed. The other commenter requested that CMS continue to collaborate with stakeholders, stating their appreciation for inclusion and opportunity to work with CMS during the implementation phases of the IMPACT Act. One commenter also

recommended that CMS establish a more formal stakeholder group to include rehabilitation professionals who can provide expertise on the provision of rehabilitation therapy in nursing facilities. This commenter noted that the more opportunities stakeholders have to dialogue and recommend CMS on the quality measures, the greater the possibility that the measures will be accurate and helpful to determining care quality.

Response: We appreciate the continued involvement of stakeholders in all phases of measure development and implementation and we recognize the value in strong public-private partnerships. We appreciate the request for increased engagement and for a formal stakeholder group. We very much agree that outreach and education are invaluable, and we intend to continue to provide easy reference information, such as a high-level walk-through information pertaining to our implementation of the IMPACT Act.

In addition to the SODF we hosted on the topic of the IMPACT Act, we have created a post-acute care quality initiatives website, which pertains primarily to the IMPACT Act required quality measures/assessment instrument domains, and allows access to a mail box for IMPACT Act provider related questions. We have additionally provided nearly a dozen presentations with various stakeholders upon their request since January, and during these presentations we have provided similar information specific to the IMPACT Act requirements, as they pertain to data standardization. We note that the slides used for the SODF are accessible on the IMPACT Act/Post-Acute Care Quality Initiatives website http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html , and these do provide high-level background and information, including timelines as they pertain to the assessment domains required under the IMPACT Act. Further, CMS is in the midst of developing plans for providing additional and

ongoing education and outreach (to include timelines) in the near future, as suggested by commenters. For further information and future postings of such documents and information, please continue to check the Post-Acute Care Quality Initiatives website (listed above), as well as the IRF Quality Reporting website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/.

We will take these suggestions into consideration as we continue to implement the IMPACT Act.

Final Decision: Having carefully considered the comments we received on the application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), we are finalizing the adoption of this measure as proposed for use in the IRF QRP as proposed.

3. IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review)

The third quality measure that we proposed for the FY 2018 payment determination and subsequent years is an outcome measure entitled IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review). This quality measure estimates the risk-adjusted mean change in self-care score between admission and discharge among IRF patients. This measure was proposed under the authority of section 1886(j)(7)(C) of the Act, and is currently under review by the NQF. A summary of the measure specifications can be accessed on the NQF website at http://www.qualityforum.org/qps/2633. Detailed specifications for this quality measure can be accessed at http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2633.

IRFs are designed to provide intensive rehabilitation services to patients. Patients seeking care in IRFs are those whose illness, injury, or condition has resulted in a loss of function, and for whom rehabilitative care is expected to help regain that function. Examples of conditions treated in IRFs include stroke, spinal cord injury, hip fracture, brain injury, neurological disorders, and other diagnoses characterized by loss of function.

Given that the primary goal of rehabilitation is improvement in functional status, IRF clinicians have traditionally assessed and documented patients' functional status at admission and discharge to evaluate the effectiveness of the rehabilitation care provided to individual patients, as well as the effectiveness of the rehabilitation unit or hospital overall. Differences in IRF patients' functional outcomes have been found by geographic region, insurance type, and race/ethnicity after adjusting for key patient demographic characteristics and admission clinical status. Therefore, we believe there is an opportunity for improvement in this area. For example, Reistetter[58] examined discharge motor function and functional gain among IRF patients with stroke and found statistically significant differences in functional outcomes by U.S. geographic region, by insurance type, and race/ethnicity group after risk adjustment. O'Brien and colleagues[59] found differences in functional outcomes across race/ethnicity groups in their analysis of Medicare assessment data for patients with stroke after risk adjustment. O'Brien and colleagues[60] also noted that the overall IRF length of stay decreased 1.8 days between 2002 and 2007 and that shorter IRF stays were significantly associated with lower functioning at discharge.

[58] Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. Arch Phys Med Rehabil.95(1):29-38, Jan. 2014.
[59] O'Brien SR, Xue Y, Ingersoll G, et al. Shorter length of stay is associated with worse functional outcomes for medicare beneficiaries with stroke. Physical Therapy. 93(12):1592-1602, Dec. 2013.
[60] O'Brien SR, Xue Y, Ingersoll G, et al. Shorter length of stay is associated with worse functional outcomes for medicare beneficiaries with stroke. Physical Therapy. 93(12):1592-1602, Dec. 2013.

The functional assessment items included in this quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the CARE Tool,[61] which was designed to standardize assessment of patients' status across acute and post-acute providers, including IRFs, SNFs, HHAs and LTCHs. The functional status items on the CARE Tool are daily activities that clinicians typically assess at the time of admission and/or discharge to determine patients' needs, evaluate patient progress and prepare patients and families for a transition to home or to another provider.

This outcome measure requires the collection of admission and discharge functional status data by trained clinicians using standardized clinical assessment items, or data elements that assess specific functional self-care activities (for example, eating, oral hygiene, toileting hygiene). The self-care function items are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. In addition, this measure requires the collection of risk factors data, such as patient functioning prior to the current reason for admission, bladder continence, communication ability and cognitive function, at the time of admission.

This self-care quality measure will also standardize the collection of functional status data, which can improve communication when patients are transferred between providers. Most IRF patients receive care in an acute care hospital prior to the IRF stay, and many IRF patients receive care from another provider after the IRF stay. Use of standardized clinical data to describe a patient´s status across providers can facilitate communication across providers. Rehabilitation programs have traditionally conceptualized functional status in terms of the need

[61] Barbara Gage et al., "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set" (RTI International, 2012).

for assistance from another person. This is the conceptual basis for the IRF-PAI/FIM®* instrument (used in IRFs), the MDS function items (used in nursing homes), and the Outcome and Assessment Information Set (OASIS) function items (used in home health). However, the functional status items on the IRF-PAI, MDS and OASIS are different even when items are similar; the item definitions and rating scales are different. In a patient-centered health care system, there is a need for standardized terminology and assessment items because patients often receive care from more than 1 provider. The use of standardized items and terminology facilitates clinicians speaking a common language that can be understood across clinical disciplines and practice settings.

We released draft specifications for the function quality measures, and requested public comment between February 21 and March 14, 2014. We received 40 responses from stakeholders with comments and suggestions during the public comment period and have updated the specifications based on these comments and suggestions. This quality measure was submitted to the NQF on November 9, 2014, has been undergoing review at NQF.

Based on the evidence previously discussed, we proposed to adopt the quality measure entitled IRF Functional Outcome Measure: Change in Self-care Score for Medical Rehabilitation Patients (NQF #2633; under review), for the IRF QRP for the FY 2018 payment determination and subsequent years. As described in more detail in section IX.I.2. of this final rule, the first data collection period is 3 months (October 1, 2016 to December 31, 2016) for the FY 2018 payment determination, and the subsequent data collection periods are 12-months in length and follow the calendar year (that is, January 1 to December 31).

The list of measures under consideration for the IRF QRP, including this quality measure, was released to the public on December 1, 2014, and early comments were submitted between

December 1 and December 5, 2014. The MAP met on December 12, 2014, sought public comment on this measure from December 23, 2014 to January 13, 2015, and met on January 26, 2015. The NQF provided the MAP's input to us as required under section 1890A(a)(3) of the Act in the final report, MAP 2015 Considerations for Selection of Measures for Federal Programs: Post-Acute/Long-Term Care, which is available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx. The MAP conditionally supported this measure. Refer to section IX.B. of this final rule for more information on the MAP.

In section 1886(j)(7)(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 the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed quality measures focused on assessment of functional status for patients in the IRF setting. There are related measures, but they are not endorsed for IRFs and several focus on 1 condition (for example, knee or shoulder impairment). We are not aware a of any other quality measures for functional assessment that have been endorsed or adopted by another consensus organization for the IRF setting. Therefore, we proposed to adopt this measure, IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review), for use in the IRF QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures.

The specifications and data elements for the quality measure are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

We proposed that data for the quality measure be collected using the IRF-PAI, with the submission through the QIES ASAP system. For more information on IRF QRP reporting through the QIES ASAP system, refer to the CMS website at http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html and http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html

We proposed to revise the IRF-PAI to include new items that assess functional status and the risk factor items. The function items, which assess specific self-care functional activities, are based on functional items included in the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set.

We sought public comments on our proposal to adopt the quality measure entitled IRF Functional Outcome Measure: Change in Self-care Score for Medical Rehabilitation Patients (NQF #2633; under review) for the IRF QRP, with data collection starting on October 1, 2016, for the FY 2018 payment determination and subsequent years. Refer to section IX.I.2. of this final rule for more information on the proposed data collection and submission timeline for this quality measure. The responses to public comments on this measure are discussed below in this section of the final rule. We note that we received many comments about the standardized (that is, CARE) items that pertain to several of the 5 proposed function quality measures. Many of these comments are provided above in section IX.G.2. of this final rule as part of the review of comments about the quality measure, an Application Percent of LTCH Patients with an

Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). We also received many comments pertaining to more than 1 of the 4 functional outcomes measures. We provide these comments and our responses below as well as 1 comment that uniquely applies to this measure, IRF Functional Outcome Measure: Change in Self-care Score for Medical Rehabilitation Patients (NQF #2633; under review).

Comment: MedPAC expressed support for the 4 function outcome measures that we proposed for the IRF QRP, and noted measures added to the IRF QRP should contribute to meaningful differences in IRF patients' outcomes or meaningful comparison of patients' outcomes across post-acute care settings.

Response: We appreciate MedPAC's support for the 4 proposed functional outcome measures. These functional status quality measures are calculated using standardized functional assessment (that is, CARE) data, which is the primary data source for not only these 4 functional outcome measures, but also for the standardized cross-setting function process measure. Therefore, we are proposing 5 functional status quality measures that are derived from 1 data source (CARE data) and use the same set of assessment items.

Comment*:* One commenter supported the concepts of the 4 IRF outcome measures, and was pleased that prior mobility devices were risk adjustors for the outcome measures. This commenter encouraged CMS to continue to examine data for this quality measure and the risk adjustment methodology.

Response: We appreciate the commenter's support for the proposed function quality measure concepts and appreciate the commenter's input on risk adjustment. The risk adjustors selected for these proposed quality measures were selected based on rigorous literature reviews, clinical relevance, TEP input, and empirical findings from the PAC-PRD analyses. We also

requested input on suggested risk adjustors as part of the public comment process, and we appreciate this commenter's input during this process. As part of our measure maintenance process, we will continue to examine data and refine measures.

Comment*:* One commenter encourages CMS to add wheelchair mobility items in the mobility quality measures to reflect that some patients use a wheelchair as a primary method of mobility, and directed CMS's attention to quality measure, CARE: Improvement in Mobility (NQF #2612). The commenter encouraged CMS to examine this measure during the implementation phase (by which we assume they meant the implementation phase of the five IRF function quality measures).

Response*:* We appreciate the commenter's suggestion to add wheelchair mobility items in the mobility quality measure, and will explore that refinement as we further develop and refine these quality measures. As part of our maintenance process, we will continue to examine data, refine measures, and examine and evaluate the use of other quality measures for considerations of future measure modifications.

Comment: One commenter was pleased to see the 4 IRF function outcome measures proposed as part of the FY 2016 IRF PPS Proposed Rule. The commenter encouraged CMS to propose functional outcome measures for LTCHs, SNFs and HHAs in future rulemaking for quality of care and payment.

Response*:* We agree that the use of outcome measures is important. We would like to note that we adopted the quality measure Long-Term Care Hospital Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support (NQF #2632; endorsed on July 23, 2015) in the FY 2015 final rule and data collection for this outcome measure begins in LTCHs on April 1, 2016. We are currently developing functional outcome

measures, specifically self-care and mobility quality measures, which may be used for SNFs and HHAs. These functional outcome quality measures are intentionally being designed to use the same standardized functional assessment items that are included in the cross-setting person- and family-centered function process measure in order to capitalize on the data collected using the process measure, which will inform further development, while allowing for the consideration of limited additional burden.

Comment: One commenter questioned whether the 4 proposed functional outcome measures meet the IMPACT Act's requirement of being "standardized and interoperable" and noted the 4 measures were not proposed for the SNF QRP and LTCH QRP.

Response: The 4 proposed functional outcome measures were developed for data collection and reporting for the IRF QRP prior to the implementation of the IMPACT Act of 2014. We would like to clarify that the quality measure, the Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), meets the requirements of the IMPACT Act. We note that the 4 proposed IRF QRP functional outcome quality measures contain a common core subset of function items that ultimately will allow tracking of patients' functional status across settings, as these items also appear in the quality measure, the Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed July 23, 2015), that was developed to meet the requirements of the IMPACT Act. For this measure, there are a set of core items that are identical across the settings; that is, the item definitions in each setting are the same. The exchangeability of data rests upon common terminology and standardized data. The core items use such standardized definitions, enabling interoperability. It should be noted, we are currently

developing functional outcome measures that use the same standardized functional assessment items included in the cross-setting function process measure in order to capitalize on the data collected using the currently proposed process measure in SNFs and LTCHs, which allow for the consideration of limited additional burden. We would also like to note that while the IMPACT Act requires that we adopt cross-setting quality measures in specified measures domains, it does not prohibit the development of future setting-specific quality measures.

Comment: One commenter noted that according to the proposed rule, CMS's rationale for proposing the measures was due to differences in IRF patients' functional outcomes have been found by geographic region, insurance type, and race/ethnicity, after adjusting for key patient demographic characteristics and admission clinical status, and questioned how CMS might use the new measure data to address these concerns. The commenter had concerns that the introduction of the new items could affect the validity and reliability of all function data submitted to CMS.

Response: We understand the comment suggests the introduction of the new items could affect the validity and reliability of all function data submitted to CMS. Also, the commenter believes that the use of a new standardized functional assessment items for quality reporting along with the existing functional assessment data used for payment purposes could affect the validity and reliability of all of the data submitted. We disagree with the commenter's suggestion that the utilization of the new functional assessment items for purposes of quality reporting will affect the reliability and validity of either the new or the existing data because IRFs have received training on the current items, which are currently in use, and CMS would provide comprehensive training for the new standardized items. We would like to note that the inclusion of discussion of the variation by geographic region, insurance type, race and ethnicity

described by the commenter pertains to one of the concerns underlying the need for standardized data, as well the need for function quality measures in IRFs. The proposed CARE function items, which have acceptable reliability in both the IRF setting and other PAC settings, will be useful for measuring the impact of rehabilitation services across settings and underscore the value of IRF level services for the patients they appropriately treat. The IMPACT Act sets the foundation for future reporting of quality across the PAC settings. However, we will further monitor these key characteristics as we move to future measure development and testing.

Comment*:* One commenter is concerned that while the proposed functional outcome measures do address functional improvement, they do not measure the ability for a patient to return to the community. The commenter was concerned that some patients--for example, patients with complete cervical spinal cord injury or dense hemiplegia from a stroke--may not make significant functional gains, but do return to the community. This commenter noted the need to consider psychosocial and family financial support in prediction models. This commenter encouraged CMS to develop quality measures that relate to patient and family engagement as PAC reform implementation evolves.

Response*:* We appreciate the commenter's concern about specific patients who may not show improvement with functional activities that are commonly assessed for most IRF patients. We recognized this issue during the development of the CARE tool, and specifically addressed this topic in the report entitled, "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set. Volume 1 of 3," which is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-

Set-Final-Report-on-the-Development-of-the-CARE-Item-Set-Volume-1-of-3.pdf. In section 7 of this report, entitled "The CARE Tool: Potential Challenges and Future Enhancements," we describe the need to have items that focus on special populations, and we address the spinal cord injury and stroke populations that the commenter noted. As noted in the FY 2016 IRF PPS proposed rule (80 FR 23332 at 23399), for the 4 proposed functional outcome measures, we took into consideration literature reviews and discussions with the TEP members convened by our measure development contractor, and we excluded patients with certain conditions due to limited expected improvement or unpredictable course. The exclusion criteria for the proposed functional outcome measures are patients with: coma or persistent vegetative state on admission; complete tetraplegia; locked-in syndrome; severe anoxic brain damage, cerebral edema, or compression of brain. Excluding these patients from the quality measure calculation means that a facility that admits these patients will not have a lower average functional improvement score attributed to these patients. We believe this is an important issue, because including these patients in the quality measure may create access barriers.

We also appreciate the commenter suggesting that we incorporate patient and family engagement into the development of our quality measures. The proposed function quality measure, the Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), is a person- and family-centered process measure that reports standardized functional assessment data at admission and discharge, as well as at least one functional status discharge goal. The function goal is established at admission by the IRF clinicians with input from the patient and family, demonstrating person and family-centered care. As we continue our quality measurement development process, we will take into full consideration the person and family

engagement and process of care perspective.

Comment: One commenter expressed concerns regarding the sensitivity to change of the CARE-based functional outcome measures, in terms of their precision and ability to capture functional improvement, and asked CMS to refrain from implementing the CARE-based functional quality measures.

Response: The self-care and mobility items in the CARE-based functional outcome measures were carefully selected to represent a wide range of item difficulty, and cover a wide range of patient functioning, from low to high functioning. The self-care measure includes 7 items, and the mobility measure includes 15 items. Inclusion of this number of items allows the patient the opportunity to demonstrate gains in a variety of functional activities and tasks. Rehabilitation care typically focuses on several aspects of functioning, and patients may be expected to make varying amounts of improvement, from minimal to large improvement, across different functional tasks. In the event that a patient may not demonstrate gains in a specific self-care or mobility item, inclusion of a range of self-care and mobility items in our measures ensures that patients can demonstrate functional gains in other items. In addition to improving their ability to capture change, including items that target a wide range of patient functioning is a key factor for items to be applicable across the wide range of patients seen in IRFs, LTCHs, SNFs and HHAs.

We examined patient-level sensitivity to change of the CARE-based self-care and mobility outcome measures using data from the PAC-PRD. Table 19 shows the distribution of patient-level unadjusted (observed) change in self-care scores in 4,769 patients, and change in mobility scores in 4,776 patients. Both self-care and mobility change scores demonstrated excellent variability at the patient level, with a wide range and close to normal distribution. The

mean patient-level unadjusted self-care change score was 9.92 ± 6.47, while the median self-care change score was 10.00. Patient-level self-care change scores ranged from -25.00 to 33.00, with a range of 58.00 and an interquartile range of 9.00. The mean patient-level unadjusted mobility change score was 21.45 ± 13.69, while the median mobility change score was 20.50. Patient-level mobility change scores ranged from -20.00 to 66.00, with a range of 86.00 and an interquartile range of 20.00.

TABLE 19. Distribution of Patient-Level Unadjusted (Observed) Change in Self-Care and Mobility Scores for Medical Rehabilitation Patients

Patient-Level Unadjusted (Observed) Change Score	Number	Mean (SD)	Range (IQR)	Median
Change in Self-Care	4,769	9.92 (6.47)	58 (9)	10.00
Change in Mobility	4,776	21.45 (13.69)	86 (20)	20.50

N = Number of patients; SD = standard deviation; IQR = interquartile range

In addition to patient-level sensitivity to change, facility-level variability is a key psychometric characteristic desired for quality measures to ensure that the measures can distinguished among facilities with varying performance on the measure. The CARE-based risk-adjusted self-care and mobility outcome measures demonstrate very good variability at the facility-level. The mean risk adjusted facility-level change in self-care scores have a mean of 10.02 ± 1.72, a median of 9.82, a range of 6.53 to 14.78, and an interquartile range of 2.07. The mean risk adjusted facility-level change in mobility scores have a mean of 20.90 ± 4.67, a median of 21.34,range of 9.82 to 31.88, and an interquartile range of 6.03 (Table 20). Therefore, we believe that the items developed, tested, and chosen to develop the proposed functional quality measures are able to assess appropriately functional change, allowing CMS to collect and evaluate functional improvement for patients within and across settings. Thus, testing of these

items demonstrated excellent variability at the patient level and very good variability at the facility level, and we are confident that they cover a wide range of item difficulty and a wide range of patient functioning.

TABLE 20. Distribution of Facility-Level Risk Adjusted Change in Mobility Scores for Inpatient Rehabilitation Facilities

Risk-Adjusted Facility-Level Change Score	N	Mean (SD)	Median
Change in Self-Care	38	10.02 (1.72)	9.82
Change in Mobility	38	20.90 (4.67)	21.34

N = Number of facilities; SD = standard deviation;

Comment*:* One commenter raised concerns that level 06 on the CARE function item rating scale groups patients who are independent with use of an assistive device, and those who are independent without a device. The commenters also suggest that a patient, who is independent with use of an assistive device, thus receiving a score of 06, may fail to receive home health services because the clinician sees that the patient has the maximum functional score. The commenter considers the level 06 overly broad. The commenter considered these issues safety concerns and indicated that they pilot tested the CARE function items in the proposed IRF-PAI. The commenter expressed that patients who otherwise demonstrated functional progress on the existing numerical functional measures on the current IRF-PAI, showed no progress in their CARE functional score between admission and discharge.

Response*:* Rehabilitation care typically focuses on improvement in several aspects of functioning, and patients may be expected to make varying amounts of improvement across different functional activities. In the event that a patient may not demonstrate gains in one self-care or mobility item, an IRF patient will often improve in another activity. The inclusion of a 7 self-care and 15 mobility items in the proposed quality measures ensures that most patients can

demonstrate functional gains one or more items.

The proposed quality measure, IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review), includes an 'upper body dressing' item to address self-care. A patient who makes gains in upper body bathing is also very likely to make gains in upper body dressing; thus, this patient would demonstrate improvement in upper body dressing score. We believe that such a patient is also likely to make gains in other self-care items primarily requiring upper extremity use, such as eating, and oral hygiene. In addition, for the proposed quality measure, IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review), we have included items related to ambulation and car transfer. We developed the CARE function items based on the approach of the World Health Organization's (WHO) International Classification of Functioning, Disability, and Health (ICF) that recognizes functional independence and ability regardless of the use of assistive devices.[62] The CARE items measure a person's ability to perform functional activities, with or without assistive devices. Use of assistive devices remains an important part of the patient's functional assessment.

The CARE Tool used during the PAC-PRD included a list of devices used by a patient in order to document the type of device that was used. The decision to include devices on the CARE Tool was based on input from clinicians who wanted to document that a patient's status improved as they transition from one type of device to another. For example, a patient may transition from walking with a walker to walking with the straight cane. This progress is not currently captured on the IRF-PAI, as the FIM® instrument does not include information about

[62] World Health Organization. International Classification of Functioning, Disability and Health: ICF. Geneva, Switzerland: World Health Organization; 2001. Retrieved from http://www.who.int/classifications/icf/icf_more/en/

the type of device used. Even if the rating scale integrates use of an assistive device, the type of device used by the patient is not apparent.

Patients can use an assistive devices regardless of their level performance, from 01-Dependent through 06-Independent. For example, a patient who uses a wheelchair may be scored level 01-Dependent through 06-Independent. We do not believe it is important to only differentiate between independent function with a device and independent function without a device. Rather, to ensure patient safety, documentation of assistive device use for every level of patient performance is critical. Separate documentation of a patient's functional ability and need for an assistive device, together provide clinicians with the information needed regarding the patient's functional status. In the proposed rule, we proposed including wheelchair as a device as part of the admission and discharge assessment. We are very sensitive to the issue of burden associated with data collection and proposed only the minimal number of items needed to calculate the proposed quality measures. We would like to note that devices used prior to the current illness, injury or exacerbation are included on the proposed IRF-PAI version 1.4, because they are important factors associated with functional outcomes and are risk adjustors for our functional outcome measures.

We would also like to state that individual CARE function items are not intended to be stand-alone indicators of a patient's need for services, such as home health services, after discharge from the IRF. Determination of need for home health services should be based on comprehensive patient assessment; not on a patient's ability to perform a single activity.

Regarding the CARE function item rating scale, our decision to use a 6-level rating scale was based on input from the clinical communities and research examining the relationship

between minutes of assistance and functional assessment scores. Hamilton et al[63] found that the relationship between function scores and minutes of assistance per day was curvilinear, and that persons with high function scores frequently did not require any daily assistance. During PAC-PRD on-site training, when we explained differences between the existing and CARE rating scales, we received positive feedback about the CARE rating scale. We also conducted exit interviews with participating sites. The feedback was incorporated into the items that we have proposed for the function measure. Based on our experiences, we believe that the CARE items and associated rating scale represent a simple, but comprehensive method of documenting functional limitations at admission and discharge.

Comment*:* Several commenters were concerned that the four (4) functional outcome measures are not NQF-endorsed. Some of these commenters suggested that CMS delay implementation of these quality measures until they are NQF-endorsed for all PAC settings.

Response*:* We appreciate the commenters' feedback, and we agree that the NQF endorsement process is an important part of measure development. As previously noted, two of the proposed functional outcome quality measures are undergoing review by NQF at this time, and two of the measures were endorsed on July 23, 2015. As previously discussed, where such measures do not exist for the IRF setting, we may adopt measures that are not NQF-endorsed under the Secretary's exception authority with respect to the IMPACT Act in section 1899B(e)(2)(B) and with respect to the IRF QRP in section 1886(j)(7)(D)(ii) of the Act. It should be noted that for all quality measures, we provided a through and rigorous process of construct testing and measure selection, guided by the technical expert panels, public comments

[63] Hamilton BB, Deutsch A, Russell C, Fiedler RC, Granger CV Relation of disability costs to function: spinal cord injury Arch. Phys. Med. Rehabil. 80(4):385-391, Apr. 1999.

from stakeholders, and recommendations by the MAP.

Comment: One commenter expressed concern about the reliability and validity of the measures based on their belief that the PAC PRD was a cross-sectional study. They noted that the study data is now more than 5 years old, and that IRFs now admit an increasing population with neurological conditions. The commenter also expressed concern that the demonstration project did not follow patients across venues of care, limiting applicability across care settings.

Response: We would like to clarify that the PAC-PRD was a prospective cohort study that collected data at the time of admission and discharge form the PAC settings. Coupled with PAC settings, the PAC-PRD also collected data in acute care hospitals. The study also linked the PAC assessment data with hospital claims, and thus did follow patients across care settings. The commenter is correct that the data were collected more than 5 years ago. For the data, we would like to note that when we adopt quality measures for its QRPs, we also implement a process to evaluate quality measures each year by examining data submitted for the measure. In addition, there is a process in place for endorsement maintenance that also involves systematic analyses of measure data, literature reviews, and stakeholder input. Finally, the proposed function meaures that use CARE data contain a core set of function items selected for cross-setting use and chosen for their applicability across all post-acute settings, standardized to one another by item and through the use of the standardized 6-level rating scale. Items, while tested within each setting, were also tested among settings to develop a core set of items that could be used and re-used for many purposes across settings. The core set of items were developed with TEP input.

Comment: One commenter asked if CMS intends to ultimately use the CARE data for payment purposes, such as performance-based payment, and expressed concerns about potential effects on beneficiary access to IRF services of doing so.

Response*:* As we did not propose to use the CARE data items for any payment purposes, this comment is outside the scope of the proposed rule. However, we will note the commenter's concerns and consider them carefully should we ever consider extending use of the CARE data items to payment.

Comment*:* One commenter encouraged CMS to continue ongoing stakeholder engagement as the function quality measures evolve and as new function measures, such as gait speed, are considered.

Response*:* We will consider the input for measure concepts as we move through the development of current and future measures for the IRF QRP. TEPs are engaged to provide feedback and input on measure development.

Comment*:* One commenter supported the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review), noting that the measure considers essential information such as prior functioning.

Response: CMS appreciate the commenter for their comment and support of the proposed quality measure, Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review). We understand the commenter's comment to refer to the importance of setting function goals and consideration of prior functioning when determining the expected functional improvement. IRF staff can report goals for each self-care and mobility item, although that is not required for this measure. For this measure and all self-care and mobility outcome measures, we do apply a risk adjustment for prior functioning. We appreciate the comment's support of including prior functioning as risk adjustors.

Final Decision: Having carefully considered the comments we received on the IRF Functional Outcome Measure: Change in Self-care Score for Medical Rehabilitation Patients

(NQF #2633, under review), we are finalizing the adoption of this measure for use in the IRF QRP as proposed.

4. IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review)

The fourth quality measure we proposed for the FY 2018 payment determination and subsequent years is an outcome quality measure entitled IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review). This quality measure estimates the risk-adjusted mean change in mobility score between admission and discharge among IRF patients. This measure was proposed under the authority of section 1886(j)(7)(C) of the Act, and is under review at NQF. A summary of this quality measure can be accessed on the NQF website at http://www.qualityforum.org/qps/2634. More detailed specifications for this quality measure can be accessed at http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2634.

This outcome measure requires the collection of admission and discharge functional status data by trained clinicians using standardized clinical assessment items, or data elements that assess specific functional mobility activities (for example, toilet transfer and walking). The mobility function items are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. In addition, this measure requires the collection of risk factors data, such as patient functioning prior to the current reason for admission, history of falls, bladder continence, communication ability and cognitive function, at the time of admission.

As noted in the previous section, IRFs provide intensive rehabilitation services to patients with a goal of improving patient functioning.

We released draft specifications for the function quality measures, and requested public comment between February 21 and March 14, 2014. We received 40 comments from stakeholders and have updated the measures specifications based on these comments and suggestions. The quality measure was developed by us and was submitted for endorsement review to NQF in November 2014. A summary of the quality measure can be accessed on the NQF website at http://www.qualityforum.org/qps/2634. More detailed specifications for this quality measure can be accessed at http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2634.

Based on the evidence previously discussed, we proposed to adopt for the IRF QRP for the FY 2018 payment determination and subsequent years the quality measure entitled IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review). As described in more detail in section IX.I.2. of this final rule, the first data collection period is 3 months (October 1, 2016 to December 31, 2016), and the subsequent data collection periods are 12-months in length and follow the calendar year (that is, January 1 to December 31).

The list of measures under consideration for the IRF QRP, including this quality measure, was released to the public on December 1, 2014, and early comments were submitted between December 1 and December 5, 2014. The MAP met on December 9 2014, sought public comment on this measure from December 23, 2014 to January 13, 2015, and met on January 26, 2015. They provided input to us as required under section 1890A(a)(3) of the Act in the final report, MAP 2015 Considerations for Selection of Measures for Federal Programs: Post-Acute/Long-Term Care, which is available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx. The

MAP conditionally supported this measure. Refer to section IX.B. of this final rule for more information on the MAP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed quality measures focused on assessment of functional status for patients in the IRF setting. There are related measures--for example, Improvement in ambulation/locomotion (NQF #0167), Improvement in bed transferring (NQF #0175), Functional status change for patients with Knee impairments (NQF #0422), Functional status change for patients with Hip impairments (NQF #0423)--but they are not endorsed for IRFs, and several focus on 1 condition (for example, knee or hip impairment). We are not aware of any other quality measures for functional assessment that have been endorsed or adopted by another consensus organization for the IRF setting. Therefore, we proposed to adopt this measure, IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review), for use in the IRF QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures.

The specifications and data elements for the quality measure are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

We proposed that data for the quality measure be collected using the IRF-PAI, with submission through the QIES ASAP system. For more information on IRF QRP reporting through the QIES ASAP system, refer to the CMS website at http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html and http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html.

We sought public comments on our proposal to adopt the quality measure entitled IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review) for the IRF QRP, with data collection starting on October 1, 2016, for the FY 2018 payment determination and subsequent years. Refer to section IX.I.2.of this final rule for more information on the data collection and submission timeline for this quality measure. The responses to public comments on this measure are discussed in this section of the final rule. We note that we received many comments about the standardized (that is, CARE) items that pertain to several of the 5 proposed function quality measures. These comments are provided in section IX.G.2 of this final rule as part of review of comments about the measure, an Application Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). We also received many comments pertaining to several of the 4 function outcomes measures, and we provide these comments in section IX.G.3 of this final rule as part of our review of comments about the measure, IRF Functional Outcome Measure: Change in Self-care Score for Medical Rehabilitation Patients (NQF #2633; under review). Comments that uniquely apply to the measure, IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review), are provided below.

Comment: One commenter supported the concept of change in mobility and noted that measuring mobility is important in determining the patient's ability to be independent, and that access to occupational and physical therapy services is necessary to improve patient functioning.

Response: We appreciate the commenter's support of this quality measure and agree that access to occupational and physical therapy services to assist patients to improve functioning is important. In addition, we note that it is important for the IRF clinician teams to work

collaboratively to help support established therapy goals (for example, by mobilizing patients when occupational and physical therapy services are not available).

Final Decision: Having carefully considered the comments we received on the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review), we are finalizing the adoption of this measure for use in the IRF QRP as proposed.

5. IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015)

The fifth quality measure we proposed for the FY 2018 payment determination and subsequent years is an outcome quality measure entitled: IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015). This quality measure estimates the percentage of IRF patients who meet or exceed an expected discharge self-care score. This measure was proposed under the authority of section 1886(j)(7)(C) of the Act and was endorsed by NQF on July 23, 2015.

This outcome measure requires the collection of admission and discharge functional status data by trained clinicians using standardized clinical assessment items, or data elements that assess specific functional mobility activities (for example, eating, oral hygiene, and dressing). The self-care function items are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. In addition, this measure requires the collection of risk factors data, such as patient functioning prior to the current reason for admission, bladder continence, communication ability and cognitive function, at the time of admission. The data collection required for this measure is the same as the data required for the measure: IRF Functional Outcome Measure: Change in Self-

Care Score for Medical Rehabilitation Patients (NQF #2633; under review).

As noted in the previous section, IRFs provide intensive rehabilitation services to patients with a goal of improving patient functioning.

We released draft specifications for the function quality measures, and requested public comment between February 21 and March 14, 2014. We received 40 comments from stakeholders and have updated all 4 IRF quality measures specifications based on these comments and suggestions. A summary of this quality measure can be accessed on the NQF website at http://www.qualityforum.org/qps/2634. More detailed specifications for this quality measure can be accessed at http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2634.

Based on the evidence previously discussed, we proposed to adopt for the IRF QRP for the FY 2018 payment determination and subsequent years the quality measure entitled IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015).

The list of measures under consideration for the IRF QRP, including this quality measure, was released to the public on December 1, 2014, and early comments were submitted between December 1 and December 5, 2014. The MAP met on December 9, 2014, sought public comment on this measure from December 23, 2014 to January 13, 2015, and met on January 26, 2015. They provided input to us as required under section 1890A(a)(3) of the Act in the final report, MAP 2015 Considerations for Selection of Measures for Federal Programs: Post-Acute/Long-Term Care, which is available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx. The MAP conditionally supported this measure. Refer to section IX.B. of this final rule for more

information on the MAP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed quality measures focused on assessment of functional status for patients in the IRF setting. There are related measures, but they are not endorsed for IRFs and several focus on one condition (for example, knee or shoulder impairment). We are not aware of any other quality measures for functional outcomes that have been endorsed or adopted by another consensus organization for the IRF setting. Therefore, we proposed to adopt this measure, IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015), for use in the IRF QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures. As described in more detail in section IX.I.2 of this final rule, the first data collection period is 3 months (October 1, 2016 to December 31, 2016), and the subsequent data collection periods are 12-months in length and follow the calendar year (that is, January 1 to December 31).

The specifications and data elements for the quality measure are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

We proposed that data for the quality measure be collected using the IRF-PAI, with submission through the QIES ASAP system. For more information on IRF QRP reporting through the QIES ASAP system, refer to the CMS website at http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html and http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html

We sought public comments on our proposal to adopt the quality measure entitled IRF

Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015) for the IRF QRP, with data collection starting on October 1, 2016, for the FY 2018 payment determination and subsequent years. For more information on the proposed data collection and submission timeline for this proposed quality measure, refer to section IX.I.2, of this final rule. The responses to public comments on this measure are discussed below in this section of the final rule. We note that we received many comments about the standardized (that is, CARE) items that pertain to several of the 5 proposed function quality measures. These comments are provided in section IX.G.2 of this final rule as part of review of comments about the measure, an Application Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). We also received many comments pertaining to several of the 4 function outcomes measures, and we provide these comments in section IX.G.3 of this final rule as part of our review of comments about the measure, IRF Functional Outcome Measure: Change in Self-care Score for Medical Rehabilitation Patients (NQF #2633; under review). Comments that specifically apply to the measure, IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015), are provided below.

Comment: One commenter noted that this measure is important for discharge planning that will enable the ability to achieve the best outcomes and avoid readmissions.

Response: We appreciate the commenter's support of this quality measure. We believe that examining patient functioning at discharge will help IRFs focus on optimizing patients' functioning and discharge planning and supporting patients' transition from the IRF to home or another setting.

Final Decision: Having carefully considered the comments that we received on the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015), we are finalizing the adoption of this measure for use in the IRF QRP as proposed.

6. IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015)

The sixth quality measure we proposed for the FY 2016 implementation and the FY 2018 payment determination and subsequent years is an outcome quality measure entitled: IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015). This quality measure estimates the percentage of IRF patients who meet or exceed an expected discharge mobility score. This measure was proposed under the authority of section 1886(j)(7)(C) of the Act, was endorsed by NQF on July 23, 2015. A summary of this quality measure can be accessed on the NQF website at http://www.qualityforum.org/qps/2636. More detailed specifications for this quality measure can be accessed at http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2636.

This outcome measure requires the collection of admission and discharge functional status data by trained clinicians using standardized clinical assessment items, or data elements that assess specific functional mobility activities (for example, bed mobility and walking). The mobility function items are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. In addition, this measure requires the collection of risk factors data, such as patient functioning prior to the current reason for admission, history of falls, bladder continence, communication ability and

cognitive function, at the time of admission. Note that the data collection required for this measure is the same as the data required for the measure: IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2634; endorsed on July 23, 2015).

As noted in the previous section, IRFs provide intensive rehabilitation services to patients with a goal of improving patient functioning.

We released draft specifications for the function quality measures, and requested public comment between February 21 and March 14, 2014. We received 40 comments from stakeholders and have updated all 4 IRF outcome quality measures specifications based on these comments and suggestions.

Based on the evidence discussed earlier, we proposed to adopt for the IRF QRP for the FY 2018 payment determination and subsequent years the quality measure entitled IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015). As described in more detail in section IX.I.2. of this final rule, the first data collection period is 3 months (October 1, 2016 to December 31, 2016), and the subsequent data collection periods are 12-months in length and follow the calendar year (that is, January 1 to December 31).

The list of measures under consideration for the IRF QRP, including this quality measure, was released to the public on December 1, 2014, and early comments were submitted between December 1 and December 5, 2014. The MAP met on December 9, 2014, sought public comment on this measure from December 23, 2014 to January 13, 2015, and met on January 26, 2015. They provided input to us as required under section 1890A(a)(3) of the Act in the final report, MAP 2015 Considerations for Selection of Measures for Federal Programs: Post-

Acute/Long-Term Care, which is available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx. The MAP conditionally supported this measure. Refer to section IX.B. of this final rule for more information on the MAP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed quality measures focused on assessment of functional status for patients in the IRF setting. There are related measures, but they are not endorsed for IRFs and several focus on one condition (for example, knee or shoulder impairment). We are not aware of any other quality measures for functional outcomes that have been endorsed or adopted by another consensus organization for the IRF setting. Therefore, we proposed to adopt this measure, IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015), for use in the IRF QRP for the FY 2018 payment determination and subsequent years.

We proposed that data for this quality measure be collected using the IRF-PAI, with submission through the QIES ASAP system. For more information on IRF QRP reporting through the QIES ASAP system, refer to the CMS website at http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html and http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html .

We sought public comments on the quality measure entitled IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015) for the IRF QRP, with data collection starting on October 1, 2016, for the FY 2018 payment determination and subsequent years. Refer to section IX.I. of this final rule for

more information on the proposed data collection and submission timeline for this quality measure.. The responses to public comments on this measure are discussed below in this section of the final rule. We note that we received many comments about the standardized (that is, CARE) items that pertain to several of the 5 proposed function quality measures. These comments are provided in section IX.G.2 of this final rule as part of review of comments about the measure, an Application Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). We also received many comments pertaining to several of the 4 function outcomes measures, and we provide these comments in section IX G.3 of this final rule as part of our review of comments about the measure, IRF Functional Outcome Measure: Change in Self-care Score for Medical Rehabilitation Patients (NQF #2633; under review). Comments that specifically apply to the measure, IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015).

Comment: One commenter noted that the measure IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015) is important for discharge planning so that an individual is able to achieve the best outcomes.

Response: We appreciate the commenter's support of this quality measure. We agree that patient functioning is critical information to consider as part of discharge planning. Examining patient functioning at discharge will help IRFs focus on optimizing patients' functioning and supporting patients' transition from the IRF to home or another setting.

Final Decision: Having carefully considered the comments regarding the CARE items in Section IX.G.2. of this final rule and the comments about the IRF functional outcome measures

in section IX.G.3. of this final rule and the comment that we received about the measure, IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015), we are finalizing the adoption of this measure for use in the IRF QRP as proposed.

TABLE 21: Summary of IRF QRP Measures Affecting the FY 2017 and FY 2018 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors

Continued IRF QRP Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors: • NQF #0138: National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure[1] • NQF #0431: Influenza Vaccination Coverage among Healthcare Personnel[1] • NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) • NQF #1716: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure[1] • NQF #1717: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure[1] • NQF #2502: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs[4,2] • NQF #0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)[4]
Newly adopted IRF QRP Measures Affecting FY 2018 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors • NQF #2502: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs[4,2] • NQF #0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)[4,3] • NQF #0674: An application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay)[5,3] • NQF #2631; endorsed on July 23, 2015: An application of Percent of LTCH Patients with a an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function[5,3] • NQF #2633; under review: IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients [6, 3] • NQF #2634; under review: IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients [6,3] • NQF #2635; endorsed on July 23, 2015 IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients [,3] • NQF #2636; endorsed on July 23, 2015: IRF Functional Outcome Measure: Discharge

Mobility Score for Medical Rehabilitation Patients [3]
1. Using CDC/NHSN 2. Medicare Fee-for-Service claims data 3. New or modified IRF-PAI items 4. Previously adopted quality measure that was re-adopted for FY2018 and subsequent years 5. Not NQF-endorsed for the IRF setting. 6. Not NQF-endorsed, CMS submitted the measure for NQF review in November 2014

H. IRF QRP Quality Measures and Measure Concepts under Consideration for Future Years

We sought public comments on relevance and applicability of each of the quality measures and quality measure concepts listed in Table 22 for future years in the IRF QRP. Specifically, we sought public comments regarding the clinical importance, the feasibility of data collection and implementation to inform and improve quality of care delivered to IRF patients. The responses to public comments on future measures are discussed below in this section of the final rule.

TABLE 22: Future Measures and Measure Concepts under Consideration for the IRF Quality Reporting Program

National Quality Strategy Priority: Patient Safety
Venous Thromboembolism Prophylaxis
Medication Reconciliation*
National Quality Strategy Priority: Effective Communication and Coordination of Care
Transfer of health information and care preferences when an individual transitions*
All-Condition Risk-Adjusted Potentially Preventable Hospital Readmission Rates*
National Quality Strategy Priority: Patient- and Caregiver-Centered Care
Discharge to Community*
Patient Experience of Care
Percent of Patients with Moderate to Severe Pain
National Quality Strategy Priority: Affordable Care
Medicare Spending per Beneficiary*

* Indicates that this is a cross-setting measure domain listed in the IMPACT Act of 2014.

Comment: We received several comments about the relevance and applicability of each of the quality measures and quality measure concepts listed for future years in the IRF QRP. For example, several supported measures related to skin integrity, medication reconciliation, major

falls, transfer of health information, functional improvement and discharge to home, noting that these are already areas of ongoing focus in the IRF industry. Some commenters noted that while they support measures related to functional improvement and discharge to home, they believed they were already reporting these outcomes using the FIM® instrument on the IRF-PAI.

Response: We will take these comments into consideration to inform our ongoing measure development efforts for this measure and our ongoing consideration of the potential to adopt these measures in the IRF QRP through future rulemaking. We are aware of the perception of duplicative reporting with regard to the data items that inform the functional status measures that we are finalizing in this final rule and the current and continued use of the FIM® instrument, which is used for payment purposes. For an expanded discussion on this topic, we refer you to the comments and responses under section IX.G.2 of this final rule.

Comment: One commenter recommends that CMS adopt a more direct approach for engaging patients to ensure the transfer of health information and care preferences of a patient is accurately communicated.

Response: We thank the commenter for their comment. We are dedicated to the consideration and inclusion of patient preferences as they relate to the care that patients receive. It is our contractor's policy to include patients as part of the TEPs that it convenes throughout all stages of measure development.

Comment: Some commenters noted suggestions related to specific quality measures included in our list of potential future measures. One commenter noted that Discharge to Community should be amended to include Long-Term Care/Intermediate Care Facilities as a community discharge if this is the level of modified independence the patient chooses as a best option for themselves. One commenter noted that Patient Experience of Care should be

measured utilizing a tool that evaluated the patient's experience as an interdisciplinary event, but cautioned CMS against survey fatigue. One commenter recommended that SNFs and LTCHs also be required to report the same FIM® change, length of stay efficiency, and successful discharge to community, noting that this would give CMS beneficiaries a better picture of the quality of different post-acute care settings. Another commenter stated Medication Reconciliation depends heavily on the information provided by the transferring facility and that approximately 95 percent of all patients admitted to an IRF come directly from an acute care hospital, noting that IRFs are typically the recipient of information and have far less control of the accuracy and completeness of the data received.

Response: We will take these recommendations into account throughout the measure development process.

Comment: One commenter stated that they did not support the addition of further process measures to the IRF QRP, and noted that outcome measures are more meaningful to patients and healthcare providers. A few commenters recommended that CMS postpone any additional measures outside the requirements of the IMPACT Act, due to the increased burden on providers.

Response: While we agree that outcome measures are important and meaningful, and we intend to implement outcomes based measures throughout the life of the IRF QRP, we also believe that process measures are important. We believe that by monitoring facility and provider activities by using process measures initially will allow for the development of more robust outcome-based quality measures. While some commenters feel that we should suspend quality measures not related to the IMPACT Act, we would also like to note that while the IMPACT Act does require that we adopt specific cross-setting quality measures, it does not prohibit the

development of future setting-specific quality measures. We also believe that while cross-setting metrics are important for comparison purposes, setting-specific measures are equally important, as the patient populations for each PAC setting are unique, and thus have unique considerations for patient care and quality.

I. Form, Manner, and Timing of Quality Data Submission for the FY 2018 Payment Determination and Subsequent Years

1. Background

Section 1886(j)(7)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each IRF submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(j)(7)(F) of the Act, as added by the IMPACT Act, requires that, for the FY beginning on the specified application date, as defined in section 1899B(a)(2)(E) of the Act, and each subsequent year, each IRF submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under section 1886(j)(7)(C) and (F) must be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(j)(7)(A)(i) of the Act, for any IRF that does not submit data in accordance with section 1886(j)(7)(C) and (F) of the Act with respect to a given fiscal year, the annual increase factor for payments for discharges occurring during the fiscal year must be reduced by 2 percentage points.

2. Timeline for Data Submission under the IRF QRP for the FY 2018 and FY 2019 Payment Determinations

We proposed the following data submission timeline for the quality measures for the FY 2018 adjustments to the IRF PPS annual increase factor. We proposed that IRFs would be required to submit IRF-PAI data on discharges occurring between October 1, 2016 and

December 31, 2016 (first quarter), for the FY 2018 adjustments to the IRF PPS annual increase factor. For FY 2019, we proposed that IRFs would be required to submit data on discharges occurring between January 1, 2017 and December 31, 2017 (1 year). We proposed this time frame because we believe this will provide sufficient time for IRFs, and we can put processes and procedures in place to meet the additional quality reporting requirements. Given that these measures are collected via the IRF-PAI, and IRFs are already familiar with the QIES ASAP system, we believe this proposed timeframe would allow IRFs ample opportunity to begin reporting the newly proposed measures, should they be finalized. We also proposed that the quarterly data submission deadlines (for submitting IRF-PAI corrections) for the FY 2018 and FY 2019 adjustments to the IRF PPS annual increase factor would occur approximately 135 days after the end of the quarter, as outlined in the Table 23 (FY 2018) and Table 24 (FY 2019). Each quarterly deadline would be the date by which all data collected during the preceding quarter would be required to be submitted to us for measures using the IRF-PAI.

We sought public comment on these proposed timelines for data submission for the proposed IRF QRP quality measures for the FY 2018 and FY 2019 adjustments to the IRF PPS annual increase factor. The responses to public comments on timelines for data submission are discussed in this section of the final rule.

Comment: Several commenters suggested using the patient's admission date instead of their discharge date for the effective date for the IRF-PAI Version 1.4, citing EMR burden and uncertainty about which IRF-PAI items would be required for which patients at the time of their admission.

Response: Because the IRF-PAI is submitted to CMS for payment purposes, as well as quality purposes, and both the admission data and discharge data are only submitted upon

discharge of the patient, we believe requiring any discharge that occurs on or after the date of implementation of a new version of the IRF-PAI allows for the reporting of the most accurate and current data. We historically released, and will continue to release, training manuals that accompany new iterations of our data collection instruments. Additionally, we plan on providing national-level training for IRFs related to the release of the IRF-PAI version 1.4. Please continue to check the IRF Quality Reporting Training webpage for information on such trainings. The IRF Quality Reporting Training webpage is accessible at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Training.html.

Final Decision: After consideration of public comments on the timeline for data submission under the IRF QRP for the FY 2018 and FY 2019 payment determinations, we are finalizing this policy, as proposed.

Table 23: Data Collection Time Frame and Submission Deadlines for IRF QRP Quality Data for Measures* using IRF-PAI as Data Collection Mechanism, FY 2018 Adjustments to the Annual Increase Factor

Quarter (Calendar Year)	Data Collection Time Frame	Deadline Submission of IRF-PAI Corrections	Annual Increase Factor Affected
Quarter 4 (CY 2016)	October 1, 2016 – December 31, 2016	May 15, 2017	FY 2018

* includes data required for the 3 cross-setting IMPACT Act measures.

Table 24: Data Collection Time Frame and Submission Deadlines for IRF QRP Quality Data for Measures using IRF-PAI as Data Collection Mechanism, FY 2019 Adjustments to the Annual Increase Factor

Quarter (Calendar Year)	Data Collection Time Frame	Deadline Submission of IRF-PAI Corrections	Annual Increase Factor Affected
Quarter 1 (CY 2017)	January 1, 2017 – March 31, 2017	August 15, 2017	FY 2019
Quarter 2 (CY 2017)	April 1, 2017 – June 30, 2017	November 15, 2017	FY 2019
Quarter 3	July 1, 2017 – September 30, 2017	February 15, 2018	FY 2019

Quarter (Calendar Year)	Data Collection Time Frame	Deadline Submission of IRF-PAI Corrections	Annual Increase Factor Affected
(CY 2017)			
Quarter 4 (CY 2017)	October 1, 2017 – December 31, 2017	May 15, 2018	FY 2019

3. Revision to the Previously Adopted Data Collection Timelines and Submission Deadlines

We proposed that the quality measures in the IRF QRP have a data collection time frame based on the calendar year, unless there is a clinical reason for an alternative data collection time frame. For example, for Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680), the data collection period is tied to the influenza vaccination season. At this time, three of the quality measures submitted via CDC's NHSN (that is, the CAUTI measure [NQF #0138], the MRSA measure [NQF #1716], and the CDI measure [NQF #1717]) use a quarterly data collection time frame based on the calendar year. The pressure ulcer measure [NQF #0678], which is submitted using the IRF-PAI, follows a fiscal year data collection time frame due to the current fiscal-year-based release schedule of the IRF-PAI. The 2 influenza vaccination quality measures (Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine [NQF #0680], Influenza Vaccination Coverage among Healthcare Personnel [NQF #0431]) use a data collection time frame that is consistent with the influenza vaccination season (that is, October 1 [or when the vaccine becomes available] to March 31).

We proposed to revise the data collection time frame to follow the calendar year, unless there is a clinical reason for an alternative data collection time frame. We posited this change would simplify the data collection and submission time frame under the IRF QRP for IRF

providers. It would also eliminate the situation in which data collection during a quarter in the same calendar year can affect 2 different years of annual payment update determination (that is, October 1 to December 31 is first quarter of data collection for quality measures with fiscal year data collection time frame and the last quarter of data collection for quality measures with calendar data collection time frame). If this proposal was implemented, when additional quality measures that use IRF-PAI as the data collection mechanism are adopted for future use in the IRF QRP, the first data collection time frame for those newly-adopted measures will be 3 months (October to December) and subsequent data collection time frame would follow a calendar year data collection time frame.

We sought public comments on our proposal to adopt calendar year data collection time frames, unless there is a clinical reason for an alternative data collection time frame. The responses to public comments on revisions to data submission timelines are discussed in this section of the final rule.

Comment: Several commenters supported the proposal to modify data collection timelines from fiscal year to calendar year for all measures, unless there is a clinical reason for an alternative timeline.

Response: We thank the commenters for their feedback and support to revise the data collection period to calendar year for quality measures, unless there is a clinical reason for an alternate data collection period. We agree that this would simplify the data collection and reporting process.

Final Decision: After consideration of public comments, we are finalizing this policy as proposed.

4. Data Submission Mechanisms for the FY 2018 and Subsequent Years Payment Determination for Additional IRF QRP Quality Measures and for Revisions to Previously Adopted Quality Measures

We proposed that all IRFs would be required to collect data using a revised IRF-PAI Version 1.4 (IRF-PAI 1.4) for the pressure ulcer measure and the additional 6 quality measures: (1) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678); (2) an application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674); (3) an application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015); (4) IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review); (5) IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review); (6) IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; endorsed on July 23, 2015); and (7) IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015). IRF-PAI Version 1.4 would have modified pressure ulcer items collected at admission and discharge, new fall items collected at discharge, new self-care and mobility functional status items collected at admission and discharge, and new risk factor items for the self-care and mobility measures collected at admission. The proposed IRF-PAI Version 1.4 is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

The QIES ASAP system would remain the data submission mechanism for the IRF-PAI.

We will release the technical data submission specifications and update the IRF-PAI Training Manual to include items related to the new and updated quality measures in CY 2015. Further information on data submission of the IRF-PAI for the IRF QRP using the QIES ASAP system is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html. We sought public comments on these data submission requirements. The responses to public comments on data submission requirements are discussed in this section of the final rule.

Comment: Some commenters noted the need for CMS to issue direction with regard to which IRF-PAI version 1.4 data items are voluntary versus mandatory. Others noted that the IRF community needs clear training manuals and specifications.

Response: We have historically released, and are planning to release, the IRF-PAI Training Manual, as well as data submission specifications, both of which will guide providers with respect to mandatory items. Additionally, we are planning a national IRF Train the Trainer conference, during which we will also present such information. We invite providers to visit our IRF Quality Reporting Training webpage for further information on upcoming manual releases and training events. The IRF Quality Reporting Training webpage can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Training.html.

Final Decision: After consideration of public comments, we are finalizing this policy, as proposed.

J. Timing for New IRFs to Begin Submitting Quality Data under the IRF QRP for the FY 2018 Payment Determination and Subsequent Years

In the FY 2015 IRF PPS (79 FR 45918), we finalized that beginning with the FY 2017

payment determination and that of subsequent fiscal years, new IRFs are required to begin reporting data under the IRF QRP requirements no later than the first day of the calendar quarter subsequent to the quarter in which it was designated as operating in the Certification and Survey Provider Enhanced Reports (CASPER) system.

To ensure that all IRFs have a minimum amount of time to prepare to submit quality data to CMS under the requirements of the IRF QRP, we proposed that a new IRF would be required to begin reporting quality data under the IRF QRP by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter. For example, if an IRF's CCN notification letter is dated March 15th, then the IRF would be required to begin reporting quality data to CMS beginning on July 1st (March 15 + 30 days = April 14 (quarter 2). The IRF would be required to begin collecting quality data on the first day of the quarter subsequent to quarter 2, which is quarter 3, or July 1st). The collection of quality data would begin on the first day of the calendar year quarter identified as the start date, and would include all IRF admissions and subsequent discharges beginning on, and subsequent to, that day; however, the actual submission of quality data would be required by previously finalized quarterly deadlines, which fall approximately 135 days post the end of each CY quarter. To determine which quality measure data an IRF would need to begin submitting, we refer you to section IX.E of this final rule, as it will vary depending upon the timing of the CY quarter identified as a start date.

In the FY 2016 IRF PPS proposed rule, we indicated that the proposed requirements would apply beginning with the FY 2017 payment determination. We note that the inclusion of "FY 2018" in this section heading in the FY 2016 IRF PPS proposed rule was a technical error, and that the reference to FY 2017 in proposed policy was correct, and is feasible for us to

implement. However, it remains feasible for us to implement these requirements for FY 2018 payment determination and subsequent years, as we proposed. Therefore, we are not finalizing this proposal for the FY 2018 payment determination, but we are finalizing this proposal for FY 2017 payment determination and subsequent years.

We proposed to add the IRF QRP participation requirements at §412.634 and sought public comments on our proposal to the participation requirements for new IRFs. The responses to public comments on the IRF QRP participation requirements are discussed in this section of the final rule.

Comment: We received several supportive comments regarding the change to our policy that directs when new IRFs are required to begin reporting data, some stating that the expanded timeframe will be beneficial to new providers.

Response: We agree that the expanded timeframe surrounding when new IRF providers need to begin submitting quality data to CMS is beneficial in that it allows each provider ample time to begin reporting, whether their certification falls at the beginning or end of a calendar year quarter, and has removed any advantage for providers certified at the beginning of a calendar year quarter.

Final Decision: After consideration of public comments, and as previously discussed, we are finalizing this policy for the FY 2017, payment determination and subsequent years.

K. IRF QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2015 IRF PPS final rule (79 FR 45921 through 45923), we finalized IRF QRP thresholds for completeness of IRF data submissions. To ensure that IRFs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning

with the FY 2016 payment determination and for each subsequent year, IRFs must meet or exceed two separate data completeness thresholds: one threshold set at 95 percent for completion of quality measures data collected using the IRF-PAI submitted through the QIES and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN.

Additionally, we stated that we will apply the same thresholds to all measures adopted as the IRF QRP expands and IRFs begin reporting data on previously finalized measure sets. That is, as we finalize new measures through the regulatory process, IRFs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that an IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. We did not propose any changes to these policies. Refer to the FY 2015 IRF PPS final rule (79 FR 45921 through 45923) for a detailed discussion of the finalized IRF QRP data completion requirements.

While we did not seek comment on previously finalized IRF QRP thresholds for completeness of IRF data submissions, we received several comments.

Comment: One commenter expressed concerns about the data completion thresholds, citing that they are too high given CMS' acknowledgment that achieving 100 percent data completion would be difficult at best. The commenter was also concerned that the threshold would be applied to data collected in FY 2014, despite being proposed after FY 2014 had already begun, and noted that CMS should avoid policies that have a retroactive impact on payment.

The commenter suggested CMS to suspend the data completion threshold and work with stakeholders to develop a new policy.

Response: To clarify, the IRF QRP has two data completion thresholds: a threshold of 95 percent regarding quality data submitted via the IRF-PAI Quality Indicator section; and a threshold of 100 percent regarding the quality data submitted via the CDC's NHSN. We have continually maintained that providers should be submitting complete and accurate data, and the adoption of the data completion thresholds in the FY 2015 IRF PPS final rule did not change this policy. We believe that both data completion thresholds are achievable, as evidenced by the 91 percent of IRFs that were able to achieve these thresholds for purposes of the FY 2015 payment determination. We have also taken strides to increase compliance, including regular notification of upcoming deadlines, updated guidance documents, increased alarms for incomplete data submissions, and the development of several reports which will help providers better determine where they stand with respect to compliance throughout the year.

L. Proposed Suspension of the IRF QRP Data Validation Process for the FY 2016 Payment Determination and Subsequent Years

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(j)(7)(E) and 1899B(g) of the Act. In the FY 2015 IRF PPS rule (79 FR 45923), we finalized, for the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent years, a process to validate the data submitted for quality purposes. In the FY 2016 IRF PPS proposed rule (80 FR 23386), we proposed to temporarily suspend the implementation of this policy. We proposed that, through the suspension of this previously finalized policy, data accuracy validation will have no bearing on the applicable FY annual increase factor reduction for FY 2016 and subsequent years unless and until we propose

to either reenact this policy, or propose to adopt a new validation policy through future rulemaking. At this time, we are working to develop a more comprehensive data validation policy that is aligned across the PAC quality reporting programs, and believe that we can implement a policy that increases the efficiency with which data validation is performed. We are also considering ways to reduce the labor and cost burden on IRFs through the development of a new data accuracy validation policy.

We sought comment on our proposal.

Comment: Several commenters supported CMS' proposal to temporarily suspend the data validation policy.

Response: We appreciate the commenters for their support.

Final Decision: After careful consideration of public comments, we are finalizing our decision to temporarily suspend the IRF data accuracy validation policy, as proposed.

M. Previously Adopted and Proposed IRF QRP Submission Exception and Extension Requirements for the FY 2017 Payment Determination and Subsequent Years

In the FY 2014 IRF PPS final rule (78 FR 47920), we finalized a process for IRF providers to request and for us to grant exceptions or extensions for the reporting requirements of the IRF QRP for one or more quarters, beginning with the FY 2015 payment determination and for subsequent years when there are extraordinary circumstances beyond the control of the provider. We also finalized a policy that allows us to grant exemptions or extensions to IRFs that did not request them when it is determined that an extraordinary circumstance affects an entire region or locale.

In the FY 2015 IRF PPS final rule (79 FR 45920 through 45921), we adopted the policies and procedures previously finalized in the FY 2014 IRF PPS final rule for the FY 2017 payment

determination and that of subsequent years. We also finalized the policy that grants an exception or extension to IRFs if we determine that a systemic problem with 1 of our data collection systems directly affected the ability of an IRF to submit data.

We did not propose any changes to the previously finalized policies and procedures for the FY 2018 payment determination and beyond.

In the FY 2014 IRF PPS final rule and the FY 2015 IRF PPS final rule, we stated that IRFs must request an exception or extension by submitting a written request along with all supporting documentation to CMS via email to the IRF QRP mailbox at IRFQRPReconsiderations@cms.hhs.gov. We further stated that exception or extension requests sent to us through any other channel would not be considered as a valid request for an exception or extension from the IRF QRP's reporting requirements for any payment determination. To be considered, a request for an exception or extension must contain all of the requirements as outlined on CMS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Reconsideration-and-Exception-and-Extension.html.

We proposed to add the IRF QRP Submission Exception and Extension Requirements at §412.634. Refer to the FY 2014 IRF PPS final rule (78 FR 47920) and the FY 2015 IRF PPS final rule (79 FR 45920 through 45921) for detailed discussions of the IRF QRP Submission Exception and Extension Requirements.

Final Decision: We did not receive any public comments on this previously finalized policy, and, as such, are not making any changes to the policy. We are finalizing our proposal to codify our Data Submission Exception and Extension Requirements at §412.634.

N. Previously Adopted and Proposed IRF QRP Reconsideration and Appeals Procedures for the FY 2017 Payment Determination and Subsequent Years

At the conclusion of each FY reporting cycle, we review the data received from each IRF to determine if the IRF met the reporting requirements set forth for that reporting cycle. IRFs that are found to be non-compliant will receive a reduction in the amount of 2 percentage points to their annual payment update for the applicable fiscal year. In the FY 2015 IRF PPS final rule (79 FR 45919 through 45920), we described and adopted an updated process that enables an IRF to request a reconsideration of our initial noncompliance decision in the event that an IRF believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its IRF PPS annual increase factor due to noncompliance with the IRF QRP reporting requirements for a given reporting period.

Any IRF that wishes to submit a reconsideration request must do so by submitting an email to CMS containing all of the requirements listed on the IRF program website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Reconsideration-and-Exception-and-Extension.html. Email sent to IRFQRPReconsiderations@cms.hhs.gov is the only form of submission that will be accepted by us. Any reconsideration requests received through another channel, including U.S. postal service or phone, will not be considered as a valid reconsideration request.

We proposed to continue using the IRF QRP Reconsideration and Appeals Procedures that were adopted in the FY 2015 IRF PPS final rule (79 FR 45919 through 45920) for the FY 2017 payment determination and subsequent years with an exception regarding the way in which non-compliant IRFs are notified of this determination.

Currently IRFs found to be non-compliant with the reporting requirements set forth for a

given payment determination received a notification of this finding along with instructions for requesting reconsideration in the form of a certified United States Postal Service (USPS) letter. In an effort to communicate as quickly, efficiently, and broadly as possible with IRFs regarding annual compliance, we proposed changes to our communications method regarding annual notification of reporting compliance in the IRF QRP. In addition to sending letters via regular USPS mail, beginning with the FY 2016 payment determination and for subsequent fiscal years, we proposed to use the QIES as a mechanism to communicate to IRFs regarding their compliance with the reporting requirements for the given reporting cycle.

We proposed that all Medicare-certified IRF compliance letters be uploaded into the QIES system for each IRF to access. Instructions to download files from QIES may be found at https://www.qtso.com/irfpai.html. We proposed to disseminate communications regarding the availability of compliance reports in IRFs' QIES files through routine channels to IRFs and vendors, including, but not limited to, issuing memos, emails, Medicare Learning Network (MLN) announcements, and notices on http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html.

The purpose of the compliance letter is to notify an IRF that it has been identified as either being compliant or non-compliant with the IRF QRP reporting requirements for the given reporting cycle. If the IRF is determined to be non-compliant, then the notification would indicate that the IRF is scheduled to receive a 2 percentage point reduction to its upcoming annual payment update and that it may file a reconsideration request if it disagrees with this finding. IRFs may request a reconsideration of a non-compliance determination through the CMS reconsideration request process. We also proposed that the notifications of our decision

regarding all received reconsideration requests will be made available through the QIES system. We did not propose to change the process or requirements for requesting reconsideration. Refer to the FY 2015 IRF PPS final rule (79 FR 45919 through 45920) for a detailed discussion of the IRF QRP Reconsideration and Appeals Procedures.

Below, we discuss a proposal to publish a list of IRFs who successfully meet the reporting requirements for the applicable payment determination on the IRF QRP website http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/. As proposed, we also update the list of IRFs who successfully meet the reporting requirements after all reconsideration requests have been processed on an annual basis.

We proposed to add the IRF QRP Reconsideration and Appeal Procedures at §412.634.

We sought comment on the proposals to change the communication mechanism to the QIES system for the dissemination of compliance notifications and reconsideration decisions and to add these processes at §412.634.

Comment: Several commenters supported CMS' proposal to notify non-compliant IRFs using QIES, as well as via USPS.

Response: We appreciated the commenters for their support.

Comment: One commenter appreciated CMS' attempts to improve communication but suggested CMS to consider transferring the IRF QRP reporting to QualityNet, which is the current clearinghouse for all other Medicare quality reporting programs. This commenter suggested that doing so would reduce provider confusion, promote program alignment, and enhance compliance rates

Response: We thank the commenter for their feedback about communication and will take their suggestion into consideration for future rulemaking.

Final Decision: After careful consideration of public comments, we are finalizing these policies, as proposed.

O. Proposed Public Display of Quality Measure Data for the IRF QRP

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF QRP data available to the public. In so doing, the Secretary must ensure that IRFs have the opportunity to review any such data with respect to the IRF prior to its release to the public. Section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance of individual PAC providers with respect to the measures required under section 1899B of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public with respect to the PAC provider prior to such data being made public. We proposed a policy to display performance information regarding the quality measures, as applicable, required by the IRF QRP by fall 2016 on a CMS website, such as the Hospital Compare website at http://www.hospitalcompare.hhs.gov, after a 30-day preview period. Additional information about preview report content and delivery will be announced on the IRF QRP website.

The Hospital Compare website 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 providers to discuss the quality of care provided to patients, by providing an additional incentive to providers to improve the quality of care that they furnish. As we have done on other CMS compare websites, we will, at

some point in the future, report public data using a quality rating system that gives each IRF a rating between 1 and 5 stars. Initially, however, we will not use the 5-star methodology, until such time that we are publicly reporting a sufficient number of quality metrics to allow for variation and the differentiation between IRFs using this methodology. Decisions regarding how the rating system will determine a provider's star rating and methods used for calculations, as well as a proposed timeline for implementation, will be announced via regular IRF QRP communication channels, including listening sessions, memos, email notification, provider association calls, Open Door Forums, and Web postings. Providers would be notified via CMS listservs, CMS mass e-mails, and memorandums, IRF QRP website announcements and MLN announcements regarding the release of IRF Provider Preview Reports followed by the posting of data.

The initial display of information would contain IRF provider performance on the following 3 quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678).
- NHSN CAUTI Outcome Measure (NQF #0138).
- All-Cause Unplanned Readmission Measure for 30 Days Post Discharge From IRFs (NQF #2502).

For the first 2 listed measures, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) and NHSN CAUTI Outcome Measure (NQF #0138), we proposed publicly reporting data beginning with data collected on these measures for discharges beginning January 1, 2015. Rates would be displayed based on 4 rolling quarters of data and would initially be reported using discharges from January 1, 2015 through

December 31, 2015, for calculation. As each quarter advances, we would add the subsequent calendar year quarter and remove the earliest calendar year quarter. For example, initially we would use data from discharges occurring from January 1, 2015 through December 31, 2015. The next quarter, we would display performance data using discharges that occurred between the dates of April 1, 2015 through March 31, 2016, etc.

For the measure All-Cause Unplanned Readmission Measure for 30 Days Post Discharge From IRFs (NQF #2502), we proposed to publicly report data beginning with data collected for discharges beginning January 1, 2013. Rates would be displayed based on 2 consecutive years of data and would initially be reported using discharges from January 1, 2013 through December 31, 2014. As each calendar year advances, we would add the subsequent calendar year quarter and remove the earliest calendar year.

Calculations for the CAUTI measure adjust for differences in the characteristics of hospitals and patients using a Standardized Infection Ratio (SIR). The SIR is a summary measure that takes into account differences in the types of patients a hospital treats. The SIR may take into account the type of patient care location, laboratory testing methods, hospital affiliation with a medical school, bed size of the hospital, and bed size of specific patient care locations. It compares the actual number of Healthcare Associated Infections (HAIs) in a facility or state to a national benchmark based on previous years of reported data and adjusts the data based on several risk factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within that interval. An SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or state than were predicted, and the facility is classified as "Worse than the U.S. National Benchmark". If the SIR has an upper limit that is less than 1, then the

facility had fewer HAIs than were predicted and is classified as "Better than the U.S. National Benchmark". If the confidence interval includes the value of 1, then there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is classified as "No Different than U.S. National Benchmark". If the number of predicted infections is a specific value less than 1, the SIR and confidence interval cannot be calculated.

Calculations for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened measure application (NQF #0678) will be risk-adjusted. Resident- or patient-level covariate risk adjustment is performed. Resident- or patient-level covariates are used in a logistic regression model to calculate a resident- or patient-level expected quality measure (QM) score (the probability that the resident or patient will evidence the outcome, given the presence or absence of patient characteristics measured by the covariates). Then, an average of all resident- or patient-level expected QM scores for the facility is calculated to create a facility-level expected QM score. The final facility-level adjusted QM score is based on a calculation which combines the facility-level expected score and the facility level observed score. Additional information about the covariates can be found at www.qualityforum.org/QPS/0678.

Finally, calculation for performance on the measure All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) will also be risk-adjusted. The risk adjustment methodology is available, along with the specifications for this measure, on our IRF Quality Reporting Measures Information webpage at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

We are currently developing reports that will allow providers to view the data that is submitted to CMS via the QIES ASAP system and the CDC's NHSN (Percent of Residents or

Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) and NHSN CAUTI Outcome Measure (NQF #0138), respectively). Although initial reports will not allow providers to view this data, subsequent iterations of these reports will also include provider performance on any currently reported quality measure that is calculated based on CMS claims data that we plan on publicly reporting (All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502)). Although real time results will not be available, the report will refresh all of the data submitted at least once a month. We proposed a process to give providers an opportunity to review and correct data submitted to the QIES ASAP system or to the CDC's NHSN system by utilizing that report. Under this process, providers would to have the opportunity to review and correct data they submit on all assessment-based measures. Providers can begin submitting data on the first discharge day of any reporting quarter. Providers are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before the quarterly submission deadline. The data would be populated into reports that are updated at least once a month with all data that have been submitted. That report would contain the provider's performance on each measure calculated based on assessment submissions to the QIES ASAP or CDC NHSN system. We believe that the submission deadline timeframe, which is 4.5 months beyond the end of each calendar year quarter, is sufficient time for providers to be able to submit, review data, make corrections to the data, and view their data. We note that the quarterly data submission deadline/timeframe only applies to the quality indicator section of the IRF-PAI, and has no bearing on the current deadline of 27 days that is imposed for payment items. We proposed that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES ASAP or CDC NHSN system, we would consider the provider to have been given the

opportunity to review and correct this data. We would not allow patient-level data correction after the submission deadline or for previous years. This is because we must set a deadline to ensure timely computation of measure rates and payment adjustment factors. Before we display this information, providers will be permitted 30 days to review their information as recorded in the QIES ASAP or CDC NHSN system.

In addition to our proposal, we proposed to publish a list of IRFs who successfully meet the reporting requirements for the applicable payment determination on the IRF QRP website http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/. We proposed updating the list after reconsideration requests are processed on an annual basis.

We sought public comment on the listed proposals.

Comment: One commenter supported the public display of the NHSN CAUTI Outcome Measure (NQF #0138). This commenter also mentioned displaying the SIR information for this measure.

Response: We would like to clarify that while the SIR calculation will be communicated to each IRF provider in their Preview Report that will be issued during the 30-day preview period prior to public reporting, the IRF public reporting website will not display this information, but rather will display ratings based on whether or not an IRF is the same, higher than, or lower than the national average with respect to their performance on the CAUTI measure.

Comment: Several commenters supported public display of IRF QRP data, but requested an opportunity to submit corrections during the preview period.

Response: We would like to clarify that once we issue the Preview Report to IRF

providers, they will have 30 days during which to contest the measure calculations contained within that report. We will not allow providers to correct patient level data during the preview period, as this would have the effect of negating our data submission deadlines. We maintain that IRFs have 135 days beyond the end of each calendar year quarter during which to review and correct patient-level data, and believe that this is a sufficient amount of time. While providers may use this time as an extended data submission deadline, the original intent of this grace period was to allow for provider review and correction of their patient-level data. Our public reporting preview period policy aligns with that of the HIQR and other CMS QRPs. We suggested to providers to submit data as soon as possible, in order to ensure enough time for review and correction of that data.

Final Decision: After careful consideration of public comments, we are finalizing our policy related to the public display of quality measure data for the IRF QRP, as proposed.

P. Method for Applying the Reduction to the FY 2016 IRF Increase Factor for IRFs That Fail to Meet the Quality Reporting Requirements

As previously noted, section 1886(j)(7)(A)(i) of the Act requires the application of a 2-percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. In compliance with 1886(j)(7)(A)(i) of the Act, we will apply a 2-percentage point reduction to the applicable FY 2016 market basket increase factor (1.7 percent) in calculating an adjusted FY 2016 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As previously noted, application of the 2-percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the

market basket increase factor will not be cumulative; they will only apply for the FY involved. Table 25 shows the calculation of the adjusted FY 2016 standard payment conversion factor that will be used to compute IRF PPS payment rates for any IRF that failed to meet the quality reporting requirements for the period from January 1, 2014, through December 31, 2014.

TABLE 25: Calculations to Determine the Adjusted FY 2016 Standard Payment Conversion Factor for IRFs That Failed to Meet the Quality Reporting Requirement

Explanation for Adjustment	Calculations	
Standard Payment Conversion Factor for FY 2015		$15,198
Market Basket Increase Factor for FY 2016 (2.4 percent), reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, reduced by 0.2 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement	x	0.9970
Budget Neutrality Factor for the Wage Index and Labor-Related Share	x	1.0033
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	x	0.9981
Final Adjusted FY 2016 Standard Payment Conversion Factor	=	$15,174

We received no comments on the proposed method for applying the reduction to the FY 2016 IRF increase factor for IRFs that fail to meet the quality reporting requirements.

Final Decision: As we did not receive any comments on the proposed method for applying the reduction to the FY 2016 IRF increase factor for IRFs that fail to meet the quality reporting requirements, we are finalizing the proposed methodology.

X. Miscellaneous Comments

Comment: Although one commenter expressed support for the changes to the 60 percent rule compliance methodology that we finalized in the FY 2014 and FY 2015 IRF PPS final rules, several other commenters expressed concerns about the impact of these changes on beneficiary access to IRF services and suggested that we revisit them. In addition, several commenters suggested that we add specific ICD-10-CM codes to the list of codes that would meet the

60 percent rule under the presumptive methodology, including specific diagnosis codes related to cognition, swallowing, and communication. Further, one commenter requested that additional clarity and rationale be added to the 60 percent rule compliance data files that we posted on the CMS website in conjunction with the FY 2014 and FY 2015 IRF PPS final rules.

Response: As we did not propose any changes to the methodology for determining IRFs' compliance with the 60 percent rule, these comments are outside the scope of the proposed rule. We appreciate the commenter's suggestions, and will continue to monitor and assess the implications of the changes to the presumptive methodology that we finalized in the FY 2014 and FY 2015 IRF PPS final rules to determine if any further refinements to the methodology are needed.

Comment: Several commenters suggested that we use the most recent 3 years of data to re-examine the conditions that are included on the list of tier comorbidities, and that we revise this list for FY 2016. One commenter provided a list of specific diagnosis codes to add to the list.

Response: As we did not propose any changes to the list of tier comorbidities, these comments are outside the scope of the proposed rule. We appreciate the commenters' suggestions, and will consider these suggestions for future analyses.

Comment: One commenter suggested that CMS should be more transparent about the criteria the agency is using to determine when changes to the facility-level adjustments occur. Another commenter encouraged CMS to continue to analyze changes to the facility-level adjustments and adjust all three factors at a minimum of every three years.

Response: As we did not propose any changes to the facility-level adjustments, these comments are outside the scope of the proposed rule. The FY 2016 IRF PPS proposed rule

(80 FR 23332 at 23341) included a reminder that, in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), we froze the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking).

Comment: Several commenters suggested that we consider imposing a cap, possibly adjusted by a geographic index, on the amount of outlier payments an individual IRF can receive under the IRF PPS.

Response: Comments regarding the amount of outlier payments an individual IRF can receive are outside the scope of this rule. However, any future consideration given to imposing a limit on outlier payments would have to carefully analyze and take into consideration the effect on access to IRF care for certain high-cost populations.

Comment: One commenter requested clarification of several IRF PPS policies, including the therapy data collection that was finalized in the FY 2015 IRF PPS final rule (79 FR 45900 through 45903), the weighted motor score that is used to classify beneficiaries into CMGs, and the definition of a Medicare "discharge" under the IRF PPS.

Response: Comments regarding the therapy data collection that was finalized in the FY 2015 IRF PPS final rule are outside the scope of this rule. However, additional information on the therapy data collection that begins October 1, 2015 is available for download from the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html. Comments regarding the weighted motor score are also outside the scope of this rule. However, we refer the commenter to the detailed discussion of the weighted motor score in the FY 2006 IRF PPS final rule (70 FR 47880 at 47896 through 47900). Finally, the definition of an IRF discharge is located at §412.602.

Comment: Several commenters noted the need for consistency in payment policies and regulations across Medicare post-acute care settings, and suggested that CMS should reduce or eliminate any unnecessary or burdensome IRF regulations and documentation requirements, including those associated with the IRF coverage requirements or the IRF 60 percent rule. One commenter also discussed the Medicare Payment Advisory Commission's site-neutral payment policy recommendation for post-acute care.

Response: Comments regarding the any site-neutral payment policies or changes to IRF regulations or documentation requirements are outside the scope of this rule.

Comment: Several commenters requested that we review the ICD-10-CM codes that we finalized in the FY 2015 IRF PPS final rule (79 FR 45905 through 45908) and add specific ICD-10-CM codes to the diagnosis code lists used in the 60 percent rule presumptive methodology and in assigning tier comorbidities. In addition, one commenter suggested that we perform additional "end-to-end" testing of the ICD-10-CM coding to ensure that IRFs are able to submit their claims and IRF-PAI forms using ICD-10-CM codes in a timely manner and that contractors are able to reimburse providers based on ICD-10-CM coding in a timely manner.

Response: Comments regarding any changes to the ICD-10-CM codes for the IRF PPS are outside the scope of the proposed rule. However, we are undergoing extensive testing of ICD-10-CM coding of claims and IRF-PAIs, and will closely monitor the effects of the ICD-10-CM implementation on IRFs to ensure that IRF claims are paid appropriately and expeditiously. Once we have enough ICD-10-CM data to analyze, we also plan to assess the lists of ICD-10-CM codes for the IRF PPS to determine whether any revisions to the code lists for the 60 percent rule or the tier comorbidities might be needed.

XI. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2016 IRF proposed rule (80 FR 23332), except as noted elsewhere in the preamble. Specifically:

- We will update the FY 2016 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section IV of this final rule.

- We include a reminder that, in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), we froze the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking),as discussed in section V of this final rule.

- We will adopt the IRF-specific market basket, as discussed in section VI of this final rule.

- We will update the FY 2016 IRF PPS payment rates by the market basket increase factor, based upon the most current data available, with a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act and the productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI of this final rule.

- We will update the FY 2016 IRF PPS payment rates by the FY 2016 wage index and the labor-related share in a budget-neutral manner and the wage adjustment transition as discussed in section VI of this final rule.

- We will calculate the final IRF standard payment conversion factor for FY 2016, as discussed in section VI of this final rule.

- We will update the outlier threshold amount for FY 2016, as discussed in section VII of this final rule.

- We will update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2016, as discussed in section VII of this final rule.

- We include a reminder of the October 1, 2015 implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for the IRF PPS, as discussed in section VIII of this final rule.

- We will adopt revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section IX of this final rule.

XII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 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. 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.

This final rule makes reference to associated information collections that are not

discussed in the regulation text contained in this document.

B. Collection of Information Requirements for Updates Related to the IRF QRP

Failure to submit data required under section 1886(j)(7)(C) and (F) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary. At the time that this analysis was prepared, 91, or approximately 8 percent, of the 1166 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2015 annual payment update determination. Information is not available to determine the precise number of IRFs that will not meet the requirements to receive the full annual percentage increase for the FY 2016 payment determination.

We believe that the burden associated with the IRF QRP is the time and effort associated with data collection and reporting. As of April 1, 2015, there are approximately 1132 IRFs currently reporting quality data to CMS. In this final rule, we are finalizing 2 quality measures that have already been adopted for the IRF QRP: (1) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), to establish the newly NQF-endorsed status of this measure; and (2) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), to establish its use as a cross-setting measure that addresses the domain of skin integrity, as required by the IMPACT Act of 2014. The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) is a Medicare claims-based measure; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact. We also believe that there will be no additional burden associated with our re-proposal of the measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened

(Short-Stay) (NQF #0678), as IRFs are already submitting quality data related to this measure.

We also proposed adoption of 6 additional quality measures. These 6 new quality measures are: (1) an application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674); (2) an application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015); (3) IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review); (4) IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review); (5) IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; under review); and (6) IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015). Additionally we proposed that data for these 6 new measures will be collected and reported using the IRF-PAI (version 1.4).

Our burden calculations take into account all "new" items required on the IRF-PAI (version 1.4) to support data collection and reporting for these 6 proposed measures. New items will be included on the following assessment: IRF-PAI version 1.4 Admission and Discharge assessment. The addition of the new items required to collect the 6 newly adopted measures is for the purpose of achieving standardization of data elements.

We estimate the additional elements for the 6 newly adopted measures will take 25.5 minutes of nursing/clinical staff time to report data on admission and 16.0 minutes of nursing/clinical staff time to report data on discharge, for a total of 41.5 minutes. We believe that the additional IRF-PAI items we proposed will be completed by Registered Nurses (RN), Occupational Therapists (OT), Speech Language Pathologists (SLP) and/or Physical Therapists

(PT), depending on the item. We identified the staff type per item based on past LTCH and IRF burden calculations in conjunction with expert opinion. Our assumptions for staff type were based on the categories generally necessary to perform assessment: RN, OT, SLP, and PT. Individual providers determine the staffing resources necessary; therefore, we averaged the national average for these labor types and established a composite cost estimate. This composite estimate was calculated by weighting each salary based on the following breakdown regarding provider types most likely to collect this data: RN 59 percent; OT 11 percent; PT 20 percent; SLP 1 percent. In accordance with OMB control number 0938-0842, we estimate 390,748 discharges from all IRFs annually, with an additional burden of 41.5 minutes. This would equate to 270,267.37 total hours or 238.75 hours per IRF. We believe this work will be completed by RN, OT, PT, and SLP staff, depending on the item. We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm), and to account for overhead and fringe benefits, we have doubled the mean hourly wage. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a RN is $33.13. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $66.26 for an RN. The mean hourly wage for an OT is $37.45, doubled to $74.90 to account for overhead and fringe benefits. The mean hourly wage for a PT is $39.51, doubled to $79.02 to account for overhead and fringe benefits. The mean hourly wage for a SLP is $35.56, doubled to $71.12 to account for overhead and fringe benefits. Given these wages and time estimates, the total cost related to the six newly proposed measures is estimated at $21,239.33 per IRF annually, or $22,529,560.74-$24,042,291.01 for all IRFs annually.

For discussion purposes, we provided a detailed description of the burden associated with

the requirements in section IX of this final rule. However, the burden associated with the aforementioned requirements is exempt from the PRA under the IMPACT Act of 2014. Section 1899B(m) and the sections referenced in section 1899B(a)(2)(B) of the Act exempt modifications that are intended to achieve the standardization of patient assessment data. The requirement and burden will, however, be submitted to OMB for review and approval when the quality measures and the PAC assessment instruments are no longer used to achieve the standardization of patient assessment data.

In section IX.F. of this final rule, we are finalizing 2 quality measures that have already been adopted for the IRF QRP: (1) All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502), to establish the newly NQF-endorsed status of this measures; and (2) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), to establish its use as a cross-setting measure that addresses the domain of skin integrity, as required by the IMPACT Act of 2014. The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) is a Medicare claims-based measure; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact as a result of this measure. We also believe that there will be no additional burden associated with our proposal of the measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), as IRFs are already submitting quality data related to this measure.

In section IX.G. of this final rule, we are also finalizing adoption of six new quality measures. These 6 proposed quality measures are: (1) An application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674); (2) an application

of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015); (3) IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review); (4) IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review); (5) IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; under review); and (6) IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015). Additionally, we are finalizing that data for the 6 measures will be collected and reported using the IRF-PAI (version 1.4). While the reporting of data on quality measures is an information collection, we believe that the burden associated with modifications to the IRF-PAI discussed in this final rule fall under the PRA exceptions provided in 1899B(m) of the Act because they are required to achieve the standardization of patient assessment data . Section 1899B(m) of the Act provides that the PRA does not apply to section 1899B and the sections referenced in section 1899B(a)(2)(B) of the Act that require modification to achieve the standardization of patient assessment data. The requirement and burden will, however, be submitted to OMB for review and approval when the modifications to the IRF-PAI or other applicable PAC assessment instrument are not used to achieve the standardization of patient assessment data. Additionally, while the IMPACT Act does not specifically require the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review), IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review), IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; recommended for endorsement), and IRF Functional Outcome Measure: Discharge

Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015), the data elements used to inform those measures are part of larger set of functional status data items that have been added to the IRF-PAI version 1.4, for the purpose of providing standardized data elements under the domain of functional status, which is required by the IMPACT Act. These same data elements are used to inform different quality measures that we are finalizing, each with a different outcome.

For quality reporting during extraordinary circumstances, as discussed in section IX.M. of this final rule, we proposed to codify at §412.634 a process previously finalized for the FY 2017 payment determination and subsequent years for IRF providers to request exceptions or extensions for the IRF QRP reporting requirements when there are extraordinary circumstances beyond the control of the provider. The request must be submitted by e-mail within 90 days from the date that the extraordinary circumstances occurred.

While the preparation and submission of the request is an information collection, unlike the aforementioned temporary exemption of the data collection requirements for the 6 new quality measures, and the 2 re-proposed quality measures, the request is not expected to be submitted to OMB for formal review and approval since we estimate less than 2 requests (total) per year. Since we estimate fewer than 10 respondents annually, the information collection requirement and associated burden is not subject as stated in the implementing regulations of the PRA (5 CFR 1320.3(c)).

As discussed in section IX.N. of this final rule, we proposed to codify at §412.634 a previously finalized process that enables an IRF to request reconsiderations of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its annual increase factor due to non-compliance with the

IRF QRP reporting requirements. We believe the reconsideration and appeals requirements and the associated burden would be incurred subsequent to an administrative action. In accordance with the implementing regulations for the PRA (5 CFR 1320.4(a)(2) and (c)), the burden associated with any information collected subsequent to the administrative action is exempt from the requirements of the PRA.

Comments: Several commenters noted that there was undue burden associated with the collection of the 5 functional status measures we proposed and are finalizing, as they perceive the data items that inform these measures to be duplicative of existing items contained within the IRF-PAI.

Response: We have addressed these concerns under the comment and response section of the functional status measure proposals in sections IX.G.1. through IX.G.5. of this final rule.

Comment: Several commenters were concerned with the time and cost of updating electronic medical records systems in order to capture the new data items related to functional status. Some commenters noted that CMS only accounted for the time for the IRF-PAI and not the time for documentation in a patient's EMR to support the IRF-PAI information.

Response: While we applaud the use of EMRs to support the capture of IRF-PAI data, we do not require them. We issue free software which allows providers to capture and submit the required IRF-PAI data to us. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product are available on the CMS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html. We additionally provide data submission specifications which allow providers to integrate our requirements into their existing electronic systems; however, this is solely a business decision on the part of the provider. For the burden of

EMR documentation, we do not account for the burden of documenting data that is considered a routine part of clinical practice.

XIII. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the IRF prospective payment rates for FY 2016 as required under section 1886(j)(3)(C) of the Act. It responds to section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This final rule also implements sections 1886(j)(3)(C) and (D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 through 2019.

Furthermore, this final rule also adopts policy changes under the statutory discretion afforded to the Secretary under section 1886(j) of the Act. Specifically, we adopt an IRF-specific market basket, provide for a 1-year phase-in for the revised wage index changes for all IRFs, provide a 3-year phase-out of the rural adjustment for certain IRFs, and revise and update the quality measures and reporting requirements under the IRF quality reporting program.

B. Overall Impacts

We have examined the impacts of this final rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving

Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354) (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 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 a major final rule with economically significant effects ($100 million or more in any 1 year). We estimate the total impact of the policy updates described in this final rule by comparing the estimated payments in FY 2016 with those in FY 2015. This analysis results in an estimated $135 million increase for FY 2016 IRF PPS payments. As a result, this final rule is designated as economically "significant" under section 3(f)(1) of Executive Order 12866, and hence a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of $7.5 million to $38.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size

standards for health care industries, at 65 FR 69432 at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf, effective March 26, 2012 and updated on July 14, 2014.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,100 IRFs, of which approximately 60 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 26, we estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments by approximately 1.8 percent. However, we find that certain individual IRF providers would be expected to experience revenue impacts greater than 3 percent. We estimate that approximately 3 IRFs that would transition from urban to rural status as a result of the changes to the delineation of CBSAs issued in OMB Bulletin No. 13-01 will gain the 14.9 percent rural adjustment, and will therefore experience net increases in IRF PPS payments of 16.4 percent. As a result, we anticipate this final rule will have a net positive impact on small entities. Medicare Administrative Contractors are not considered to be small entities. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As discussed in detail below, the rates and policies set forth in this final rule will not have a significant impact (not greater than

3 percent) on a substantial number of rural hospitals based on the data of the 145 rural units and 12 rural hospitals in our database of 1,135 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-04, enacted on March 22, 1995) 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 2015, that threshold level is approximately $144 million. This final rule will not mandate spending costs on state, local, or tribal governments, in the aggregate, or by the private sector, of greater than $144 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated, this final rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

C. Detailed Economic Analysis

1. Basis and Methodology of Estimates

This final rule sets forth policy changes and updates to the IRF PPS rates contained in the FY 2015 IRF PPS final rule (79 FR 45872). Specifically, this final rule introduces an IRF-specific market basket. This final rule also updates the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This final rule applies a MFP adjustment to the FY 2016 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction to the FY 2016 IRF market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and -(D)(iv) of the Act. Further, this final rule contains revisions to the IRF quality reporting requirements that are

expected to result in some additional financial effects on IRFs. In addition, section IX of this final rule discusses the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements, in accordance with section 1886(j)(7) of the Act.

We estimate that the impact of the changes and updates described in this final rule will be a net estimated increase of $135 million in payments to IRF providers. This estimate does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements (as discussed in section XIII.C.9. of this final rule). The impact analysis in Table 26 of this final rule represents the projected effects of the updates to IRF PPS payments for FY 2016 compared with the estimated IRF PPS payments in FY 2015. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2016, we are adopting standard annual revisions described in this final rule (for example, the update to the wage and market basket indexes used to adjust the federal rates). We are also implementing a productivity adjustment to the FY 2016 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction to the FY 2016 IRF market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and -(D)(iv) of the Act. We estimate the total increase in payments to IRFs in FY 2016, relative to FY 2015, will be approximately $135 million.

This estimate is derived from the application of the FY 2016 IRF market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and -(D)(iv) of the Act, which yields an estimated increase in aggregate payments to IRFs of $130 million. Furthermore, there is an additional estimated $5 million increase in aggregate payments to IRFs due to the update to the outlier threshold amount. Outlier payments are estimated to increase from approximately 2.9 percent in FY 2015 to 3.0 percent in FY 2016. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of $135 million from FY 2015 to FY 2016.

The effects of the updates that impact IRF PPS payment rates are shown in Table 26. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 2.9 percent to 3.0 percent of total estimated payments for FY 2016, consistent with section 1886(j)(4) of the Act.

- The effects of the annual market basket update (using the IRF market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and sections 1886(j)(3)(C) and -

(D) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and -(D)(iv) of the Act.

- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.

- The effects of the budget-neutral changes to the CMG relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.

- The total change in estimated payments based on the FY 2016 payment changes relative to the estimated FY 2015 payments.

2. Description of Table 26

Table 26 categorizes IRFs by geographic location, including urban or rural location, and location for CMS's 9 Census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital (otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by disproportionate share patient percentage (DSH PP). The top row of Table 26 shows the overall impact on the 1,135 IRFs included in the analysis.

The next 12 rows of Table 26 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 978 IRFs located in

urban areas included in our analysis. Among these, there are 739 IRF units of hospitals located in urban areas and 239 freestanding IRF hospitals located in urban areas. There are 157 IRFs located in rural areas included in our analysis. Among these, there are 145 IRF units of hospitals located in rural areas and 12 freestanding IRF hospitals located in rural areas. There are 401 for-profit IRFs. Among these, there are 347 IRFs in urban areas and 54 IRFs in rural areas. There are 661 non-profit IRFs. Among these, there are 568 urban IRFs and 93 rural IRFs. There are 73 government-owned IRFs. Among these, there are 63 urban IRFs and 10 rural IRFs.

The remaining four parts of Table 26 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH PP. First, IRFs located in urban areas are categorized for their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this final rule to the facility categories listed are shown in the columns of Table 26. The description of each column is as follows:

- Column (1) shows the facility classification categories.

- Column (2) shows the number of IRFs in each category in our FY 2014 analysis file.
- Column (3) shows the number of cases in each category in our FY 2014 analysis file.
- Column (4) shows the estimated effect of the adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the update to the IRF PPS payment rates, which includes a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and -(D)(iv) of the Act.
- Column (6) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner. This represents the effect of using the most recent wage data available, without taking into account the revised OMB delineations. That is, the impact represented in this column is solely that of updating from the FY 2015 wage index to the FY 2016 wage index without any changes to the OMB delineations.
- Column (7) shows the estimated effect of adopting the updated OMB delineations for wage index purposes for FY 2016 with the blended FY 2016 wage index.
- Column (8) shows the estimated effect of applying the adjustment factor to payments to IRFs in rural areas. It includes the proposed 3 year budget-neutral phase-out of the rural adjustment for rural IRFs that are becoming urban IRFs due to the revised OMB delineations.
- Column (9) shows the estimated effect of the update to the CMG relative weights and average length of stay values, in a budget-neutral manner.
- Column (10) compares our estimates of the payments per discharge, incorporating all of the policies reflected in this final rule for FY 2016 to our estimates of payments per discharge in FY 2015.

The average estimated increase for all IRFs is approximately 1.8 percent. This estimated net increase includes the effects of the IRF market basket increase factor for FY 2016 of 2.4 percent, reduced by a productivity adjustment of 0.5 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.2 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(iv) of the Act. It also includes the approximate 0.1 percent overall increase in estimated IRF outlier payments from the update to the outlier threshold amount. Since we are making the updates to the IRF wage index and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

TABLE 26: IRF Impact Table for FY 2016 (Columns 4 through 10 in percentage)

Facility Classification	Number of IRFs	Number of Cases	Outlier	IRF Market Basket [1]	Wage Index	CBSA	Change in Rural Adjustment [2]	CMG Weights	Total Percent Change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Total	1,135	393,178	0.1	1.7	0.0	0.0	0.0	0.0	1.8
Urban unit	739	181,087	0.2	1.7	0.1	0.0	0.0	0.0	1.9
Rural unit	145	22,904	0.1	1.7	0.1	-0.2	0.3	0.0	2.0
Urban hospital	239	185,036	0.0	1.7	-0.1	0.1	0.0	0.0	1.7
Rural hospital	12	4,151	0.0	1.7	0.0	-0.7	0.0	-0.1	0.9
Urban For-Profit	347	172,770	0.1	1.7	0.0	0.0	0.0	0.0	1.7
Rural For-Profit	54	9,677	0.1	1.7	-0.1	-0.4	0.2	-0.1	1.4
Urban Non-Profit	568	174,551	0.1	1.7	0.0	0.1	0.0	0.0	2.0
Rural Non-Profit	93	15,778	0.1	1.7	0.2	-0.3	0.3	0.0	2.1
Urban Government	63	18,802	0.1	1.7	-0.4	0.0	-0.1	0.0	1.4
Rural Government	10	1,600	0.1	1.7	0.0	-0.4	0.0	0.0	1.5
Urban	978	366,123	0.1	1.7	0.0	0.0	0.0	0.0	1.8
Rural	157	27,055	0.1	1.7	0.1	-0.3	0.3	0.0	1.8
CBSA Change									
Urban to Urban	959	362,019	0.1	1.7	0.0	0.0	0.0	0.0	1.8
Rural to Rural	154	26,467	0.1	1.7	0.1	-0.3	0.0	0.0	1.6
Urban to Rural	3	588	0.2	1.7	0.7	0.8	12.4	0.2	16.4
Rural to Urban	19	4,104	0.1	1.7	0.5	1.4	-3.7	0.0	-0.1
Urban by region									
Urban New England	31	16,864	0.1	1.7	0.9	-0.2	0.0	0.1	2.6
Urban Middle Atlantic	143	58,190	0.1	1.7	0.2	0.4	0.0	0.0	2.4
Urban South Atlantic	146	69,975	0.1	1.7	-0.4	-0.1	-0.1	0.0	1.2
Urban East North Central	173	51,912	0.1	1.7	0.2	-0.1	0.0	0.0	2.0
Urban East South Central	54	25,119	0.1	1.7	-0.5	-0.1	0.0	0.0	1.1
Urban West North Central	73	19,092	0.1	1.7	0.0	0.0	0.0	0.1	1.9
Urban West South Central	179	73,556	0.1	1.7	-0.8	0.0	0.0	0.0	0.9
Urban Mountain	77	25,788	0.1	1.7	0.8	-0.1	0.0	0.0	2.5
Urban Pacific	102	25,627	0.2	1.7	1.1	-0.1	0.0	0.0	2.9
Rural by region									
Rural New England	5	1,278	0.2	1.7	0.8	-0.1	0.0	0.0	2.6
Rural Middle Atlantic	12	1,809	0.1	1.7	1.9	-2.1	0.0	0.1	1.7
Rural South Atlantic	17	4,282	0.1	1.7	-0.1	-0.3	0.4	-0.1	1.7
Rural East North Central	31	5,170	0.1	1.7	-0.3	0.1	1.0	0.0	2.8
Rural East South Central	18	3,255	0.1	1.7	-0.3	-0.2	0.0	0.0	1.4
Rural West North Central	23	2,881	0.2	1.7	0.2	-0.1	0.0	0.1	2.0
Rural West South Central	42	7,462	0.1	1.7	0.0	-0.5	0.0	0.0	1.2
Rural Mountain	7	736	0.3	1.7	-0.4	-0.1	0.0	0.0	1.6
Rural Pacific	2	182	0.6	1.7	0.8	0.0	0.0	-0.1	3.0
Teaching status									
Non-teaching	1,032	351,348	0.1	1.7	0.0	0.0	0.0	0.0	1.7

Facility Classification	Number of IRFs	Number of Cases	Outlier	IRF Market Basket [1]	Wage Index	CBSA	Change in Rural Adjustment [2]	CMG Weights	Total Percent Change
Resident to ADC less than 10%	61	28,997	0.1	1.7	0.3	-0.2	0.0	0.1	2.0
Resident to ADC 10%-19%	32	11,253	0.2	1.7	0.5	0.3	0.0	0.0	2.8
Resident to ADC greater than 19%	10	1,580	0.1	1.7	0.1	-0.3	0.0	-0.1	1.5
Disproportionate share patient percentage (DSH PP)									
DSH PP = 0%	34	4,850	0.2	1.7	-0.2	-0.1	0.0	0.1	1.7
DSH PP <5%	172	62,562	0.1	1.7	-0.2	0.3	0.0	0.0	1.9
DSH PP 5%-10%	326	133,750	0.1	1.7	-0.1	0.0	0.1	0.0	1.7
DSH PP 10%-20%	376	133,463	0.1	1.7	0.1	-0.1	-0.1	0.0	1.8
DSH PP greater than 20%	227	58,553	0.1	1.7	0.2	-0.1	0.0	0.0	1.9

[1] This column reflects the impact of the IRF market basket increase factor for FY 2016 (2.4 percent), reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.2 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(iv) of the Act.

[2] Providers changing from urban to rural status will receive a 14.9 percent rural adjustment, and providers changing from rural to urban status will receive 2/3 of the 14.9 percent rural adjustment in FY 2016. For those changing from urban to rural, the total impact shown is affected by the outlier threshold increasing, which results in smaller outlier payments as part of the total payments. For those changing from rural to urban status, the outlier threshold is being lowered by 2/3 of 14.9 percent, which results in more providers being eligible for outlier payments, increasing the outlier portion of their total payments.

3. Impact of the Update to the Outlier Threshold Amount

The estimated effects of the update to the outlier threshold adjustment are presented in column 4 of Table 26. In the FY 2015 IRF PPS final rule (79 FR 45872), we used FY 2013 IRF claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2015 so that estimated outlier payments would equal 3 percent of total estimated payments for FY 2015.

For the FY 2016 IRF PPS proposed rule, we used preliminary FY 2014 IRF claims data, and, based on that preliminary analysis, we estimated that IRF outlier payments as a percentage of total estimated IRF payments would be 3.2 percent in FY 2015(80 FR 23367). As we typically do between the proposed and final rules each year, we updated our FY 2014 IRF claims data to ensure that we are using the most recent available data in setting IRF payments.

Therefore, based on updated analysis of the most recent IRF claims data for this final rule, we now estimate that IRF outlier payments as a percentage of total estimated IRF payments are 2.9 percent in FY 2015. Thus, we are adjusting the outlier threshold amount in this final rule to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2016. The estimated change in total IRF payments for FY 2016, therefore, includes an approximate 0.1 percent increase in payments because the estimated outlier portion of total payments is estimated to increase from approximately 2.9 percent to 3 percent.

The impact of this outlier adjustment update (as shown in column 4 of Table 26) is to increase estimated overall payments to IRFs by about 0.1 percent. We estimate the largest increase in payments from the update to the outlier threshold amount to be 0.6 percent for rural IRFs in the Pacific region.

4. Impact of the Market Basket Update to the IRF PPS Payment Rates

The estimated effects of the market basket update to the IRF PPS payment rates are presented in column 5 of Table 26. In the aggregate the update would result in a net 1.7 percent increase in overall estimated payments to IRFs. This net increase reflects the estimated IRF market basket increase factor for FY 2016 of 2.4 percent, reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by the 0.2 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act.

5. Impact of the CBSA Wage Index and Labor-Related Share

In column 6 of Table 26, we present the effects of the budget-neutral update of the wage index and labor-related share without taking into account the revised OMB delineations or the effects of the 1-year phase-in of the wage index changes due to the revised OMB delineations,

which are presented separately in the next column. The changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the changes in the two have a combined effect on payments to providers. As discussed in section VI.E. of this final rule, we will increase the labor-related share from 69.294 percent in FY 2015 to 71.0 percent in FY 2016.

6. Impact of the Updated OMB Delineations

In column 7 of Table 26, we present the effects of the revised OMB delineations, and the transition to the new delineations using the blended wage index.

In the aggregate, since these updates to the wage index and the labor-related share are applied in a budget-neutral manner as required under section 1886(j)(6) of the Act, we do not estimate that these updates will affect overall estimated payments to IRFs. However, we estimate that these updates will have small distributional effects. For example, we estimate the largest increase in payments from the update to the CBSA wage index and labor-related share of 0.4 percent for urban IRFs in the Middle Atlantic region. We estimate the largest decrease in payments from the update to the CBSA wage index and labor-related share to be a 2.1 percent decrease for rural IRFs in the Middle Atlantic region.

7. Impact of the Phase-out of the Rural Adjustment for IRFs Transitioning from Rural to Urban Designations

In column 8 of Table 26, we present the effects 3-year phase-out of the rural adjustment for IRFs transitioning from rural to urban status under the new CBSA delineations. Under the IRF PPS, IRFs located in rural areas receive a 14.9 percent adjustment to their payment rates to account for the higher costs incurred in treating beneficiaries in rural areas. Under the new CBSA delineations, we estimate that 19 IRFs will transition from rural to urban status for

purposes of the IRF PPS wage index adjustment in FY 2016. Without the phase-out of the rural adjustment, these 19 IRFs would experience an automatic 14.9 percent decrease in payments as a result of this change from rural to urban status in FY 2016. To mitigate the effects of this relatively large decrease in payments, we will phase-out the rural adjustment for these providers over a 3-year period, as discussed in more detail in section VI. of this final rule. Thus, these IRF would receive two thirds of the rural adjustment in FY 2016, one third of the rural adjustment in FY 2017, and none of the rural adjustment in FY 2018, thus giving these IRFs time to adjust to the reduced payments.

Column 8 shows the effect on providers of this budget-neutral phase-out of the rural adjustment for IRFs transitioning from rural to urban status in FY 2016. Under this policy, these providers would only experience a reduction in payments of one third of the 14.9 percent rural adjustment in FY 2016. As we propose to implement this phase-out in a budget-neutral manner, it does not affect aggregate payments to IRFs, but we estimate that this policy would have small effects on the distribution of payments to IRFs. The largest increase in payments to IRFs as a result of the interaction of the rural adjustment with the changes to the CBSA delineations is a 12.4 percent increase to 3 IRFs that transition from urban to rural status under the new CBSA delineations. These 3 IRFs will receive the full 14.9 percent rural adjustment for FY 2016. The largest decrease in payments to IRFs as a result of this policy change is a 3.7 percent decrease in payments to IRFs that transition from rural to urban status under the new CBSA delineations. This is a result of these providers only receiving two thirds of the 14.9 percent rural adjustment for FY 2016. We note that the decrease in payments to these providers is substantially lessened from what it otherwise would have been as a result of the phase-out of the rural adjustment for these IRFs.

8. Impact of the Update to the CMG Relative Weights and Average Length of Stay Values.

In column 9 of Table 26, we present the effects of the budget-neutral update of the CMG relative weights and average length of stay values. In the aggregate, we do not estimate that these updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects. The largest estimated increase in payments is a 0.1 percent increase for rural IRFs in the Middle Atlantic and West North Central regions, and urban IRFs in the New England and West North Central regions. Rural IRFs in the South Atlantic and Pacific regions are estimated to experience a 0.1 percent decrease in payments due to the CMG relative weights change.

9. Effects of Requirements for the IRF QRP for FY 2018

In accordance with section 1886(j)(7) of the Act, we will implement a 2 percentage point reduction in the FY 2016 increase factor for IRFs that have failed to report the required quality reporting data to us during the most recent IRF quality reporting period. In section IX.P. of this final rule, we discuss the finalized method for applying the 2 percentage point reduction to IRFs that fail to meet the IRF QRP requirements. At the time that this analysis was prepared, 91, or approximately 8 percent, of the 1166 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2015 annual payment update determination. Information is not available to determine the precise number of IRFs that will not meet the requirements to receive the full annual percentage increase for the FY 2016 payment determination.

In section IX.L. of this final rule, we discuss our finalized policy to suspend the previously finalized data accuracy validation policy for IRFs. While we cannot estimate the increase in the number of IRFs that will meet IRF QRP compliance standards at this time, we

believe that this number will increase due to the temporary suspension of this policy. Thus, we estimate that the suspension of this policy will decrease impact on overall IRF payments, by increasing the rate of compliance, in addition to decreasing the cost of the IRF QRP to each IRF provider by approximately $47,320 per IRF, which was the estimated cost to each IRF provider to the implement the previously finalized policy.

In section IX.F. of this final rule, we are finalizing two quality measures that have already been adopted for the IRF QRP: (1) All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502), to establish the newly NQF-endorsed status of this measures; and (2) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), to establish its use as a cross-setting measure that addresses the domain of skin integrity, as required by the IMPACT Act of 2014. The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) is a Medicare claims-based measure; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact as a result of this measure. We also believe that there will be no additional burden associated with our proposal of the measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), which was finalized to establish its use as a cross-setting measure that meets the IMPACT Act requirement of adding a quality measure that stratifies the domain of skin integrity, as IRFs are already submitting quality data related to this measure.

In section VIII.G. of this final rule, we are also finalizing the adoption of 6 new quality measures. The 6 finalized quality measures are: (1) an application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); (2) an application

of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015); (3) IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633; under review); (4) IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634; under review); (5) IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635; under review); and (6) IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636; endorsed on July 23, 2015). Additionally, we have finalized that data for these six measures will be collected and reported using the IRF-PAI (version 1.4). The total cost related to the six finalized measures is estimated at $21,239.33 per IRF annually, or $24,042,291.01 for all IRFs annually. This is an average increase of 124 percent to all IRF providers over the burden discussed in the FY 2015 IRF PPS final rule (79 FR 45935), which included all quality measures that IRFs are required to report under the QRP with the exception of six new quality measures finalized in this final rule.

We intend to continue to closely monitor the effects of this new quality reporting program on IRF providers and help perpetuate successful reporting outcomes through ongoing stakeholder education, national trainings, IRF provider announcements, website postings, CMS Open Door Forums, and general and technical help desks.

We did not receive any comment on the regulatory analysis, and are finalizing the analysis, as is.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services. In recent years, IRF PPS payment rates have been updated by the RPL market basket. Thus, we did consider updating payments using the RPL market basket increase factor for FY 2016. However, as stated in section VI. of this final rule, we believe the use of an IRF market basket that reflects the cost structure of the universe of IRF providers is a technical improvement over the use of the RPL market basket. The RPL market basket reflects the input costs of two additional provider types: Inpatient Psychiatric Facilities and Long-term Care Hospitals; and also only includes data from freestanding providers. On the other hand, the IRF market basket reflects the input costs of only IRF providers. We also received support from several commenters on our proposal to replace the RPL market basket with an IRF market basket. Additionally, some commenters expressed concerns regarding our proposed methodology for deriving compensation related costs for hospital-based providers from the cost report. In response to the technical comments received, we have adjusted the methodology for deriving the wages and salaries and employee benefits for hospital-based IRFs. Based on these reasons, we are updating payments for FY 2016 using the market basket increase factor based on the IRF market basket, with slight methodological changes to the cost weights from the proposed rule. In addition, as noted previously in this final rule, section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2016, and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act require the Secretary to apply a 0.2 percentage point reduction to the market basket increase factor for FY 2016. Thus, in accordance with section 1886(j)(3)(C) of the Act, we are updating the IRF federal prospective payments in this final rule by 1.7 percent

(which equals the 2.4 percent estimated IRF market basket increase factor for FY 2016 reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act and further reduced by 0.2 percentage point). If we had instead continued to use the RPL market basket, the final update for the FY 2016 IRF federal prospective payments would have also been 1.7 percent (which equals the 2.4 percent estimated RPL market basket increase factor for FY 2016 reduced by a 0.5 percentage point productivity adjustment and further reduced by 0.2 percentage point).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2016. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered updating facility-level adjustment factors for FY 2016. However, as discussed in more detail in the FY 2015 final rule (79 FR 45872), we believe that freezing the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until the data indicate that they need to be further updated) will allow us an opportunity to monitor the effects of the substantial changes to the adjustment factors for FY 2014, and will allow IRFs time to adjust to the previous changes.

We considered maintaining the existing outlier threshold amount for FY 2016. However, analysis of updated FY 2014 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2016, by approximately 0.1 percent, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold

amount in this final rule to reflect a 0.1 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.9 percent, of aggregate estimated payments in FY 2016.

We considered a number of options for implementing the new CBSA designations. Overall, we believe implementing the new OMB delineations would result in wage index values being more representative of the actual costs of labor in a given area. Further, we recognize that some providers (10 percent) would have a higher wage index due to our proposed implementation of the new labor market area delineations. However, we also recognize that more providers (16 percent) would experience decreases in wage index values as a result of our proposed implementation of the new labor market area delineations. In prior years, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. As discussed in the FY 2006 IRF PPS final rule (70 FR 47921 through 47926), we evaluated several options to ease the transition to the new CBSA system.

In implementing the new CBSA delineations for FY 2016, we continue to have similar concerns as those expressed in the FY 2006 IRF PPS final rule. While we believe that implementing the latest OMB labor market area delineations would create a more accurate wage index system, we recognize that IRFs may experience decreases in their wage index as a result of the labor market area changes. Our analysis for the FY 2016 IRF PPS final rule indicated that a majority of IRFs either expect no change in the wage index or an increase in the wage index based on the new CBSA delineations. However, we found that 188 facilities will experience a decline in their wage index with 29 facilities experiencing a decline of 5 percent or more based on the CBSA changes. Therefore, we believe it would be appropriate to consider, as we did in

FY 2006, whether or not a transition period should be used to implement these changes to the wage index.

We considered having no transition period and fully implementing the new OMB delineations beginning in FY 2016. This would mean that we would adopt the revised OMB delineations for all IRF providers on October 1, 2015. However, this would not provide any time for IRF providers to adapt to the new OMB delineations. As previously discussed, more IRFs would experience a decrease in wage index due to implementation of the new OMB delineations than would experience an increase. Thus, we believe that it would be appropriate to provide for a transition period to mitigate the resulting short-term instability and negative impacts on these IRF providers, and to provide time for these IRFs to adjust to their new labor market area delineations.

Furthermore, in light of the comments received during the FY 2006 IRF PPS proposed rule (70 FR 30238 through 30240) to adopt the new CBSA definitions without a transition period, we continue to believe that a transition period is appropriate. Therefore, we will use a similar transition methodology to that used in FY 2006. Specifically, for the FY 2016 IRF PPS, we are adopting a budget-neutral 1-year transition policy. All IRF providers will receive a 1-year blended wage index using 50 percent of their FY 2016 wage index based on the new OMB delineations and 50 percent of their FY 2016 wage index based on the OMB delineations used in FY 2015. We will apply this 1-year blended wage index in FY 2016 for all geographic areas to assist providers in adapting to these changes. We believe a 1-year, 50/50 blend will mitigate the short-term instability and negative payment impacts due to the implementation of the new OMB delineations. This transition policy will be for a 1-year period, going into effect October 1, 2016, and continuing through September 30, 2017.

For the reasons previously discussed and based on similar concerns to those we expressed during the FY 2006 rulemaking cycle to the adoption of the new CBSA definitions, we are adopting a 3-year budget-neutral phase-out of the rural adjustment for the group of IRFs that during FY 2015 were designated as rural and for FY 2016 are designated as urban under the new CBSA system. This is in addition to implementing a 1-year blended wage index for all IRFs. We considered having no transition, but found that a multi-year transition policy would best provide a sufficient buffer for rural IRFs that may experience a reduction in payments due to being designated as urban. We believe that the incremental reduction of the FY 2015 rural adjustment is appropriate to mitigate a significant reduction in per case payment. Based on similar concerns to those we expressed during the FY 2006 rulemaking cycle to the proposed adoption of the new CBSA definitions, we considered different multi-year transition policies to provide a sufficient buffer for rural IRFs that may experience a reduction in payments due to being designated as urban. However, fewer IRFs (19) will be impacted by the transition from rural to urban status than were affected in FY 2006 (34). Additionally, the FY 2016 rural adjustment of 14.9 percent is less than the FY 2006 rural adjustment of 21.3percent. Therefore, we do not believe a transition period longer than three years would be appropriate. We believe a 3-year budget-neutral phase-out of the rural adjustment will appropriately mitigate the adverse payment impacts for these IRFs while also ensuring that payment rates for these providers are set accurately and appropriately.

E. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf), in Table 27, we have prepared an accounting statement showing the classification of the

expenditures associated with the provisions of this final rule. Table 27 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this final rule based on the data for 1,135 IRFs in our database. In addition, Table 27 presents the costs associated with the new IRF quality reporting program for FY 2016.

TABLE 27: Accounting Statement: Classification of Estimated Expenditures

Change in Estimated Transfers from FY 2015 IRF PPS to FY 2016 IRF PPS:	
Category	**Transfers**
Annualized Monetized Transfers	$135 million
From Whom to Whom?	Federal Government to IRF Medicare Providers
FY 2016 Cost to Updating the Quality Reporting Program:	
Category	**Costs**
Cost for IRFs to Submit Data for the Quality Reporting Program	$24,042,291.01

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2016 are projected to increase by 1.8 percent, compared with the estimated payments in FY 2015, as reflected in column 10 of Table 26. IRF payments per discharge are estimated to increase by 1.8 percent in both urban and rural areas, compared with estimated FY 2015 payments. Payments per discharge to rehabilitation units are estimated to increase 1.9 percent in urban areas and 2.0 in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 1.7 percent in urban areas and 0.9 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the policies in this final rule. The largest payment increase is estimated to be a 3.0 percent increase for rural IRFs located in the Pacific region.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

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), sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332), sec. 1206 of Pub. L. 113-67, and sec. 112 of Pub. L. 113-93.

2. Section 412.634 is added to read as follows:

§412.634 Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP).

(a) Participation. (1) For the FY 2018 payment determination and subsequent years, an IRF must begin reporting data under the IRF QRP requirements no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter, which designates the IRF as operating in the Certification and Survey Provider Enhanced Reports (CASPER) system.

(2) [Reserved]

(b) Submission Requirements and Payment Impact. (1) IRFs must submit to CMS data on measures specified under section 1886(j)(7)(D), 1899B(c)(1), and 1899B(d)(1)of the Act, as applicable. Sections 1886(j)(7)(C) and (j)(7)(F)(iii) of the Act require each IRF to submit data on the specified measures in the form and manner, and at a time, specified by the Secretary.

(2) As required by section 1886(j)(7)(A)(i) of the Act, any IRF that does not submit data in accordance with section 1886(j)(7)(C) and (F) of the Act for a given fiscal year will have its

annual update to the standard Federal rate for discharges for the IRF during the fiscal year reduced by two percentage points.

(c) Exception and Extension Requirements. (1) An IRF may request and CMS may grant exceptions or extensions to the quality data reporting requirements, for one or more quarters, when there are certain extraordinary circumstances beyond the control of the IRF.

(2) An IRF must request an exception or extension within 30 days of the date that the extraordinary circumstances occurred.

(3) Exception and extension requests must be submitted to CMS from the IRF by sending an email to IRFQRPReconsiderations@cms.hhs.gov containing all of the following information:

(i) IRF CMS Certification Number (CCN).

(ii) IRF Business Name.

(iii) IRF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) IRF's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the IRF believes it will be able to again submit IRF QRP data and a justification for the proposed date.

(4) CMS may grant exceptions or extensions to IRFs without a request if it is determined that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of an IRF to submit data.

(5) Email is the only form of submission that will be accepted. Any reconsideration requests received through another channel will not be considered as a valid exception or extension request.

(d) Reconsideration. (1) IRFs found to be non-compliant with the quality reporting requirements for a particular fiscal year will receive a letter of non-compliance through the Quality Improvement and Evaluation System Assessment Submission and Processing (QIES-ASAP) system, as well as through the United States Postal Service. IRFs must submit reconsideration requests no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests must be submitted to CMS by sending an email to IRFQRPReconsiderations@cms.hhs.gov containing all of the following information:

(i) IRF CCN.

(ii) IRF Business Name.

(iii) IRF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) CMS identified reason(s) for non-compliance from the non-compliance letter.

(vi) Reason(s) for requesting reconsideration.

(3) The request for reconsideration must be accompanied by supporting documentation demonstrating compliance. This documentation must be submitted electronically as an

attachment to the reconsideration request email. Any request for reconsideration that does not contain sufficient evidence of compliance with the IRF QRP requirements will be denied.

(4) Email is the only form of submission that will be accepted. Any reconsideration requests received through another channel will not be considered as a valid exception or extension request.

(5) The QIES-ASAP system and the United States Postal Service will be the two mechanisms used to distribute each IRF's compliance letter, as well as our final decision regarding any reconsideration request received from the IRF.

(e) Appeals. (1) An IRF may appeal the decision made by CMS on its reconsideration request by filing with the Provider Reimbursement Review Board (PRRB) under 42 CFR Part 405, Subpart R.

(2) [Reserved]

CMS-1624-F

Dated: July 27, 2015

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: July 29, 2015

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2015-18973 Filed: 7/31/2015 04:15 pm; Publication Date: 8/6/2015]