DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS-1628-F]

RIN 0938-AS48

Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program

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

ACTION: Final rule.

SUMMARY: This rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2016. This rule is necessary to ensure that ESRD facilities receive accurate Medicare payment amounts for furnishing outpatient maintenance dialysis treatments during calendar year 2016. This rule will also set forth requirements for the ESRD Quality Incentive Program (QIP), including for PYs 2017 through 2019.

DATES: Effective Date: These regulations are effective on January 1, 2016.

FOR FURTHER INFORMATION CONTACT:

CMS ESRD PAYMENT@cms.hhs.gov, for issues related to the ESRD PPS payment provisions.

Heidi Oumarou, (410) 786-7342, for issues related to the ESRD PPS Market Basket Update.

Tamyra Garcia, (410) 786-0856, for issues related to the ESRD QIP.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online

database through *Federal Digital System (FDsys)*, a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/*.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the **Code of Federal Regulations** (CFR).

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

ABLE	The Achieving a Better Life Experience Act of 2014
AHRQ	Agency for Healthcare Research and Quality
AMCC	Automated Multi-Channel Chemistry
ANOVA	Analysis of Variance
ARM	Adjusted Ranking Metric

ASP	Average Sales Price
ATRA	The American Taxpayer Relief Act of 2012
BCMA	Basic Case-Mix Adjustment
BEA	Bureau of Economic Analysis
BLS	Bureau of Labor Statistics
BMI	Body Mass Index
BSA	Body Surface Area
BSI	Bloodstream Infection
CB	Consolidated Billing
CBSA	Core based statistical area
CCN	CMS Certification Number
CDC	Centers for Disease Control and Prevention
CKD	Chronic Kidney Disease
CLABSI	Central Line Access Bloodstream Infections
CFR	Code of Federal Regulations
CIP	Core Indicators Project
CMS	Centers for Medicare & Medicaid Services
CPM	Clinical Performance Measure
CPT	Current Procedural Terminology
CROWNWeb	Consolidated Renal Operations in a Web-Enabled Network
CY	Calendar Year
DFC	Dialysis Facility Compare
DFR	Dialysis Facility Report

ESA	Erythropoiesis stimulating agent
ESRD	End-Stage Renal Disease
ESRDB	End-Stage Renal Disease bundled
ESRD PPS	End-Stage Renal Disease Prospective Payment System
ESRD QIP	End-Stage Renal Disease Quality Incentive Program
FDA	Food and Drug Administration
HCP	Healthcare Personnel
HD	Hemodialysis
HHD	Home Hemodialysis
HAIs	Healthcare-Acquired Infections
HCPCS	Healthcare Common Procedure Coding System
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
ICD	International Classification of Diseases
ICD-9-CM	International Classification of Disease, 9th Revision, Clinical Modification
ICD-10-CM	International Classification of Disease, 10th Revision, Clinical Modification
ICH CAHPS	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IGI	IHS Global Insight
IIC	Inflation-indexed charge
IPPS	Inpatient Prospective Payment System
IUR	Inter-unit reliability

KDIGO	Kidney Disease: Improving Global Outcomes
KDOQI	Kidney Disease Outcome Quality Initiative
Kt/V	A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO	Large Dialysis Organization
MAC	Medicare Administrative Contractor
MAP	Medicare Allowable Payment
MCP	Monthly Capitation Payment
MDO	Medium Dialysis Organization
MFP	Multifactor Productivity
MIPPA	Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275)
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003
MMEA	Medicare and Medicaid Extenders Act of 2010 Pub. L. 111-309
MSA	Metropolitan statistical areas
NAMES	National Association of Medical Equipment Suppliers
NHSN	National Healthcare Safety Network
NQF	National Quality Forum
NQS	National Quality Strategy
NHSN	National Healthcare Safety Network
NQF	National Quality Forum
NQS	National Quality Strategy
OBRA	Omnibus Budget Reconciliation Act
OMB	Office of Management and Budget

PAMA	Protecting Access to Medicare Act of 2014
PC	Product category
PD	Peritoneal Dialysis
PEN	Parenteral and Enteral nutrition
PFS	Physician Fee Schedule
PPI	Producer Price Index
PPS	Prospective Payment System
PSR	Performance Score Report
PY	Payment Year
QIP	Quality Incentive Program
RCE	Reasonable Compensation Equivalent
REMIS	Renal Management Information System
RFA	Regulatory Flexibility Act
SBA	Small Business Administration
SFA	Small Facility Adjuster
SIMS	Standard Information Management System
SRR	Standardized Readmission Ratio
SSA	Social Security Administration
STrR	Standardized Transfusion Ratio
The Act	Social Security Act
The Affordable Care Act	The Patient Protection and Affordable Care Act
The Secretary	Secretary of the Department of Health and Human Services
TPS	Total Performance Score

URR Urea reduction ratio

VAT Vascular Access Type

VBP Value Based Purchasing

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted, bundled prospective payment system for renal dialysis services furnished by ESRD facilities. This final rule will update and revise the ESRD PPS for calendar year (CY) 2016. Section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Public Law 110-275), and section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act Public Law 111-148), established that beginning CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L No. 112-240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2011, to reduce the single payment amount to reflect the Secretary's estimate of the utilization of ESRD-related drugs and biologicals. We finalized the amount of the drug utilization adjustment pursuant to this section in the CY 2014 ESRD PPS

final rule with a 3- to 4-year transition (78 FR 72161 through 72170). Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS before January 1, 2016. Section 632(c) of ATRA requires the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Congress enacted the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93). Section 217 of PAMA includes several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amend sections 1881(b)(14)(F) and (I) of the Act. We interpreted the amendments to sections 1881(b)(14)(F) and (I) as replacing the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule with specific provisions that dictate the market basket update for CY 2015 (0.0 percent) and how it will be reduced in CYs 2016 through 2018. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only drugs and biologicals used for the treatment of ESRD under the ESRD PPS prior to January 1, 2024. Section 217(c) of PAMA provides that, as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

On December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. No. 113-295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

This rule also finalizes to set forth requirements for the ESRD QIP, including for payment years (PYs) 2017, 2018, and 2019. The program is authorized under section 1881(h) of the Social Security Act (the Act). The ESRD QIP is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS.

B. Summary of the Major Provisions

1. ESRD PPS

- ESRD PPS refinement: In accordance with section 632(c) of ATRA, we analyzed the case-mix payment adjustments under the ESRD PPS using more recent data. For this final rule, we have revised the adjustments by changing the adjustment payment amounts based on our updated regression analysis using CYs 2012 and 2013 ESRD claims and cost report data. In addition, we will remove two comorbidity category payment adjustments (bacterial pneumonia and monoclonal gammopathy). Because we conducted an updated regression analysis to enable us to analyze and revise the case-mix payment adjustments, this final rule also revises the low-volume payment adjustment (LVPA) and implements a new rural adjustment based on that regression analysis. We are finalizing new patient and facility-level adjustment factors. This final rule also revises the geographic proximity eligibility criterion for the LVPA and removes grandfathering from the criteria for the adjustment.
- Drug designation process: In accordance with section 217(c) of PAMA, this final rule will implement a drug designation process for: (1) determining when a product is no longer an oral-only drug and (2) including new injectable and intravenous renal

dialysis service drugs and biologicals into the bundled payment under the ESRD PPS.

- Update to the ESRD PPS base rate for CY 2016: The final CY 2016 ESRD PPS base rate is $230.39. This amount reflects a reduced market basket increase as required by section 1881(b)(14)(F)(i)(I) (0.15 percent), application of the wage index budget-neutrality adjustment factor (1.000495), and a refinement budget-neutrality adjustment factor (0.960319). The final CY 2016 ESRD PPS base rate is $230.39 ($239.43 x 1.000495 x 1.0015 x 0.960319 = $230.39).
- Annual update to the wage index and wage index floor: We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2016, we will complete our 2-year transition to both the updated CBSA delineations and the labor-related share to which the wage index is applied (50.673 percent). In addition, we computed a wage index budget-neutrality adjustment factor of 1.000495 which is applied to the ESRD PPS base rate. We are finalizing the continuation of the application of the current wage index floor (0.4000) to areas with wage index values below the floor.
- Update to the outlier policy: We are updating the outlier policy using the most current data. Specifically, we are updating the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments (MAPs) for adult patients for CY 2016 using 2014 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries increases from $54.35 to $62.19 and the MAP amount decreases from $43.57 to $39.20, as

compared to CY 2015 values. For adult beneficiaries, the fixed-dollar loss amount increases from $86.19 to $86.97 and the MAP amount decreases from $51.29 to $50.81. The 1.0 percent target for outlier payments was not achieved in CY 2014 (0.8 percent rather than 1.0 percent). We believe using CY 2014 claims data to update the outlier MAP and fixed dollar loss amounts for CY 2016 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1.0 percent outlier percentage.

2. ESRD QIP

This rule sets forth requirements for the ESRD QIP, including for payment years (PYs) 2017, 2018 and 2019.

- PY 2019 Measure Set: For PY 2019 and future payment years, we are removing four clinical measures—(1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy—because a more broadly applicable measure for the topic has become available. We are replacing these measures with a single comprehensive Dialysis Adequacy clinical measure.

- Reinstating the In-Center Hemodialysis Consumer Assessment of Healthcare Providers (ICH CAHPS) Attestation: Beginning with PY 2017, we are reinstating the ICH CAHPS attestation in Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) previously adopted in the CY 2014 ESRD PPS final rule (78 FR 72220 through 72222) using the eligibility criteria finalized in the CY 2015 ESRD PPS final rule (79 FR 66169). This will allow facilities to attest in CROWNWeb that they did not treat enough eligible patients during the

eligibility period to receive a score on the ICH CAHPS measure and thereby avoid receiving a score for this measure.

- Revising the Small Facility Adjuster: Beginning with the PY 2017 ESRD QIP, we are revising the Small Facility Adjuster (SFA) such that it does not rely upon a pooled within-facility standard error. The revised SFA preserves the intent of the adjuster to include as many facilities in the ESRD QIP as possible while ensuring that the measure scores are reliable.

C. Summary of Costs and Benefits

In section VI of this final rule, we set forth a detailed analysis of the impacts that the changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section VI of this final rule displays the estimated change in payments to ESRD facilities in CY 2016 compared to estimated payments in CY 2015. The overall impact of the CY 2016 changes is projected to be a 0.2 percent increase in payments. Hospital-based ESRD facilities and freestanding facilities both have an estimated 0.2 percent increase in payments.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately $10 million from CY 2015 to CY 2016 which reflects the payment rate update. As a result of the projected 0.2 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 0.2 percent in CY 2016, which translates to approximately $0 million due to rounding.

2. Impacts of the Final ESRD QIP

The overall economic impact of the ESRD QIP is an estimated $11.8 million in PY 2018 and $15.5 million in PY 2019. In PY 2018, we expect the costs associated with the

collection of information requirements for the data validation studies to be approximately $21 thousand for all ESRD facilities, totaling an overall impact of approximately $11.8 million as a result of the PY 2018 ESRD QIP.[1] In PY 2019, we expect the overall impact to be approximately $15.5 million.

The ESRD QIP will continue to incentivize facilities to provide high-quality care to beneficiaries.

II. Calendar Year (CY) 2016 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background on the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the end-stage renal disease (ESRD) prospective payment system (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities based on the requirements of section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111-148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112-240)

1 We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The previously finalized aggregate impact of $11.8 million reflects the PY 2018 estimated payment reductions and the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure.

included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA requires the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Congress enacted the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L.113-93). Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CYs 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) further amended section 632(b)(1) of ATRA by requiring that in

establishing payment for oral-only drugs under the ESRD PPS, we must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, section 212 of PAMA provided that the Secretary may not adopt the International Classification of Disease 10th Revision, Clinical Modification (ICD-10-CM) code sets prior to October 1, 2015. HHS published a final rule on August 4, 2014 that adopted October 1, 2015 as the new ICD-10-CM compliance date, and required the use of International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) through September 30, 2015 (79 FR 45128).

On December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. No. 113-295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

1. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at 42 CFR 413.171 and other payment policies are included in regulations at subpart H of 42 CFR part 413. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and account for patient case-mix

variability. The adult case-mix adjusters include five categories of age, body surface area (BSA), low body mass index (BMI), onset of dialysis, six co-morbidity categories, and pediatric patient-level adjusters consisting of two age categories and dialysis modalities (42 CFR 413.235(a) and(b)).

In addition, the ESRD PPS provides for two facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (42 CFR 413.232). The second adjustment reflects differences in area wage levels developed from Core Based Statistical Areas (CBSAs) (42 CFR 413.231).

The ESRD PPS allows for a training add-on payment adjustment for home dialysis modalities (42 CFR 413.235(c)). Lastly, the ESRD PPS provides additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (42 CFR 413.237).

2. Updates to the ESRD PPS

Updates and policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS we have published annual rules to make routine updates, policy changes, and clarifications.

On November 6, 2014, we published in the **Federal Register** a final rule (79 FR 66120 through 66265) titled, "End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (hereinafter

referred to as the CY 2015 ESRD PPS final rule). In that final rule, we made a number of routine updates to the ESRD PPS for CY 2015, completed a rebasing and revision of the ESRD bundled market basket, implemented a 2-year of transition for the revised labor-related share and a 2-year transition of the new Core-Based Statistical Area (CBSA) delineations, and made policy changes and clarifications. For a summary of the provisions in that final rule, we refer readers to the CY 2016 ESRD PPS proposed rule at 80 FR 37813 (July 1, 2015).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2016 ESRD PPS Proposed Rule

The proposed rule, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program" (80 FR 37807 through 37860), (hereinafter referred to as the CY 2016 ESRD PPS proposed rule), was published in the **Federal Register** on July 1, 2015, with a comment period that ended on August 25, 2015. In that proposed rule, for the ESRD PPS, we proposed to (1) make a number of routine updates for CY 2016, (2) implement the statutory provisions set forth in ATRA and PAMA, and (3) clarified policies for reporting renal dialysis services on the ESRD facility claim. We received 233 public comments on our proposals, including comments from: ESRD facilities, national renal groups, nephrologists and patient organizations, patients and care partners, manufacturers, health care systems, and nurses. Of those comments, 67 were related to the provisions in the proposed rule. As part of the comments received, there was a write-in campaign from 200 individuals that addressed home dialysis training. We also received comments that pertained to topics that were outside of the scope of this rule, for example, network fees and Part D payment determinations.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the

CY 2016 ESRD PPS. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

1. Analysis and Revision of the Payment Adjustments under the ESRD PPS

a. Development and Implementation of the ESRD PPS Payment Adjustments

Section 153(b) of MIPPA amended section 1881(b) of the Act to require the Secretary to implement the ESRD PPS effective January 1, 2011. Section 1881(b)(14)(D)(i) requires the ESRD PPS to include a payment adjustment based on case-mix that may take into account patient weight, body mass index (BMI), comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. Section 1881(b)(14)(D)(ii) through (iv) provide that the ESRD PPS must also include an outlier payment adjustment and a low-volume payment adjustment, and may include such other payment adjustments as the Secretary determines appropriate.

In response to the MIPPA amendments to section 1881(b) requiring the new bundled ESRD PPS, we published the proposed ESRD PPS design and implementation strategy in the **Federal Register** on September 29, 2009 (74 FR 49922).

In that rule (75 FR 49033) we noted that section 623(f)(1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108-173, required the Secretary to submit to the Congress a report detailing the elements and features for the design and the implementation of the ESRD PPS. To meet this mandate we worked with the University of Michigan – Kidney Epidemiology and Cost Center (UM-KECC) in developing the ESRD PPS and used their report that provided their findings and recommendations submitted to CMS in February 2008, titled, *End-Stage Renal Disease Payment System: Results of Research on Case-*

Mix Adjustment for an Expanded Bundle (herein referred to as Technical Report) as the basis for the Secretary's February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System.* These reports can be found on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/educational_resources.html.

We received over 1400 comments from dialysis facilities, Medicare beneficiaries, physician groups, and other stakeholders in response to the proposed rule. In consideration of these comments, we finalized the case-mix and facility-level adjustments for the ESRD PPS in the CY 2011 ESRD PPS final rule (75 FR 49030). For a complete discussion of public comments and the finalized payment policies for the ESRD PPS, we refer the reader to the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214).

b. Regression Model Used to Develop Payment Adjustment Factors

i. Regression Analysis

In the CY 2011 ESRD PPS final rule (75 FR 49083), we discuss the two-equation methodology used to develop the adjustment factors that would be applied to the base rate to calculate each patient's case-mix adjusted payment per treatment. The two-equation approach used to develop the ESRD PPS included a facility–based regression model for services historically paid for under the composite rate as indicated in ESRD facility cost reports, and a patient-month-level regression model for services historically billed separately. The models used for the 2011 final rule were based on 3 years of data (CYs 2006 through 2008).

Section 632(c) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. No. 11-240) requires the Secretary, by no later than January 1, 2016, to conduct an analysis of the case-mix payment adjustments being used under section 1881(b)(14)(D)(i) of the Act and to make

appropriate revisions to such case-mix payment adjustments. In the proposed rule (80 FR 37814) we explained that while section 632(c) of ATRA only requires us to analyze and make appropriate revisions to the case-mix payment adjustments, we performed a regression analysis that updated all of the payment multipliers including the low-volume payment adjustment. Also, as discussed in more detail in section II B.d.iii of this final rule, we analyzed rural areas as a payment variable in our regression analysis and proposed to implement a new adjustment for this facility characteristic.

For purposes of analyzing and proposing revisions to the payment adjusters included in the proposed rule, we updated the two-equation methodology using CY 2012 and 2013 Medicare cost report and claims data. Data from CYs 2012 and 2013 is the most recently available information that we had to implement the refinement of the ESRD PPS in CY 2016 as required by section 632(c) of ATRA. Generally, we would have used 3 years of data as we did when we established the existing case-mix adjusters. However, 2011 was the first year under the new bundled payment system. The revised FDA *black box* warning for erythropoiesis-stimulating agents (ESAs) was also issued during 2011. These two factors may have been associated with changing practice patterns during 2011. Updating the regression analysis using the most recent claims and cost report data allows the case-mix adjustment model to reflect practice patterns that have prevailed under the incentives of the expanded bundled payment system. Therefore, we used CYs 2012 and 2013 data for the refinements to the case-mix systems.

In the proposed rule (80 FR 37817 through 37818 and 37821 through 37823, respectively), we proposed to reduce the number of comorbidity categories to which payment adjusters apply and implement an adjustment for rural facilities. Our rationale for proposing to eliminate two of the comorbidity categories for which we will make payment adjustments is

discussed in section II B.1.c.i of this final rule. The measures of resource use, specified as the dependent variables for developing the payment model in each of the two equations are explained below.

ii. Dependent Variables

1) Average Cost per Treatment for Composite Rate Services

For purposes of the proposed rule, we measured resource use, for example, time on a dialysis machine for the maintenance dialysis services included in the bundle of composite rate services, using only ESRD facility data obtained from the Medicare cost reports for freestanding ESRD facilities and hospital-based ESRD facilities. We used facility level data because no data are available at the patient-level that reflect variation in resources costs for providing composite rate services. In addition, cost report data is the only data that we have available that reports facility costs and is certified by the facility as being accurate. The average composite rate cost per treatment for each ESRD facility was calculated by dividing the total reported allowable costs for composite rate services for cost reporting periods ending in CYs 2012 and 2013 (Worksheet B, column 11A, lines 8-17 on CMS-265-11; Worksheet I-2, column 11, lines 2-11 on CMS-2552-10) by the total number of dialysis treatments (Worksheet C, column 1, lines 8-17 on CMS 265-11; Worksheet I-4, column 1, lines 1-10 on CMS-2552-10). CAPD and CCPD patient weeks were multiplied by 3 to obtain the number of HD-equivalent treatments. We note that our computation of the total composite rate costs included in this per treatment calculation includes costs incurred for training expenses, as well as all costs incurred by ESRD facilities for home dialysis patients.

The resulting cost per treatment was adjusted to eliminate the effects of varying wage levels among the areas in which ESRD facilities are located using the ESRD PPS CY 2015 wage

indices and the new CBSA delineations which were discussed in the CY 2015 ESRD PPS final rule, as well as the estimated labor-related share of costs from the composite rate market basket. This was done so that the relationship of the studied variables on dialysis facility costs would not be confounded by differences in wage levels.

The proportion of composite rate costs determined to be labor-related (53.711 percent of each ESRD facility's composite rate cost per treatment) was divided by the ESRD wage index to control for area wage differences. No floor or ceiling was imposed on the wage index values used to deflate the composite rate costs per treatment in order to give the full effect to the removal of actual differences in area wage levels from the data. We applied a natural log transformation to the wage-deflated composite rate costs per treatment to better satisfy the statistical assumptions of the regression model, and to maintain consistency with existing case-mix adjustment methods, in which a multiplicative payment adjuster is applied for each case-mix variable.

As with other health care cost data, the cost distribution for resource/dialyzing composite rate services was skewed (due to a relatively small fraction of observations accounting for a disproportionate fraction of costs). Cost per treatment values which were determined to be unusually high or low in accordance with predetermined statistical criteria were excluded from further analysis. (For an explanation of the statistical outer fence methodology used to identify unusually high and low composite rate costs per treatment, see pages 45 through 48 of the Secretary's February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System.* This document is available on the CMS website at the following link: http://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDGeneralInformation/downloads/ESRDReportToCongress.pdf.

2) Average Medicare Allowable Payment (MAP) for Previously Separately Billable Services

For purposes of the proposed rule, resource use for separately billable items and services used for the treatment of ESRD was measured at the patient-level using the utilization data on the Medicare claims by quarter for CYs 2012 and 2013 and average sales prices plus 6 percent of the drug or biological, if applicable, for each quarter. This time period corresponded to the most recent 2 years of Medicare cost report data that were available to measure resource use for composite rate services, such as time dialyzing. Measures of resource use included the following separately billable services: injectable drugs billed by ESRD facilities, including ESAs; laboratory services provided to ESRD patients, billed by freestanding laboratory suppliers and ordered by physicians who receive monthly capitation payments for treating ESRD patients, or billed by ESRD facilities; and other services billed by ESRD facilities.

iii. Independent Variables

Two types of independent or predictor variables were included in the composite rate and separately billable regression equations—case-mix payment variables and control variables. Case-mix payment variables were included as factors that may be used to adjust payments in either the composite rate or in the separately billable equation. Control variables, which generally represent characteristics of ESRD facilities such as size, type of ownership, facility type (whether hospital-based or freestanding), were specifically included to obtain accurate estimates of the payment impact of the potential payment variables in each equation. In the absence of using control variables in each regression equation, the relationship between the payment variables and measures of resource use may be biased because of correlations between facility and patient characteristics.

iv. Control Variables

Several control variables were included in the regression analysis. They were: (1) renal dialysis facility type (hospital-based versus freestanding facility); (2) facility size (4,000 dialysis treatments or fewer, but not eligible for the low-volume payment adjustment, 4,000 to 4,999, 5,000 to 9999, and 10,000 or more dialysis treatments); (3) type of ownership (independent, large dialysis organization, regional chain, unknown); (4) calendar year (2012 and 2013); and (5) home dialysis training treatments, in which the proportion of training treatments furnished by each dialysis facility is specified. The use of training treatments as a control was done in order to remove any confounding cost effects of training on other independent variables included in the payment model, particularly the onset of dialysis within 4-months variable.

The comments we received on the refinement regression methodology and our responses are set forth below:

Comment: We received several comments from dialysis associations and MedPAC questioning the validity and the stability of the current ESRD PPS payment model, that is, the two-equation regression analysis and the proposed refinements, pointing to concerns with the underlying data and statistical methodology. Some commenters made suggestions for future improvements. For example, commenters suggested that we use a one-equation model while others requested that we update the two-equation model, but retain certain multipliers from the 2011 payment model.

Response: We thoroughly reviewed these comments in consultation with our research team and other internal experts. We examined the outcomes of the current ESRD PPS specifically looking at access and quality of the PPS. Based on our comprehensive monitoring of health outcomes and access under the ESRD PPS, we believe the current payment model has been successful in allocating payments across facilities and patients while supporting access and

quality. While we recognize there can be theoretically optimal approaches to addressing payment model design, the availability of data is often an important factor in the approach ultimately undertaken. This is true with the ESRD PPS and the use of a two-equation model that relies on both claims and cost report data, as other payment systems do under Medicare.

Section 632(c) of ATRA requires the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments. Given the incentives inherent with moving to a bundled PPS and resulting changes in facility cost structure, it is appropriate to review the payment model and consider changes to support accurate payments and continued access for Medicare beneficiaries.

Both at the time the CY 2016 ESRD PPS proposed rule was published and after consideration of the public comments, we believed and continue to believe that our two-equation regression analysis is the most appropriate methodology that uses the most recently available data to develop the most accurate patient- and facility-level payment adjustments that reflect cost variation for ESRD facilities. We note that the analytical results underlying the proposed refinements are similar to past payment analyses associated with the development and implementation of the ESRD PPS and have thus been stable over time.

For example, no variables were determined to be no longer statistically significant and overall there were minimal variations in adjustment factors that resulted from the refinement. Therefore, we believe the current model, including the proposed refinements, is reliable. The only modifications to the list of payment adjusters were the addition of a rural adjustment and the elimination of two comorbidities based on administrative burden.

Throughout the comments and responses within this section, we provide details regarding

the model in response to the criticisms submitted by stakeholders to illustrate our position that this refinement was best accomplished by updating the two-equation regression analysis finalized in the CY 2011 ESRD PPS final rule. We believe that moving forward with an updated model aligns with our goals for the ESRD PPS in establishing accurate payments and safeguarding access for Medicare beneficiaries. As noted above, we modeled the ESRD PPS using methodologies that have been tested since the Basic Case-Mix Adjusted (BCMA) composite rate payment system and in using the most recently available data, we made our best estimate for predicting the payment variables that best reflect cost variation among ESRD facilities for furnishing renal dialysis services to a vulnerable population of patients. As we noted above, this refinement uses data that illustrates a fully bundled prospective payment system and reflects the practice patterns under such environment. We believe that it would not be appropriate to both perpetuate certain payment adjusters into the future that were developed using pre-PPS data and update the other adjusters using ESRD claims data and cost reports from 2012 and 2013. By using the proposed two-equation model we will better target payments to those patient- and facility-level characteristics that are necessary for patients to receive access to quality care.

We appreciate the suggestions of the commenters for improvements in the model and will continue to examine this critical area of the Medicare program.

Comment: Commenters contended that the proposed rule did not include the entire specification of the two-equation regression analysis. The commenters requested that CMS release the data reports that support the proposed changes for both the facility- and patient-based regressions, including those for the control variables. In addition, commenters said CMS should explain the calculation of the weights used to combine factors from each regression. Several

organizations commented that without data, descriptions, and explanations with regard to the proposed modifications to the ESRD PPS, it is difficult to provide a complete analysis and offer the most constructive comments possible. They explained that if this information was made available, then it would be possible for others in the community to replicate our model.

Response: As we stated above, section 632(c) of ATRA directed us to analyze and make appropriate revisions to the case-mix payment adjustments being used under section 1881(b)(14)(D)(i) of the Act. Because these adjustments were calculated using the two-equation payment model that was finalized in the CY 2011 ESRD PPS final rule, we believe it was appropriate to revise the adjustments using the same methodology. We accomplished this task through analysis of the model with updated claims and cost report data from 2012 and 2013. These comments pertain more to the initial design of the system for the 2011 implementation. Therefore, because the details of the elements and features for the design and the implementation of the ESRD PPS were made available at that time and are still available to this day, we referenced the CY 2011 ESRD PPS final rule for all the information and on the design.

As we stated above, in the CY 2011 ESRD PPS final rule (75 FR 49033) we noted that we worked with UM-KECC in developing the ESRD PPS and used their report that provided their findings and recommendations submitted to CMS in February 2008, titled, *End-Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle* (herein referred to as Technical Report) as the basis for the Secretary's February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System.* Since both of these reports and the CY 2011 ESRD PPS preamble language for the proposed and final rules are readily available and extensively detail the methodology for the two-equation regression analysis that applies to the current model, we believe that this information when

combined with the information in the proposed rule and the claims and cost reports for 2012 through 2013 would allow an accurate replication. As stated above, both reports were available on the web at the time the CY 2016 ESRD PPS proposed rule was published at the following hyperlink: https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDGeneralInformation/downloads/ESRDReportToCongress.pdf for the Secretary's February 2008 Report to Congress along with UM-KECC's Technical Report located at http://www.kecc.sph.umich.edu/sites/default/files/attachments/publications/UM_KECC_ESRD_Bundle_Report.pdf. We note that while UM-KECC's link to the Technical Report has changed since the issuance of the CY 2011 ESRD PPS final rule, their website provides assistance for locating the file. These reports and other resource materials regarding the ESRD PPS can be found on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/educational_resources.html.We also note that we are developing an updated Technical Report that will reflect the CY 2016 refinements and will notify stakeholders when it is available.

Comment: MedPAC expressed concern about continuing to use a two-equation model to estimate the ESRD PPS adjustment factors. They indicated that the costs associated with separately billable services may be included in the cost centers that are used to derive the dependent variable (composite rate cost per treatment) for the facility level regression. They specifically noted that renal dialysis supplies could be double counted in this way. They noted that the dependent variable for the patient-level regression is the payment per treatment for separately billable services. MedPAC further explained that to combine facility- and patient-based estimates for a given variable, CMS weights each estimate by the proportion of cost or payment represented by the dependent variable in each regression, and then multiplies the two

weighted estimates together to produce a final adjustment factor. They stated that if separately billable services are included in the dependent variable for both regressions, the weights will not distinguish the relative cost or payment addressed by each regression.

In addition, MedPAC expressed concern that multiplying factors from the facility-level and patient-level regressions may diminish the accuracy of the combined factors. MedPAC indicated that the distribution of average treatment cost across facilities is quite likely different than the distribution of payments for separately billable services across patients, and combining the two factors estimated based on unrelated distributions may not accurately reflect cost variation for the payment unit, a dialysis treatment. Another commenter similarly stated that the combination of coefficients from the two regressions into a single adjuster is problematic. This commenter noted that the weighting CMS used to calculate the adjuster values is not described, but that it would be incorrect to assume that the distributions for the two regressions are the same. MedPAC contended that if the distributions are not the same, then the accuracy of the resulting adjuster will be compromised.

MedPAC suggests that CMS develop payment adjustment factors using a one-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle as a solution to the issues they have identified. They indicate that it may not be feasible to develop such a methodology for CY 2016, but expect to see such a change in a future revision.

Response: MedPAC has recognized the necessity of multi-equation models in other Medicare payment systems. Specifically, Medicare's home health PPS uses a 4-equation model in order to appropriately reflect resource use and align this use with payment. However, we understand the appeal of the one- equation model in terms of simplicity. For example, the Inpatient Prospective Payment System (IPPS) relies on patient-level cost information using

facility-level charges reported on claims adjusted by a cost-to-charge ratio derived from the cost report. The ESRD PPS is not currently able to utilize a one-equation method because ESRD facilities do not report charges associated with the components of dialysis treatment costs that vary across patients, such as time on machine. In other words, patient-level claims provide line item detail on the use of the formerly separately billable (SB) services, but do not provide any information regarding variation across patients in the use of the formerly composite rate (CR) services. In addition, we believe that capturing the resource cost for furnishing renal dialysis services is complex since Medicare has historically paid a base rate (that is, composite rate payment) to account for those costs which were never itemized on a claim but were reported through the cost report. We believe that the current ESRD PPS model captures this complexity through the analysis of data on case-mix and control variables gleaned from both cost reports and claims.

We note that in the analyses completed for the CY 2011 ESRD PPS proposed rule, we tested various one-equation approaches to estimate accurate adjusters and found that such facility-level estimates did not yield reliable and precise estimates for the relationships of uncommon patient characteristics (such as comorbidities) or uncommon treatment types (such as home dialysis training treatments) and CR costs. The one-equation model had low statistical power, that is, minimal ability to effectively explain variation in cost, especially for uncommon conditions as noted above. Adjusters for factors such as uncommon comorbidities could be reliably developed in the patient-level SB model, but not in the facility-level CR model. case-mix Ultimately, having charges or line item utilization data that vary meaningfully with resource use at the patient level would allow for the estimation of a valid, one-equation model. The only feasible one-equation option using currently available data would be at the facility level, which

would make no use of available information from claims on the patient-level variation in SB costs and sacrifice the ability to derive any reliable adjustment for comorbidities, and commenters from the SDOs have supported the retention of the comorbid payment adjustments. Therefore, we believe developing a charge structure that could enable us to utilize a one-equation model may be worth exploring in the future, but for the data that currently exists, the two-equation model is valid, stable and retains its predictive value.

In summary, we appreciate the commenters' suggestions and will consider various options for a one-equation model in the future. For the reasons given above, and based on the data we currently have available to us, we believe the two-equation model is valid and is an appropriate method to revise the values of the adjusters.

We appreciate the recommendations and suggestions of the commenters and will consider soliciting ideas from our stakeholders to assist us in gathering the necessary data to consider a valid one-equation model as a valid ESRD PPS payment option in the future.

In regards to MedPAC's concerns about how the costs of separately billable services may be included in the cost centers that are used to derive the dependent variable for composite rate cost per treatment, we believe that the potential magnitude of double-counting certain costs such as dialysis supplies in both equations is minimal. We provide instructions to the ESRD facilities not to report items and services on their claims that are considered in the composite rate. Since we analyze claims data each year for rulemaking, we are aware of what ESRD facilities are reporting on claims with respect to utilization of renal dialysis services. Over the years, we have found that those costs associated with composite rate services was near zero. ESRD facilities have historically not reported supplies on their claims. We only allow two supplies to count toward the outlier payment: A4657 syringe, with or without needle, each of which covers the

injection administration-supply charge (includes the cost of alcohol swab, syringe, and gloves) and A4913 miscellaneous dialysis supplies, not otherwise specified, which covers the intravenous administration-supply charge (includes the cost of intravenous solution administration set, alcohol swab, syringe, and gloves). Therefore, we only expect to see these two supplies reported on the claim because prior to the implementation of the PPS they were separately payable when they were used in the administration of intravenous drugs during dialysis and it would be appropriate for their inclusion in both models. Also, the costs associated with these items are minimal. Approximately $17,000 of supply costs were reported in 2014 claims based on the June 2015 claims file, which included approximately 4 million claims with a total Medicare payment of approximately $9 billion. Therefore, even if 100 percent of these costs were also reported as CR costs on the cost reports, the consequent double-counting would have a negligible impact on estimated cost per treatment, and will not have the effect with which MedPAC is concerned, namely, accurately distinguishing the relative cost or payment addressed by each regression.

In regards to MedPAC's and other commenters' concerns about how multiplying factors from the two equations could diminish the accuracy of the combined factors, we believe the impact of this concern is also minimal. The method of combination, weighting the CR or SB equation's multiplier by the share of total per treatment costs, is unchanged from when the ESRD PPS was first implemented in 2011. The only change is that the weight assigned to the SB equation has declined due to changes in practice patterns following the implementation of the ESRD PPS (primarily reductions in use of previously separately-billed drugs); the share of per treatment costs attributed to SB services declined from 32.1 percent in the 2011 payment model to 19.2 percent in the 2016 payment model. Therefore, the CR analysis estimates the facility-

level relationship between case-mix measures aggregated across patients and average cost per treatment for composite rate services. The facility-level model has been successfully used to estimate statistically significant relationships between a number of case-mix characteristics measured at the facility level and average cost per treatment at the facility level since the BCMA composite rate payment system was implemented in 2004. As noted above, the facility-level model has not allowed us to estimate accurate payment adjustments for uncommon conditions such as the comorbidities that are included in the patient level SB model or the effects of uncommon treatment types such as home dialysis training. Therefore, we have refrained from estimating such payment adjusters from a facility-level model.

Comment: MedPAC also noted that through the various revisions of the two-equation model the reference group for the age adjustment shifted from ages 45-59 in the CY 2011 ESRD PPS proposed rule to ages 60-69 in the CY 2011 ESRD PPS final rule, and to ages 70-79 for the CY 2016 ESRD PPS proposed rule. MedPAC indicated that they would expect that the relative cost of dialysis across age categories to remain relatively stable over time and expressed concern that such shifts could indicate that the estimated factors are highly sensitive to the model's specification and that the model lacks robustness. They further stated that the two-equation approach might contribute to the shifting in reference groups through the various revisions to the model.

Response: We do not believe the change is as significant as MedPAC has expressed as there was very little variation in the age coefficients between the 2011 model and the 2016 model. Furthermore, in the 2011 model, the 70-79 age category only had costs 1.1 percent higher than the reference group of 60-69. Historically, we have had narrowly defined age categories. In the analyses for both payment year 2011 and payment year 2016, the highest costs

were observed for the youngest adult age group (ages 18-44), and there were relatively smaller differences in cost across the middle age categories. We expected some variation in the 2016 multipliers as a result of updated claims and cost report data since they were first derived in 2011. The final 2011 regression analysis used 2006, 2007 and 2008 claims and cost report information while the 2016 regression analysis used 2012 and 2013 claims and cost report information. Considering the significant changes that have occurred in the practice patterns of ESRD facilities, such as the significant reduction in the use of ESAs and other renal dialysis services, the minimal overall change in the coefficients appears to indicate that the model is stable. We believe this result confirms the ability of the two-equation methodology to appropriately recognize the costs for providing renal dialysis services in an ESRD facility. For these reasons, we do not believe the change in the age reference group over time indicates a problem with the regression model.

Comment: MedPAC expressed concern that using unaudited cost reports could pose a threat to the validity of the payment adjustment factors since historically facilities' cost reports have included costs that Medicare does not allow. They noted that PAMA funded CMS to audit a representative sample of ESRD facility cost reports beginning in 2014. They indicated that they knew the audits have not been completed at the time of this final rule but would be interested in learning if there are any differences in the payment adjustment factors that are derived from pre- versus post- audited data.

With respect to the use of hospital-based cost reports to derive the payment adjustment factors, MedPAC expressed that there is no guarantee of consistency in the methods used to allocate hospital costs to dialysis departments and to dialysis cost categories. They noted that CMS has said that expense data for hospital-based cost reports reflect the allocation of overhead

over the entire institution, and that the expenses of each hospital-based component may be skewed. MedPAC further noted that for these reasons, the inclusion of hospital-based cost reports likely increases statistical noise in the two-equation regression methodology.

Response: As for the use of unaudited cost report data, we used the best available data for this refinement. We do not expect to have results from audits of ESRD cost reports required by section 217(e) of PAMA for some time. We believe this refinement is necessary because it reflects costs and practice patterns under the ESRD PPS. In addition, section 632(c) of ATRA requires us to analyze and make appropriate revisions to the case-mix payment adjustments by not later than January 1, 2016, and therefore, we cannot wait until after cost reports have been audited to revise the case-mix adjustments. After analyzing the adjustments, we believe the revisions we are adopting are appropriate and necessary to reflect the drop in the use of ESAs and other renal dialysis drugs.

With regard to the use of hospital-based cost reports, we agree that the issue of allocation of costs to the dialysis unit is unique to hospital-based cost reports. As part of the cost reporting process, hospitals can allocate costs to hospital-based dialysis facilities. There may be variation among hospitals regarding the methodology of cost allocation, with some hospitals under-allocating and others over-allocating costs to hospital-based dialysis facilities. The model does include an indicator of hospital-based status as a control variable. This will capture differences between hospital-based and freestanding facilities on average. Our preference is to include hospital-based facilities, while acknowledging concerns about the data, in order to represent the cost experience of all providers. We believe the concerns about the data would be more salient if the data were being used to set the base rate rather than being used only to determine the relative costliness of different case-mix factors. Also, we note that the freestanding cost reports were

available before the hospital-based cost reports, so preliminary analyses did not include hospital-based cost reports. When the hospital-based cost reports were added, the payment multipliers did not change substantially, suggesting that the decision to include or exclude hospital-based reports will not have a significant impact. Including them reflects our preference that the data used to determine payment adjusters is as broadly reflective of the patients and facilities being paid under the ESRD PPS as possible.

Comment: MedPAC expressed concern that data from 2012 may not reflect current practice patterns particularly with the use of renal dialysis drugs and biologicals because drug use has continued to decline in recent years. MedPAC suggested that we use data from 2013 and beyond to update the payment adjusters since they believe that using only 2013 data would ensure better accuracy of the payment adjusters.

Response: The 2011 model was based on 3 years of data and we wanted to maintain that approach for the refinement. However, for the 2016 payment year, we did not use 1 year (2011) of data due to concerns similar to those raised by MedPAC. However eliminating an additional year, 2012, of data would decrease the accuracy of the CR model due to the decrease in the amount of data available to estimate the statistical relationships between case-mix and cost. Specifically, the sample size would be halved. For this reason, we did not adopt this suggestion and retained CY 2012 data in the regression analyses.

As we stated above, we brought the commenter's criticisms to our experts in order to ensure commenter's concerns were addressed. Their opinion was that dropping 2012 for the SB model only would still result in an accurate SB model due to the large sample size since this is a patient-level model, but then would be inconsistent with the timing of the data used in the CR model. As a result of these discussions, we continue to believe that the refinement for CY 2016

is appropriate because 1) we used year as a control variable in the regression model; therefore, any differences in average cost across the 2 years is accounted for, and 2) we are using the model to estimate the multiplicative adjusters, not the base rate. MedPAC's main concern appears to be with changes in *average* treatment patterns between 2012 and 2013, not with changes in the *relative* costs associated with different patient characteristics, and the multiplicative adjusters reflect relative costs.

Comment: Several dialysis organizations pointed out that variation in the average facility cost per treatment derived from cost reports is not directly associated with variation in patient characteristics and because of this, the variable concepts for the payment adjustments cannot be measured by the cost report data. One large dialysis organization (LDO) stated they are very concerned that CMS believes it is appropriate to use "total facility cost" derived from the ESRD cost reports for the development of patient-level adjuster values. The LDO stated that the overall cost report data cannot be directly linked to any specific patient characteristic and that these data only provide information on total costs to operate a facility, which are generally a reflection of the number of patients the facility serves, management capabilities, and geographic location, not specific patient characteristics. The commenters believe analysis of facility cost reports does not yield conclusive observations regarding individual patient characteristics. They recommend that CMS refrain from using cost report data to develop patient-level adjusters because they believe cost reports are only reliable for determining facility characteristics for use in developing the facility-level adjusters, such as the low-volume adjuster.

Response: We believe that the two-equation regression methodology is appropriate and has successfully estimated statistically significant patient- and facility-level payment adjusters. Below we provide an explanation as to how the two equations work together to derive the

payment adjusters.

Within the cost report, we start with using the worksheet level detailed data and the total cost per treatment that is reported. Then we construct the average cost per treatment for each ESRD facility. At this point, we recognize that corporate costs may not be allocated to facilities in a uniform fashion across dialysis organizations. This variation in cost accounting creates unwanted variation in the cost report data. The control variables discussed below help account for these cost variations.

Next, we attach the distribution of patient characteristics at the facility-level to the cost at the facility-level. For example, for age, we would take the percentage of patients in each of the age categories at the facility level and attach that to the facility's average cost. There is one observation per facility, not one per patient. Stated differently, it is not the facility characteristic that is being attached to the patient, but rather the average case-mix characteristic being attached to the facility. Specifically, the observation is a facility year. The dependent variable is the average cost per treatment across all the treatments provided by that facility in that year. The case-mix factors that are being used to develop multipliers are also aggregated at the facility level from claims. For example, for BSA, it is the average BSA for all the patients treated at the facility during the year. The model evaluates whether facilities that have a disproportionate share of a certain characteristic (for example, high BSA) have higher/lower costs than facilities that have a smaller share of patients with those characteristics. For several of these characteristics, variations across facilities in the average values across all of their patients do predict CR costs.

We believe that this method along with the control variables described below allows us to distinguish variation in cost per treatment in the cost reports from variation arising from

treatment volume and corporate policies. We note that differences in cost related to certain facility-level (aggregate) case-mix factors (patient age and body size) have been statistically estimated in the models that underlie the BCMA composite rate payment system implemented in 2004, the ESRD PPS implemented in 2011, and the CY 2016 ESRD PPS proposed rule. All of these models use the same basic methodology and have not come under this level of scrutiny in the past, which could indicate that it was accepted by the dialysis industry as an appropriate method for estimating cost variation.

The facility control variables of volume and ownership-related differences serve as proxies for the factors raised by the commenters. As proxies, they serve to not only adjust out their correlation with reported cost per treatment, but also ensure that the multipliers for the patient characteristics are not biased. The goal is to eliminate bias occurring by any existing correlations between patient characteristics and the control variables. For example, it is expected, due to sheer volume, that the LDOs have greater buying and negotiating power for drugs and supplies than a SDO or independent dialysis organization, but we do not have access to that information for our analysis in the model. For precisely this reason, we use control variables such as ownership because we do not have access to proprietary measures for factors such as purchasing policies raised by the commenter.

Comment: Several LDOs and a national association of ESRD stakeholders expressed concern that CMS and its contractor used statistical methodologies and identified adjuster variables in a manner that cannot produce valid or reliable adjuster values. One commenter stated that statistical methods are only valid if the data to which they are applied are a fit to the methods. The commenter further explained that statistical methods applied to data that do not meet the requirements for reliability and validity will produce results that are not accurate, may

not be meaningful, and can be volatile from year to year. This commenter claimed that the fundamental requirements of a regression model were not met in the analyses used to design the ESRD PPS payment adjusters. The commenter further stated that to produce valid and reliable results, a regression analysis must be based on a sound research design and must adequately address the assumptions made by the mathematical properties of the regression analysis. They then provided the major assumptions that they claim underlie regression methods and noted that these assumptions are not valid for the CY 2016 proposed rule adjusters.

We address each core assumption that the commenter referred to in the next four comments and responses. Our general response is below.

Response: We acknowledge that the concerns raised about the regression model are reasonable concerns to have about any regression model. However, we disagree with the notion that the existence of these concerns implies that the analyses "violate the core assumptions for a valid analysis." No regression model using real data conforms perfectly to the textbook ideals of a model that includes every potentially relevant variable, each of which is measured perfectly and perfectly represents the concept it is trying to measure, and is uncorrelated with any other variable of interest. We acknowledge that our regression analysis has limitations with regard to issues such as data availability, as does every regression model. We have provided responses to the wide variety of criticisms regarding the regression approach, data, etc., and we believe these responses support a model that is valid and stable. We believe we have selected an approach that mitigates such concerns as much as is feasible, and yields valid results, and that the model we are using most accurately aligns payment with resource use and accounts for both case-mix and facility adjustments in the most accurate way possible for a real-life scenario.

Comment: Commenters stated that the two-equation regression analysis used to produce

the adjustor values is not correctly specified and stated that correct specification requires that all variables be statistically significant or theoretically related to the dependent variable in the regression model. Commenters further explained that correct specification requires that all variables that could predict change in the dependent variable (that is, the cost per treatment in the first equation, cost of separately billed items in the second equation) were included in the model. The commenters also stated that correct specifications require that the coefficients of the independent variables (the value assigned to the adjuster as a result of the regression) are assumed to not change during the period of analysis. They contend that if a regression model is not correctly specified, the results will be biased and will not reflect an accurate impact of the independent variables on the dependent variable.

The commenter noted that the process for selecting variables and evaluating them for inclusion in the two-equation regression analysis was not comprehensive and there is reason to believe that the variables selected were not those that drive cost variation. The commenters indicated that the methods that CMS and its contractor used appear to produce results that cannot be directly linked to costs of providing dialysis care and are not directly linked to analysis of underlying patient clinical characteristics. Specifically, the commenters have indicated to us that our model is not capturing those characteristics that they see as having an effect on their cost, namely the ambulatory status and cognitive abilities of the very young and the elderly; cardiovascular instability or diabetes-related limb amputations; and, the extra time, supplies, and infection risk of central venous catheters. One dialysis organization provided the following list of drivers of variation in patient treatment costs, some of which overlap with the other commenter's list: use of central venous catheters, frailty, obesity, ambulatory status, cognitive capabilities, characteristics, conditions, and illness or race or ethnicity that are associated with an

increased need for ESAs or vitamin D, chronic inflammation (difficult to define by specific disease), infection, chronic gastrointestinal bleeding, and myelodysplasias. They also claim that no independent research is referenced to support the use of those variables that are included.

Response: We believe that the commenter is referring to the reasoning and testing of different variables that were or were not included in the two-equation regression analysis used for the CY 2011 ESRD PPS final rule. The basic modeling approach for the ESRD PPS has been subjected to extensive development and testing for over a decade. Using cost report data, the composite rate equation development dates back to the work supporting the BCMA composite rate payment system implemented in 2004. In the development of the final rule for the 2011 implementation of the ESRD PPS, the two-equation approach was extensively tested and documented (in the Technical Report), along with testing many variables. We agree that many of the suggested payment variables may have an impact on treatment costs; however, adopting these suggestions would require additional reporting by ESRD facilities as to patient diagnoses or conditions. With regard to the cost drivers associated with race and ethnicity, which are related to an increased need for ESAs, we note that renal dialysis service drugs and biologicals are eligible outlier services, and as such, the outlier policy could pick up part of the cost of increased use of ESA and Vitamin D. We discuss race and ethnicity in the CY 2011 ESRD PPS final rule (75 FR 49108 through 49115) and provide detail on why we did not finalize those characteristics as payment adjustments.

The refinements focused on using more recent data, which reflect changes in practices and incentives under the ESRD PPS. We believe that the information that the commenter is referring to with respect to testing variables is available in the Technical Report developed by UM-KECC. In addition, we have provided theoretical reasons why the chosen variables could

influence patients' care requirements throughout the CY 2011 and 2016 ESRD PPS final rule's preamble language where we discuss the analytical work behind each adjustment factor, which is also available in the Technical Report. We note that all of the adjusters have demonstrated statistical relationships to the dependent variables (average cost per treatment for composite rate services and the average Medicare Allowable Payment (MAP) for previously separately billable services) as evidenced by the results of the model. All patient-level variables (age, comorbidities, body surface area/body mass index, onset of dialysis) have been reviewed by expert clinicians and all facility-level variables (low-volume payment adjustment and rural adjustment) have been reviewed by health economists. These subject matter experts have opined that the two-equation model is statistically sound and appropriate for estimating cost variation for ESRD facilities. We appreciate the examples commenters provided that communicated to us the characteristics they consider to be related to increase in cost in furnishing dialysis. In order to capture most of the characteristics that were provided by commenters (for example, ambulatory status or cognitive function), we would need to develop ways for the information to be submitted. We will keep these comments in mind for future refinements.

As we discuss above, the primary purpose of the refinement was to test the assumption that the values had not changed since 2006 through 2008, and to refine the payment model to account for any changes that had occurred. Therefore, we developed adjusters using more recent data that were derived under the current payment system rather than continuing to use payment adjusters derived in the past. In addition, we analyzed rural areas and are finalizing a rural payment adjustment which is discussed in section II.B.1.d.iii.

Because we used updated data, we would expect the coefficients to have changed between 2006 through 2008 (the time period over which the current model was estimated) and

2012 through 2013 (the time period over which the proposed model was estimated). In fact, while the exact multipliers have changed overall slightly, the basic relationships (for example, U-shaped effect of age, higher costs soon after ESRD incidence) have been quite stable. With respect to referencing independent research to support the use of the variables in the model, the 2008 Report to Congress or Technical Report cite what was available in the literature at the time.

We do not have any reason to expect that the coefficients changed between 2012 and 2013. As noted by MedPAC, practices were still changing somewhat, but it is not clear that this would necessarily create any meaningful bias in the coefficients. As noted in response to MedPAC's comment above, the model controlled for year (that is, adjusted for the mean difference between the 2 years) therefore any difference in average costs across the 2 years is accounted for. Notably, when the model is estimated on a single year of data, the multipliers do not change appreciably. However, the preference is for using 2 years of data because doing so stabilizes the estimates for the facility-level composite rate model.

Comment: The next core assumption that the commenter expressed concern about was regarding the independence of observations. Specifically, the commenter stated that in a correctly specified regression model, the observations are uncorrelated with each other, which means that all treatments are assumed to be independent of each other. The commenter stated that in the ESRD context, treatments occur in a sequence linked to an individual patient such that treatment cost for one treatment may be related to prior treatment, the duration between treatments, events that interrupt treatments, such as hospitalization, and the patient's health status at the time of treatment. Therefore, treatments are not independent of each other and thus the assumption is not valid under the ESRD PPS model. The commenter specifically indicated that if CMS and their contractors used the ordinary least squares test, the results of treatments

not being independent of each other will be that it is no longer possible to trust significant tests. In addition, the commenter stated that if observations are, in fact, related as is the case with dialysis treatments, then this correlation between observations should be modeled in the regression using generalized least squares (another test used during the development of a model). The commenter claimed that they found no documentation to suggest that this method was used.

Response: It is our understanding from the comment that the commenter believed the unit of analysis (or observation as they labeled the term) in the model was a *dialysis treatment*. However, the unit of analysis for the two-equation regression analysis is not observed treatments (for example, a full year patient on thrice weekly dialysis could contribute up to 156 observations to the model each year), rather, it is each patient-month level. Specifically, the SB models are estimated at the patient-month level, not the treatment level. Therefore, there is a separate observation for each patient month, rather than for each treatment. In prior analyses, using 3years of patient-month level data from 2006 through 2008, the effect of the correlation within patients was tested and it did not impact results. In addition, the primary concern from correlated (or clustered) observations is that the standard errors would be underestimated, not that the coefficients would be biased. The SB models have a very large number of observations and consequently almost all payment variables (and all that have large multipliers) are not of marginal statistical significance. Therefore, we believe that our unit of analysis, the patient-month, does not violate a core assumption of a valid analysis. A more detailed discussion on the unit of analysis, that is, patient-month, for the ESRD PPS model is available in the Technical Report beginning on page 39.

Comment: The next core assumption that commenters expressed concern about was

regarding random error. Specifically, the commenter stated that a correctly specified regression assumes that there is not random error built into the independent variables. The commenters claimed that there is considerable error in the cost report data used and, as a result, the payment adjustments are biased and do not reflect the effect of the independent variable on the dependent variable. The commenter further explained that there are large amounts of missing data in the fields that are rolled up into the total cost field used in the analysis. In addition, the commenter stated that CMS has not disclosed how it handled trimming data for unbelievable values and other types of error. Lastly, the commenter indicated that hospital cost reports are frequently highly inconsistent with freestanding facility cost reports and are often missing, or have large amounts of missing data. The commenter stated that without addressing the known level of error in the data source, the assumption that the data are error free is violated. However, the commenter noted that the claims data used may meet the condition for this assumption.

Response: Our understanding of the comment is that the commenter believes that the independent variables are derived from the cost report. While we link patient characteristics to the cost at the facility level using cost report data (as we discuss above), the independent variables that are used as payment adjusters are derived primarily from claims for patient characteristics and other CMS data sources for facility characteristics (for example, size, low-volume status, rural status, organizational characteristics). We believe that the commenter's concern about accuracy is about the cost per treatment measure derived from the cost reports for use in the composite rate equation. That is, the error to which they refer is on the dependent variable (average cost per treatment for composite rate services), not on the independent (or predictor) variables (case-mix and control variables) as they state.

We note that classical measurement error (that is, when a variable of interest – either an

explanatory or dependent variable – has some measurement error independent of its value) on independent variables can bias coefficients (typically downward, implying that estimates of the effect would be conservative). For example, classical measurement error on a low BMI could bias the coefficient downward, resulting in an underestimation of the additional resource use needed by the thin, frail patient. On the other hand, classical measurement error on the dependent variable affects the precision of the estimates of the coefficients on the independent variables due to the extra "noise" in the data, but does not bias the coefficients. Further, one reason for including a number of facility-level control variables in the model is to control for some of the facility or organizational factors that might contribute to variation in cost per treatment that arises for factors other than variation in patient characteristics.

The commenters assert that they have data that demonstrate the factors, such as profit status and dialysis organization affiliation have no impact on composite rate cost per treatment on the cost report. This evidence was not presented in the comment and we would find it helpful to have this data shared with us. While they assert that factors such as financial policies and negotiated medication prices do matter, these are precisely the factors that would vary across organizations. We use the differences such as affiliation and hospital-based status between large, medium, and small dialysis organizations as proxies to capture these differences. Unless a mechanism is developed to require that all dialysis organizations share information such as their acquisition costs for dialyzers and negotiated medication prices with CMS, which they may consider proprietary, it would not be possible to adjust directly for those items in the model.

Comment: The last core assumption that commenters expressed concern about was correlation of variables. Specifically, commenters stated that the independent variables should not be correlated with each other. The commenters find that there is considerable correlation

among the independent variables which reduces the accuracy of the adjustment factor. A medium dialysis organization (MDO) commented that use of the BMI and BSA is a concern as they are both variables for the same patient characteristic and essentially cancel each other out. They stated that preferably, these variables should not be used as the independent variables for the case-mix adjusters.

Response: It is correct that correlation between variables makes it more difficult to statistically distinguish their independent effects on the dependent variable, but only very high correlations necessarily render it impossible. As long as the variables have some independence from each other (one does not precisely predict the other), it may still be possible to estimate their separate associations with outcomes.

With respect to BSA and low BMI, these variables represent different characteristics that have individual effects on cost. In particular, BSA (which is a continuous variable that increases as the patient's body size rises) is empirically associated with higher composite rate costs. The fact that larger patients on average generate higher composite rate costs may reflect the longer dialysis time which is required to effectively dialyze larger patients. In contrast, the low BMI categorical variable identifies particularly frail patients, that is, those with BMI less than 18.5. This measure of frailty is empirically associated with higher separately billable costs. These very frail patients require more expensive drug therapies.

While BSA is negatively correlated with low BMI, the correlation is not perfect. BSA and the low-BMI indicator variables measure related, but different concepts and complement each other (that is, small and frail are not the same).The low-BMI multiplier helps avoid the potential of payments not reflecting the higher costs of caring for frail patients. Therefore, elimination of the low-BMI adjuster could reduce frail patients' access to care by encouraging

perverse incentives in facilities, who may try to avoid such patients if their costs are not reflected in the payment system. If there was only a BSA adjustment, then the heavier beneficiaries requiring more dialysis time would be accounted for by the facilities receiving the additional payment, with the lighter weight beneficiaries not receiving as much, to the detriment of those at the lowest end of the scale, the thin and frail. In other words, having the low-BMI adjustment in opposite direction of the BSA adjustment for small, frail patients is the intended effect. Dropping the low-BMI adjuster could place frail patients at increased risk of being denied access to care if there is only a downward adjustment for small BSA.

Further, we note that even if BSA and BMI are strongly correlated when measured as continuous variables (a variable that can take any value between two numbers), this is not how they appear in the model. Only BSA is entered continuously. BMI is entered as a discrete indicator variable for being below the accepted cutoff indicating potential undernourishment/frailty, which is at the extreme of the distribution. The correlation between that discrete indicator of an extreme value for BMI and the entire continuous range of BSA is not exceptionally high. In short, these two variables complement one another in the payment model since low-BMI is a proxy for frail and malnourished patients and BSA is a proxy for time on machine and other high resource use. Similarly, while there is some correlation between rural status and low-volume status, the other specific instance of co-linearity raised by the commenters, those are both dichotomous indicators and there are substantial numbers of facilities having each of the four possible combinations of the two variables. If there were no low-volume, non-rural facilities, and no non-low-volume rural facilities, it would be impossible to statistically distinguish the low-volume effect from a rural effect, but in fact many such facilities exist. We discuss BSA and low BMI and facility-level adjustments in greater depth in

section II.B.1.c.2 of this final rule.

Comment: Commenters stated that because the adjuster variables explain less than 10 percent of the variation in cost, the model should have been reevaluated before being proposed. They explained that the R-squared results for the proposed adjusters were not provided, despite being requested.

Response: Because the model is estimated as two equations at different units of analysis (facility and patient-year), there is not a single, accepted method of calculating a combined R-squared. R-squared values have been provided for each equation. The coefficient of determination, denoted R^2 or r^2, is a number that indicates how well data fit a statistical model – sometimes simply a line or a curve. An R^2 of 1 indicates that the regression line perfectly fits the data, while an R^2 of 0 indicates that the line does not fit the data at all. This latter can be because the data is utterly non-linear, or because it is random. It is a statistic used in the context of statistical models whose main purpose is either the prediction of future outcomes or the testing of hypotheses, on the basis of other related information. It provides a measure of how well observed outcomes are replicated by the model, as the proportion of total variation of outcomes explained by the model. Obviously, higher R-squared values are preferred, as this would reflect greater ability to predict cost. However, many case-mix adjustment models do not achieve high R-squared values because medical costs inherently have a large random component. We disagree with the commenter's suggestion that a model must explain 10 percent of the variation, and have had our experts concur with the validity of the two-equation model. There was no concurrence among the experts regarding a10 percent statistical cutoff rule for variance explanation in a model.

What is more significant is that the payment adjusters have a statistically significant

effect on costs, and that that effect is meaningful in magnitude (that is, large enough that failure to account for it would results in payments substantially below costs). If the model demonstrates that there are characteristics of individual patients that are systematically and meaningfully related to costs, adjusting payments for those characteristics can be important independent of the model's overall R-squared, regardless of whether the overall R-squared is high, medium or low. It is important that adjustments be made for the organizations that care for a disproportionate share of resource-intensive patients, particularly if those organizations do not have many dialysis units across which they can diversify that risk to receive payment that reflects the characteristics of their patients that are related to cost of care. Equally important is the prevention of access to care problems for patients with those characteristics. Failure to provide adjustments could result in access problems, such as incentives for cherry-picking, and these issues could occur regardless of the size of the dialysis organization.

Comment: Commenters had specific concerns about how variables were chosen for the two-equation regression analysis and expressed concern that exaggerated statistical significance of variables based on a universe, not a sample, has resulted in adjusters with questionable statistical or clinical significance. The commenter expressed concern that the large number of facilities and treatments used in the two regressions has resulted in exaggerated statistical significance of coefficients. They further explained that this is because coefficients become more statistically significant as the size of a *sample* increases and statistical significance is most useful to evaluate selection of variables when actual samples are being used. The commenter claimed that CMS uses as much of the universe as it can, rather than having statistically sampled the universe. They stated that the result of this is statistical significance as used by CMS no longer has the meaning it does with actual samples. The commenter pointed to the 2008 Report

to Congress and stated that the age categories 45 to 59 and 70 to 79 were not significant at the .05 level. They indicated that given the large sample size, if age were an independent driver of cost, they would expect a greater level of significance. The commenter noted that none of these specifications were disclosed for the updated regressions used to estimate the proposed 2016 payment adjusters.

Response: In the work leading to the CY 2011 ESRD PPS payment rule, this issue was addressed. One variable selection criterion was that a comorbidity would be considered for a payment adjustment if its relationship to cost was both statistically and economically significant. As noted by the commenter, even a very small multiplier could be statistically significant due to the large sample. All of the proposed comorbidity adjusters have economically meaningful multipliers.

As noted by the commenter, the interpretation of statistical significance changes when the data include a universe rather than a random sample. Essentially, when the universe is used, the coefficients can be interpreted as being perfectly accurate (they perfectly reflect the universe, because they are derived from the universe). However, statistical significance remains relevant for two reasons. First, it is a tool to assess the closeness of the relationship between the predictors and outcomes. Second, and more importantly, even a near universe of claims from a given time period represents a sample of time periods (for example, 2012 and 2013 claims are being used to project relationships in 2016). The commenter's solution, to use less data than are available in order to estimate the relationships, sacrifices precision in the estimates. As noted at the beginning of this response, we prefer to use all the data and assess whether the relationships have sufficient economic size to potentially warrant adjustment. For example, a comorbidity could be associated with a trivial 0.1 percent increase in costs that could nonetheless be

statistically significant due to the very large sample size. Such a comorbidity would not have been chosen for inclusion in the payment model.

Comment: Commenters stated that because of the poor fit of the model to appropriate data, the high level of correlation among the adjuster variables, and the many violations of assumptions required for valid regression, they do not believe that this regression model can be fixed. Due to these concerns about the methodology and based upon their clinical experience, they recommend that we retain the current (CY 2015) age adjuster and payment multipliers rather than adopt the proposed modifications; retain the CY 2015 low-BMI adjuster to address underweight patients and establish a high BMI adjuster to address overweight patients tied to the NIH guidelines for defining overweight patients using BMI rather than applying the BSA adjustment; retain and recalculate the onset of dialysis adjustment; remove all comorbidities adjustments; and retain the LVPA modifications and develop a two-tiered LVPA in place of the rural adjustment. Several commenters proposed estimating new multipliers for some factors (for example, onset of dialysis, obesity, two-tiered rural adjustment) while retaining some current adjusters.

One LDO's overall concern is that any adjuster must be clinically relevant and serve the purpose of ensuring that the ESRD PPS does not discriminate against high-cost patients. They believe that several of the adjusters as currently structured do not meet this end goal. They requested that we eliminate a number of adjusters for CY 2016 (comorbidities, age, and body mass index (BMI)/body surface area (BSA)) in their current constructs because they are not based on clinical data, are executed ineffectively or inaccurately, or they do not represent actual incremental facility costs. They believe that absent the ability to put needed changes in place for CY 2016, elimination of these adjustments during the upcoming year will provide CMS the time

needed for re-analysis of the true impact. The LDO states that a 1-year hiatus for all adjustments with the exception of the onset of dialysis and low-volume adjusters (as defined in 2015), true drivers of incremental costs, will allow the Agency to take the necessary time to implement improvements that reflect the current dialysis unit cost reality.

Response: We continue to believe that moving forward with an updated model aligns with our goals for the prospective payment system in establishing accurate payments and safeguarding access for Medicare beneficiaries. As noted above, we modeled the ESRD PPS using methodologies that have been tested since the Basic Case-Mix Adjusted (BCMA) composite rate payment system and in using the most recently available data, we made our best estimate for predicting the payment variables that best reflect cost variation among ESRD facilities for furnishing renal dialysis services to a vulnerable population of patients. This refinement uses data that illustrates a fully bundled prospective payment system and reflects the practice patterns under such environment. We believe that it would not be appropriate to both perpetuate certain payment adjusters into the future that were developed using pre-PPS data and update the other adjusters using ESRD claims data and cost reports from 2012 and 2013.

While we appreciate the suggestions from commenters, we are unsure how the new adjusters would be estimated using the commenter's proposals. They did not specify whether we would force the retained CY 2015 multipliers to take on their old values when estimating the new model or allow the retained variables to take on the new values they have using the updated model, but only use new values for the other factors. We believe the proposed approach of blending in some unspecified way multipliers derived from different time periods and different statistical models into a single payment system would not provide a meaningful empirical basis for the payment model.

Comment: A national association of kidney patients expressed concern that because of the data sources such as unaudited cost reports and the two-equation methodology used (as discussed throughout the comments and responses above), the payment for the patient-level adjusters are not serving the policy intention of protecting access to care for beneficiaries who are perceived to be more costly. The association's health professional membership, which includes nephrologists, nurses, advanced practitioners, dietitians, and social workers have stated that while age is not always a predictor of costs, it is a legitimate proxy for higher costs associated with older patients. Similarly, underweight patients and overweight patents also contribute to increased costs to the dialysis facility. However, the rationale for these higher costs is not necessarily always reflected in claims data and dialysis facility cost reports because patients, that is, the overweight, the frail and the aged, are not distinct categories in the cost reports or the claims, and typically require more staff time devoted to them.

Response: We agree with the commenter that there are relationships of cost to age and body size. The age, BSA, and low-BMI adjustments in the CY 2016 ESRD PPS proposed rule incorporate those adjustments based on what can be statistically estimated from facility-level data on dialysis costs and patient-level data on costs of formerly separately billable items. These obviously and necessarily represent average relationships, while, as the commenter notes, for example, age is associated with cost but not necessarily for every patient. We believe that the age adjustments may serve to capture cost variation that is not captured by the other adjustments. As mentioned in a previous response, we would ideally like to have cost data at the patient-level rather than the facility-level, but data limitations preclude us from estimating that relationship at the patient-level. Rather, the estimated relationship is between average patient characteristics (for example, percentage in each age group, average BSA, percentage at onset of ESRD) and

average cost at the facility. Failure to adjust for these empirically derived relationships between case-mix and costs provides facilities with an incentive to cherry pick patients with low cost characteristics and avoid patients with high cost characteristics.

Comment: A patient group noted that in proposing the new age adjusters, CMS engaged in *data dredging*, the practice of analyzing large volumes of data to seek statistically significant relationships, without being guided by any hypothesis or explicit theory about behavior.

Response: The original modeling effort to establish the 2011 payment adjusters for the bundled ESRD PPS examined a large number of comorbidities and patient characteristics that could be related to costs. The examination was broad as the impact on cost could theoretically occur through several channels, both direct (for example, more staff effort in the dialysis unit) and indirect (for example, patients with certain conditions are more likely to be hospitalized or otherwise skip treatments, which could increase costs per treatment delivered due to greater unanticipated holes in facilities' schedules, as well as other research published by the contractor in conjunction with this project that identified that hospitalized patients used more injectables per treatment on an outpatient basis, presumably making up for smaller or missed doses away from the facility). As described in the 2008 Report to Congress and Technical Report, other criteria were applied to guard against *data dredging*. Notably, comorbidities with a very small relationship to cost could still be statistically significant in the SB model due to high degree of statistical precision allowed by the very large sample size; such variables were excluded as payment adjusters. They were deliberately excluded to avoid *data dredging*.

Comment: A patient group commented that the methodology has taken the characteristics of groups of patients at the facility-level to make inferences about individual patients. They indicate that it appears this was done solely by reason of the convenience of

having cost data available at the facility-level, but not at the patient-level.

Response: This is an inherent limitation of the currently available data, not a choice made for convenience. If we had access to cost information at the patient-level for formerly CR services, we would have estimated that model at the patient level rather than at the facility level. As we discuss above, such information is unavailable, primarily because ESRD facilities do not report their actual charges or resource costs for various renal dialysis services formerly paid under the composite rate on their claims, and facilities do not report charges for cost-relevant elements of the dialysis treatment, such as their charges for the dialysis filter which would reflect their policies regarding reuse of dialysis filters and other supplies. If the ESRD facilities reported charges in a way that was sensitive to variations in actual resource used across their individual patients, we could use reported charges adjusted by the cost-to-charge ratio developed from cost reports to estimate their cost for the ESRD PPS bundle of services. Such an analysis would infer the effect of patient characteristics on costs based on how facility average cost per treatment varies with the average characteristics of patients within the facility. This is an acknowledged limitation, but it arises by necessity given the nature of the available data.

Comment: A professional organization commented with the hypothesis that in the current time of decreased ESA use, the original set of conditions, such as age, comorbidities, BSA/BMI and onset of dialysis, likely has less influence on overall dialysis facility expenses. They commented similarly that it is possible that certain high risk patients, who previously made relatively minor contributions to overall costs, now have a larger cost impact and provided the example of patients with mental illness, lower socioeconomic status, and fewer resources available at home, which may contribute in different ways to higher resource consumption and expenditures for delivery of dialysis care. Additionally, patients initiating dialysis in the hospital

with multiple medical comorbidities and complex disease states also can require more resources in order to coordinate care. The complex interactions among multiple comorbidities and social circumstances are not captured through current risk assessment tools.

Additionally, the organization points out that the focus of the current case-mix regression models ignores several other important dialysis facility costs and could limit access to care. The organization stated that when patients (either due to non-adherence, mental illness, social stress, frequent hospitalization due to severity of their illness or other identifiable but unadjusted-for causes) are either unable to or refuse to attend outpatient dialysis treatments, facilities do not receive payment. The fixed costs borne by the facility for a patient missing dialysis treatment as well as the opportunity costs associated with the lost revenues that could have been collected by a facility if a different patient who would not have missed dialysis had instead been dialyzed are not captured in the case-mix adjustments.

To maximize access to care for high risk patients, the organization urged CMS to explore methods of case-mix adjustment that further refine characterizing high risk patients. They also suggest that the costs associated with meeting more recent QIP goals in high-risk patients as well as the cost of potential QIP penalties in patients for whom facilities are unable to improve QIP-related metrics despite appropriate efforts to do so are currently not reflected in the case-mix adjustments. They urged consideration of these costs in order to ensure access to care among high-risk patients and urged CMS to actively monitor whether dialysis facilities decline to care for higher risk patients.

Response: While it may be true to some extent that in the current time of decreased ESA use, the original set of conditions has less influence on overall dialysis facility expenses, all of the ESRD PPS payment adjusters continue to be predictive of higher costs. However, the overall

multipliers reflect the decreased use of injectable medications through the weighting of the separately billable equation. While we are unsure about what risk assessment tools the commenter is referring to, we agree that the current model does not capture the conditions suggested by the commenter primarily because conditions that may lead to missed treatments are not captured on ESRD facility claims or in cost report information, the two sources of data currently available for use in the regression analysis. In addition, ESRD facilities have reported significant problems in obtaining diagnostic information for the comorbidity adjustments as discussed in section II of this final rule, and would likely have similar problems in obtaining the information suggested. However, some of the adjusters in the model (for example, onset, age) are likely related to missed treatments, and their multipliers will partially reflect the effect of missed treatments on costs.

For future refinement, we are willing to explore what information would have to be reported by ESRD facilities in their claims in order to assess the impact of commenters' suggested factors on the regression. With respect to the comment regarding consideration of costs that are associated with meeting QIP goals in high-risk patients, it would not be appropriate to include the cost of QIP penalties in the case-mix adjustments. However, as we stated above, we would be interested in obtaining more information from ESRD facilities on those specific characteristics mentioned in the comment so that we could analyze the information for future refinements.

Comment: One commenter requested that CMS only provide adjusters that protect patient access.

Response: The most recent regression analysis confirms that the payment adjusters implemented in 2011 continue to be indicators of high cost patients. For this reason, we continue

to believe that the case-mix and facility adjustments are necessary to protect access to renal dialysis services for high cost patients. All of our adjusters were developed to serve as patient protectors. The patient adjusters (case-mix) recognize the higher costs associated with dialyzing/treating patients with co-morbid conditions that facilities may not be willing to otherwise treat because of the monetary loss. The facility-level adjusters protect patient access by providing additional monies to facilities in more economically or geographically restricted areas that encourage their opening and operating to serve those beneficiaries who may not otherwise have access.

For the reasons described above, we continue to believe that the two-equation regression methodology is sound and that it confirms the continued relevance and significance of the case-mix and other adjustments. More importantly, finalizing the regression methodology is appropriate so that future payments reflect the bundled environment under the ESRD PPS with the associated drop in the utilization of ESAs, other renal dialysis service drugs and laboratory testing. Accordingly, we are finalizing the use of the two-equation regression methodology to update the payment adjustments as proposed.

c. Analysis and Revision of the Payment Adjustments

As required by section 632(c) of ATRA, we have analyzed and are finalizing revisions to the case-mix payment adjustments below. We are also finalizing revisions to the facility-level adjustments for uniformity as described below.

i. Adult Case-Mix Payment Adjustments

1) Patient Age

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's age. In the CY 2011 ESRD

PPS final rule (75 FR 49088), we noted that the basic case-mix adjusted composite rate payment system in effect from CYs 2005 through 2010 included payment adjustments for age based on five age groups. Our analysis for the CY 2011 ESRD PPS final rule demonstrated a significant relationship between composite rate and separately billable costs and patient age, with a U-shaped relationship between age and cost where the youngest and oldest age groups showed the highest costs. As a result of this analysis, we established five age groups and identified the payment multipliers through regression analysis. We established age group 60 to 69 as the reference group (the group with the lowest cost per treatment) and the payment multipliers reflect the increase in facility costs for each age group compared to the reference age group. We established the group with the lowest cost per treatment as the reference group in order to avoid age adjustments with negative multipliers. We proposed and finalized payment adjustment multipliers for five age groups; ages 18 to 44; 45 to 59; 60 to 69; 70 to 79; and 80 and older. We also finalized pediatric payment adjustments for age, which are discussed in section II.B.1.e. of this final rule.

Commenters and stakeholders were largely supportive of a case-mix adjustment for age when the ESRD PPS was implemented. We noted in our CY 2011 ESRD PPS final rule (75 FR 49088) that several commenters stated that age is an objective and easily collected variable, demonstrably related to cost, and that continuing to collect age data would not be burdensome or require systems changes. In addition, a few commenters requested that CMS consider an additional adjustment for patient frailty and/or advanced age (75 FR 49089). In the CY 2011 ESRD PPS final rule, we responded to these comments by noting that we included an age adjustment for patients 80 years of age or older, but that advanced age and frailty did not result in the identification of additional age groups for the application of case-mix adjustments based

on age. In addition, we noted that the analysis did not identify a separate variable for patient frailty, as this would be very difficult to quantify.

As we discuss in the CY 2016 ESRD PPS proposed rule (80 FR 37815), the analysis we conducted to determine whether to revise the case-mix payment variable of patient age demonstrates the same U-shaped relationship between facility costs and patient age as the analysis we conducted when the ESRD PPS was implemented, however, the reference group has changed to age group 70 to 79, and we note significantly higher costs for older patients. For this final rule, we continue to believe that the regression analysis performed on CY 2012 through 2013 Medicare cost reports and claims has appropriately recognized increased facility costs when caring for patients 80 years old or older, and that this adjustment accounts for increased frailty in the aged. Age may serve as a proxy for several characteristics that cannot be easily measured and entered directly into the model. For example, younger patients may be more costly due to greater likelihood of skipped treatments, HIV infection, or drug dependence, while older patients might be more expensive due to greater likelihood of cognitive impairment or functional/mobility limitations.

The public comments we received on the proposed age adjustments and our responses are presented below.

Comment: MedPAC commented that through various revisions to the model, the empirically-determined lowest-cost reference group shifted from ages 45-59 in the CY 2011 ESRD PPS proposed rule, to ages 60 to 69 in the CY 2011 ESRD PPS final rule, and to 70-79 in the CY 2016 ESRD PPS proposed rule. They would expect that the relative cost of dialysis treatment across age categories would remain relatively stable over time. They expressed concern that such shifts indicate that the estimated factors are highly sensitive to the model's

specification and that the model lacks robustness. They indicated that the two-equation approach might contribute to these results.

Response: As we explained previously, we do not agree with MedPAC. In both models using 5 age groups, costs followed a U-shaped pattern with age, with highest costs occurring in the 18 to 44 group, the second highest costs occurring in the 80+ group, and the lowest costs in the three middle groups. The only qualitative changes are that the U-shape is now a bit more pronounced (higher multipliers for the youngest and oldest group), and among the three middle groups, the lowest cost group shifted from 60 to 69 to 70 to 79. Notably, the cost difference between the three middle age groups in the original 2006 through 2008 model was very small, so the shift from one of those categories being singled out as the lowest cost (reference) group rather than another is not very meaningful. In other words, the middle groups were so close to each other in cost in the 2006 through 2008 model that having a different one of the middle groups being the lowest cost group in the 2012 through 2013 data is not surprising and does not indicate flaws in the model. Only small changes in the data and the relationships between age and cost would be needed to cause such a change.

Comment: Two national dialysis organizations noted that the proposed change in the age adjustments is $7.47 per treatment to $19.36 per treatment, but that they are unable to identify any correlation that justifies a 159 percent increase for the age adjustments. They stated that the age adjuster randomizes payment, rather than targeting payments to patients with specific characteristics associated with higher costs. They recommended that we defer the change in the age adjustment and retain CY 2015 weights and values. An LDO, in analyzing its facility data, cannot validate a direct relationship between patient's age and cost of care. They do not believe it is appropriate to move forward with what they contend are arbitrary adjustments that they

believe are not based upon analysis of specific clinical patient characteristics.

Response: As we explained previously, the current CY 2015 age values were derived from the same methodology applied to the refinement analysis but are based on pre-PPS data. Using updated data confirmed that age correlates with differences in resource use and that the age adjustments are not arbitrary. Rather, we believe the age adjustments reflect differences in health status that are not otherwise reflected in the ESRD PPS payment adjustments and support facilities treating patients in the youngest and oldest age categories who have higher per treatment costs on average. We believe retaining the current age values would not be appropriate because we have updated data available for analysis that reflects the changes in practice patterns that have occurred under the ESRD PPS. Additionally, we continue to believe the age adjustments are appropriate and do not believe they randomize payment. Rather they target payments primarily to the two highest cost categories: ages 18 to 44 and age 80 or older.

While we are uncertain as to how the commenter calculated an increase in the age adjustments of $7.47 per treatment to $19.36 per treatment, as we mentioned in the previous section, the payment multipliers were derived using an analysis that attached the distribution of patient characteristics at the facility-level to the cost at the facility-level. For example, for age, we would take the percentage of patients in each of the age categories at the facility-level and attach that to the facilities' average cost. Therefore, the payment multipliers represent empirical relationships derived from the national ESRD facility data, and target payment for patients in the various age groups according to their resource use and cost. Thus, we believe the multipliers are appropriate and not arbitrary.

Comment: An organization of home dialysis patients, a nonprofit dialysis organization, and an organization representing small and medium dialysis facilities expressed concern that the

11 percent age adjuster increase of $24.58 for patients 80 years and older may have the unintended effect of reducing the use of medical management of their kidney disease instead of dialysis. They are concerned that there will be an incentive to dialyze elderly people and not fully explore all options for treating their kidney disease. Commenters also noted that medical management of care may be the best option for the end of life care. They requested that CMS return the dollars withheld for this age category to the base rate to help provide the best care to all patients. An organization of nonprofit SDOs agreed and suggested that the increased cost of care for this age group may be due to patients who are not good candidates for dialysis who would benefit from medical management instead of dialysis to treat their kidney disease.

Response: We believe it vitally important for all chronic kidney disease patients to receive kidney disease education services as described in section 1861(ggg)(1) of the Act to discuss all treatment options, including medical management of their kidney disease with their nephrologist so that the patients have complete information about their treatment options. Decisions about whether to continue medical management of patients' kidney disease or to begin dialysis once the patients' condition has reached Stage V (ESRD) are made by the patient and their nephrologist. We do not believe that the best approach to accomplish the goal of ensuring appropriate management of elderly patients' kidney disease is to remove the age adjustments and to increase the base payment paid for all dialysis treatments. We are concerned that this approach, which would not recognize the full cost of caring for patients 80 years and older, could create access problems for those patients for whom dialysis is the best treatment option.

Comment: A national kidney association commented that their health professional membership, which includes nephrologists, nurses, advanced practitioners, dietitians, and social workers, have stated that while age is not always a predictor of costs, it is a legitimate proxy for

higher costs associated with older patients. They pointed out that older patients are more susceptible to falls, requiring greater facility staff assistance to obtain their weights and assist them in and out of the dialysis chair. Commenters explained that elderly patients are also more likely to have a catheter, which increases the risk of bloodstream infections requiring antibiotics, blood cultures, and more frequent hospitalizations. They also tend to have more comorbid conditions, which could require frequent adjustments in the dialysis prescription and closer surveillance of the multitude of medication they may be on. Given this, it does not make sense that the age group of 70 to 79 would not have a payment adjustment while the 60 to 69 year old population would have a 7 percent payment adjustment.

Another organization commented that there should be an adjustment for patients aged 70 to 79 and that failure to adjust payments for patients in this age group implies that these patients require fewer services than those in the other age groups. They recommended that CMS provide more information about this counter-intuitive effect. An SDO questioned what has changed since implementation of the ESRD PPS in 2011 that would have resulted in such a shift in the reference group. An organization of nonprofit SDOs agreed and indicated that, as MedPAC suggests, it may be the result of the two-equation regression methodology or other factors in the model. The organization stated that the better course at this time is to leave the reference group unchanged pending further analysis and urged CMS to do so. Two nursing associations urged CMS to maintain the current reference group (ages 60 to 69) because in their experience, patients in the 70 to 79 age group often have greater needs and suffer more complications than younger adults.

Response: We agree with the comment that age is a legitimate proxy for higher costs associated with older patients that are not otherwise reflected in the model. As stated previously,

we established a reference group that reflects the age group with the lowest cost per treatment and compared the cost per treatment for all other age groups to the reference group so that all the other adjustments for age would be increases in payment. In the regression analysis, we determined that the age group 70 to 79 is the group with the lowest cost per treatment on average, despite the fact that some patients in the group may have greater needs and high cost per treatment. With regard to the question about what changed since implementation of the ESRD PPS that would explain the shift in the age reference group, we reiterate that, over time, there has been limited cost variation across the middle age categories and the change in the reference group does not indicate a flaw in the methodology.

Comment: An MDO questioned the payment multipliers for age for the outlier adjustment, which they believe were different from the payment multipliers when the original bundle was finalized. They indicated the multipliers were not listed in the CY 2016 ESRD PPS proposed rule, asked if the multipliers changed due to the regression, asked when the multipliers would be available, and questioned whether they would have an opportunity to comment before they are finalized.

Response: We believe that the commenter is referring to the coefficients that are derived from the separately billable model, which are used in determining outlier eligibility. Specifically, as discussed in the Medicare Benefit Policy Manual (Pub. 100-02, Chapter 11, section 60.D), the outlier payment computations use the case-mix adjusters for separately billable services to predict the per treatment MAP amount for outlier services. We provided the separately billable multipliers in the CY 2016 ESRD PPS proposed rule in Table 4 titled, CY 2016 PROPOSED ADULT CASE-MIX AND FACILITY-LEVEL PAYMENT ADJUSTMENTS(80 FR 37823) for the adults and in Table 5, titled, CY 2016 PROPOSED

PEDIATRIC CASE-MIX PAYMENT ADJUSTMENTS (80 FR 37824) for pediatric patients. These multipliers have not changed and are reprinted in this final rule in Table 4 titled, CY 2016 ADULT CASE-MIX AND FACILITY-LEVEL PAYMENT ADJUSTMENTS for the adults and in Table 5 titled, CY 2016 PEDIATRIC CASE-MIX PAYMENT ADJUSTMENTS. The outlier policy is described in detail in section II.B.2.c. of this final rule.

After consideration of the comments, effective January 1, 2016, we are adopting the proposed age payment multipliers provided in Table 1 of the CY ESRD PPS proposed rule (80 FR 37815) and reproduced below in Table 1.

TABLE 1: CY 2016 FINAL PAYMENT MULTIPLIERS FOR AGE

Age	Final Payment Multipliers
18-44	1.257
45-59	1.068
60-69	1.070
70-79	1.000
80 +	1.109

2) Body Surface Area (BSA) and Body Mass Index (BMI)

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account patient weight, body mass index (BMI), and other appropriate factors. Through the use of claims data, we evaluated the patient characteristics of height and weight and established two measurements for body size when the ESRD PPS was implemented: body surface area (BSA) and BMI. In our analysis for the CY 2011 ESRD PPS final rule, we found that the BSA of larger patients and low BMI (< 18.5 kg/m^2) for malnourished patients were independent variables in the regression analysis that predicted variations in payments for renal dialysis services. As such, we finalized two separate payment adjustments for body size in our CY 2011 ESRD PPS final rule (75 FR 49089 through

49090).

Commenters were supportive of BSA and BMI payment adjustments in 2011, noting that body size was a payment adjustment under the composite rate payment system, and that ESRD facilities would be able to capture this information on the claim form without any additional burden. A few commenters expressed concern regarding pre- versus post-dialysis weight. In response to these comments we clarified that a patient's weight should be taken after the last dialysis treatment of the month, as directed in the Medicare Claims Processing Manual, Pub. 100-04, Chapter 8, Section 50.3.

For the CY 2016 ESRD PPS proposed rule, we analyzed both BSA and low BMI ($<18.5 kg/m^2$) individually as part of the regression analysis and found that both body size measures are strong predictors of variation in payments for ESRD patients.

Body Surface Area (BSA)

Since CY 2005, Medicare payment for renal dialysis services has included a payment adjustment for BSA. The current payment adjustment under the ESRD PPS is l.020, which implies a 2.0 percent elevated cost for every 0.l m^2 increase in BSA compared to the national average BSA of ESRD patients. The increased costs suggest that there are longer treatment times and additional resources for larger patients. Including the BSA variable improved the model's ability to predict ESRD facility costs compared to using BMI or weight alone.

In the CY 2011 ESRD PPS proposed rule (74 FR 49951), we discussed how we adopted the DuBois and DuBois formula to establish an ESRD patient's BSA because this formula was the most widely known and accepted. That is, a patient's BSA equals their Weight $^{0.425}$ * Height $^{0.725}$* 0.007184, where weight is in kilograms and height is in centimeters. (DuBois D. and DuBois, EF. ''A Formula to Estimate the Approximate Surface Area if Height and Weight be

Known’’: Arch. Int. Med. 1916 17:863–71.) Once the patient’s BSA is determined, the payment methodology compares the patient’s BSA with the national average BSA of ESRD beneficiaries and computes the patient-level payment adjustment using the average cost increase for changes in BSA (per $0.1m^2$).

In developing the BSA payment adjustment under the ESRD PPS, we explored several options for setting the reference values for the BSA (74 FR 49951). We examined the distributions for both the midpoint of the BSA and the count of dialysis patients by age, body surface and low BMI. Based on that analysis, in our CY 2012 ESRD PPS final rule (76 FR 70244) we set the reference point at a BSA of 1.87 which is the Medicare ESRD patient national average BSA. Setting the reference point at the average BSA reflects the relationship of a specific patient’s BSA to the average BSA of all ESRD patients. As a result, some payment adjusters would be greater than 1.0 and some would be less than 1.0. In this way, we were able to minimize the magnitude of the budget-neutrality offset to the ESRD PPS base rate. (For more information on this discussion, we refer readers to the CY 2005 Physician Fee Schedule final rule (69 FR 66239, 66328 through 66329) and the CY 2011 ESRD PPS proposed rule (74 FR 49951)). The BSA factor is defined as an exponent equal to the value of the patient’s BSA minus the reference BSA of 1.87 divided by 0.1.

In the CY 2012 ESRD PPS final rule (76 FR 70245) and the CY 2013 ESRD PPS proposed rule (77 FR 40957), we stated our intent to review claims data from CY 2012 and every 5 years thereafter to determine if any adjustment to the national average BSA of Medicare ESRD beneficiaries is required. Although the CY 2012 claims showed an increase in the national average BSA, we did not implement an update in the CY 2013 ESRD PPS rule. Rather, in light of the requirement in section 632(c) of ATRA that we analyze and make appropriate revisions to

the ESRD PPS case-mix adjustments for CY 2016, we decided to incorporate the new national average BSA into the overall refinement of our payment adjustments that we are making as a result of that requirement.

In accordance with our commitment to update the Medicare national average BSA and because of the statutory requirement to analyze and make appropriate revisions to the case-mix payment adjustments for CY 2016, in the CY 2016 ESRD PPS proposed rule (80 FR 37816) we proposed to update the BSA Medicare national average from $1.87m^2$ to $1.90\ m^2$ for CY 2016 to reflect the new Medicare ESRD national average BSA. The average is based on an analysis of the patient height and weight information reported on ESRD facility claims in CY 2013. We note that this average is an increase of 1.6 percent over the Medicare ESRD national average BSA of $1.87m^2$ used to compute the payment adjustment when the ESRD PPS was implemented in CY 2011.

Based upon the regression analysis for CY 2016 using the DuBois and DuBois formula for computing a patient's BSA and the updated Medicare national average BSA of $l.90m^2$, we proposed that the BSA payment adjustment would be 1.032 and the BSA payment adjustment would be based on the following formula:

$$1.032^{((\text{Patient's BSA}- 1.90)/0.1).}$$

Low-Body Mass Index (BMI)

The basic case-mix adjusted composite rate payment system in effect from CYs 2005 through 2010 and the current ESRD PPS include a payment adjustment for low BMI. In order to be consistent with other Department of Health and Human Services components (that is, Centers for Disease Control and Prevention and National Institutes for Health), we defined low BMI as less than 18.5 kg/m^2. The regression indicated that patients who are underweight consume more

resources than other patients. The current payment adjustment for low BMI under the ESRD PPS is 1.025.

Based on the regression analysis conducted for the proposed rule, we continue to find low BMI to be a strong predictor of cost variation among ESRD patients. We proposed a payment adjustment of 1.017, reflective of the regression analysis based upon CY 2012 and 2013 Medicare cost report and claims data.

The comments we received and our responses are presented below.

Comment: MedPAC pointed out that in considering both body size adjustments, for patients with low BMI, the ESRD PPS applies an adjustment factor that increases payment by 2.5 percent; however, those patients tend to have BSA values less than the average, for which the ESRD applies an adjustment factor that decreases payment. They expressed concern that CMS has not stated exactly how each variable is incorporated in the regression models and that the proposed adjustment factors do not accurately account for the inherent correlation between patient BMI and BSA. They point out that the BSA is empirically estimated only in the facility-based regression, while the low-BMI adjustment factor is estimated only in the patient-based regression. MedPAC contends that this specification does not address the joint effect of patient BSA and BMI in each regression.

MedPAC conducted a regression in which they defined the dependent variable as the average cost per treatment (for services included in the PPS payment bundle), included the same independent and control variables as the CMS model and specified a set of BSA variables to take into account the distribution of BSA values at each facility. This approach allowed them to assess the joint effect of low BMI and BSA. With this specification, they found that the low BMI factor is statistically significant and increases payment by enough to offset reductions in

payment resulting from low BSA. To account for this correlation, MedPAC recommended that CMS refine the low BMI and BSA adjustment to reflect the factors' joint effect on facility costs. One method they suggested could be to continue applying the same adjustment for BSA when patient BMI values are 18.5 kg/m^2 or greater, but for BMI values less than 18.5 kg/m^2, apply a single adjustment factor that takes into account the joint effect of patient BSA and low BMI. Their analysis suggests that a joint BSA and low BMI adjustment factor would be about 1.02 to 1.03.

Response: As we explained in the previous section, the BSA and low-BMI variables represent different characteristics that have individual effects on cost. In particular, BSA (which is a continuous variable that increases as the patient's body size rises) is empirically associated with higher composite rate costs. The low BMI categorical variable identifies particularly frail patients, that is, those with BMI less than 18.5 kg/m^2 and is empirically associated with higher separately billable costs because these very frail patients require more expensive drug therapies. Because of the continued importance of both body size adjustments to account for the costs associated with overweight and underweight patients, we appreciate the modeling that MedPAC conducted, which retains both body size adjusters.

The proposed example from MedPAC is not substantially different from the current model. The payment multipliers take account the joint effect of BSA and BMI: one effect for those with low BMI (BSA effect *1.017) and one effect for those without a low BMI (BSA effect). Their proposal is essentially two continuous effects which start at differing cost averages (as indicated by the presence or absence of low BMI which moves the average costs up by 1.017). The ultimate effect is very similar to our model. We will, however, consider this approach for future refinement.

Comment: National dialysis organizations and two nursing associations also pointed out that a patient with a low BMI frequently has a negative BSA, eliminating the benefit of the low BMI adjustment for that patient. A national association of kidney patients and a nonprofit dialysis organization agreed and referred to an analysis that concluded that the BSA adjuster is canceling out the BMI adjuster in most cases for underweight patients. The commenters' healthcare professionals attest that both underweight and overweight patients require additional staff time devoted to their care and overweight patients may require the facility to provide additional equipment. To ensure that the patient level adjusters are achieving the intended policy purpose of protecting these seemingly more costly patients from adverse selection, the commenters recommend maintaining the current (2015) age adjuster, eliminating the BSA adjuster, and applying a BMI adjuster only for underweight patients, adding a BMI adjuster for overweight patients (using the National Institutes of Health definition) for 2016, and working with the kidney community to develop new data sources for patient characteristics from which appropriate age and weight adjusters could be calculated in future years.

Response: We agree with the commenters that both underweight and overweight patients require additional resources devoted to their care. Also, the commenters are correct that the BSA adjustment would be negative for frail patients and the low-BMI adjustment counteracts this effect. While BSA is negatively correlated with low BMI, the correlation is not perfect. The low BMI adjustment does not just counteract the negative BSA adjustment. Rather, where a patient's BMI is under the threshold of 18.5 kg/m^2, the combined effect of the low BMI and the BSA adjustment is an increase in payment for frail patients. We discuss the interaction between the BSA and low BMI variable in section II.B.1.

The suggestion that we retain elements from the current model, such as the current (2015)

age adjusters, and adopt new measures based on the updated regression using ESRD PPS data, would not be appropriate. We must either retain the current case-mix adjustments in their entirety or adopt the proposed adjustment multipliers derived from the updated regression analysis; adopting a mixture of adjustments from different regression analyses would remove the empirical basis of the payment system. We are unable to consider a new BMI-based adjustor for overweight patients for implementation in CY 2016. We would first need to consider the various options suggested, decide on a methodology, run the regression analysis using the new adjustor, and obtain public comments. We will consider this approach for future refinement of the ESRD PPS.

Comment: A large dialysis organization suggested that CMS eliminate the BSA adjuster for 2016 and beyond. They recommend that CMS retain the BMI adjuster, but only with modifications so that it addresses both underweight and overweight patients. This could be achieved by establishing a threshold for overweight patients and using theexisting dollars from the BSA adjuster pool to fund this new category. Alternatively, the organization provides a proposal on how to possibly combine the two adjusters into one based on BMI and ensure differential reimbursement for overweight and underweight patients. The alternative BMI adjuster would be based on the number of cubed deviations (deviation equal to two points in BMI) from the average dialysis patient BMI (~28.9 kg/m^2). The LDO's proposed formula for a patient's BMI adjuster would be as follows:

$$\text{BMI adjustor} = 1.00007^{([\text{Patient BMI} - \text{Average BMI}]/2)^3}$$

Using this method, the LDO stated that the new BMI adjuster would maintain budget neutrality and, most importantly from its point of view, align more closely with the policy objectives than using the proposed threshold methodology. The commenter indicated that

applying a BMI threshold is somewhat arbitrary and would result in drastically different reimbursement for patients who have very similar BMI (that is, a patient with BMI of 25 kg/m^2 would receive incremental reimbursement but a patient with BMI of 24.9 kg/m^2 would not). The commenter noted that presumably, costs and reimbursement should be quite similar for patients with numerically close BMI scores.

Response: We selected BSA and low BMI because they improve the model's ability to predict costs compared to using BMI or weight alone. We provided the BSA adjustment as a proxy for time on the dialysis machine and additional staff or supply resources for overweight patients. As noted in the previous response, we are unable to implement a high-BMI adjustment in CY 2016. With regard to the suggestion that we fund this new BMI-based adjustment and achieve budget neutrality by using the payments currently paid through the BSA adjustment, we would instead need to estimate a regression model with the new specification and determine the budget-neutrality factor needed to fund the adjuster.

In the current model, the BSA adjustment is unique as it is standardized to the mean, and therefore does not contribute to the overall budget-neutrality factor (that is, the multiplier is 1.0 on average, with larger patients adjusted upward and smaller patients adjusted downward. For all other case-mix adjusters, the value of 1.0 is assigned to the lowest cost group, and all adjustments are upward, which is what necessitates the budget-neutrality factor. Alternative approaches to accounting for body size might be explored for future payment years. If such an alternative retained the property of the BSA adjustment in which the average multiplier is standardized to 1.0, it would not require a budget-neutrality adjustment.

We do not understand the example provided to illustrate the commenter's view that applying a BMI threshold is somewhat arbitrary and would result in drastically different

reimbursement for patients who have very similar BMI. In the example, a patient with a BMI of 24.9 kg/m^2 is compared to a patient with a BMI of 25 kg/m^2. As the BMI adjuster is not applied unless the patient has a BMI of 18.5 kg/m^2, we note that neither of the patients in the example would receive the low-BMI adjustment.

Comment: An organization of nonprofit SDOs asked CMS to address the potential interaction of the two related but separate adjustment factors addressing body size. They suggested that we create a floor below which a negative BSA adjustment would not apply to avoid interaction with the BMI adjustment. Specifically, they recommended that the BSA adjustor not be applied to a patient with a BMI of less than 18.5kg/m.

Response: The regression model assumes that the low-BMI adjuster is tempered by the BSA adjustment. As a result, if we were to adopt the commenter's suggestion to remove the interaction between the two variables by creating a floor for the BSA at the low-BMI level, the proposed low-BMI adjuster would be too high and would need to be recalculated.

Comment: An MDO noted that the payment multiplier for low-BMI dropped from 1.025 to 1.017 and asked why we feel the adjustment warrants a decrease and what the regression showed that prompted us to propose this change. They pointed out that patients with a low BMI need more care, so they should continue to receive the higher adjustment amount.

Response: The updated regression analysis is based on ESRD PPS data and reflects reduced utilization of ESAs and other renal dialysis service drugs, biologicals, and laboratory testing. The decrease in separately billable services resulted in a decrease in the weight applied to the separately billable multipliers in the calculation of the payment multipliers. The actual multiplier for low BMI rose slightly from 1.078 in the analysis for CY 2011 to 1.090 in the analysis for the CY 2016. Therefore, the decline in the overall payment multiplier for low BMI

noted by the commenter arose entirely from the lower overall weight attached to SB services given their substantial decline following the implementation of the expanded bundled payment system.

Comment: A professional association requested that CMS clearly define the methodology for calculating BMI and BSA. For example, for PD patients, they asked whether the weight measured when the patient has an empty peritoneal cavity or a full peritoneal cavity. The association notes this is particularly relevant for those patients who have high volume dwells at all times, as the full volume could theoretically be subtracted from the weight to derive a value that more closely approximates body weight. Similarly, for hemodialysis, the association requests that CMS define when weight is assessed in regard to dialysis schedule.

Response: The Medicare Claims Processing Manual (Pub. 100-4, Chapter 8, section 50.3) states that the weight of the patient should be measured after the last dialysis session of the month and is reported in kilograms. Additionally, the Medicare Benefit Policy Manual (Pub. 100-02, Chapter 11, section 60.A.3) states that although height and weight are taken at intervals throughout any given month of dialysis treatment, the measurements for the purpose of payment must be taken as follows: The dry weight of the patient is measured and recorded in kilograms immediately following the last dialysis session of the month. For PD patients, dry weight occurs when the patient has an empty peritoneal cavity, which can be obtained by subtracting the remaining volume from the patient's weight. We will consider the commenter's suggestion in future revisions to those manuals.

After consideration of the public comments, effective January 1, 2016, we are adopting the proposed payment multipliers for the BSA (1.032) and low-BMI (1.017) payment adjustments which are included in Table 4 of this final rule. We are also updating the average

Medicare ESRD patient national average weight used in the BSA formula to 1.90 m^2.

3) Comorbidities

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account patient comorbidities. In our CY 2011 ESRD PPS proposed and final rules (74 FR 49952 through 49961 and 75 FR 49094 through 49108, respectively), we described the proposed and finalized comorbidity payment adjustors under the ESRD PPS. Our analysis found that certain comorbidity categories are predictors of variation in costs for ESRD patients and, as such, we proposed the following comorbidity categories as payment adjustors: cardiac arrest; pericarditis; alcohol or drug dependence; positive HIV status or AIDS; gastrointestinal tract bleeding; cancer (excluding non-melanoma skin cancer); septicemia/shock; bacterial pneumonia and other pneumonias/opportunistic infections; monoclonal gammopathy; myelodysplastic syndrome; hereditary hemolytic or sickle cell anemias; and hepatitis B (74 FR 49954).

While all of the proposed comorbidity categories demonstrated a statistically significant relationship with additional cost in the payment model, the various issues and concerns raised in the public comments regarding the proposed categories caused us to do further evaluations. Specifically, we created exclusion criteria that assisted in deciding which categories would be recognized for the payment adjustment. As discussed in the CY 2011 ESRD PPS final rule (75 FR 49095) we further evaluated the comorbidity categories with regard to-- (1) inability to create accurate clinical definitions; (2) potential for adverse incentives regarding care; and (3) potential for ESRD facilities to directly influence the prevalence of the comorbidity either by altering dialysis care or diagnostic testing patterns, or liberalizing the diagnostic criteria. As a result of this evaluation, we finalized 6 comorbid patient conditions eligible for additional payment under

the ESRD PPS (75 FR 49099 through 49100): pericarditis, bacterial pneumonia, gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemias, myelodysplastic syndrome, and monoclonal gammopathy.

Many stakeholders have criticized the comorbidity payment adjustments available under the ESRD PPS. Through industry public comments and stakeholder meetings we have become aware of the perceived documentation burden placed upon facilities in their effort to obtain discharge information from hospitals or other providers or diagnostic information from physicians and other practitioners necessary to substantiate the comorbidity on the facility claim form. Public comments have suggested that we remove all comorbidity payment adjustments from the payment system and return any allocated monies to the base rate. Other commenters have indicated that patient privacy laws have also limited the ability of facilities to obtain the diagnosis documentation necessary in order to append the appropriate International Classification of Diseases code on the claim form.

Acute Comorbidity Categories

There are three acute comorbidity categories (pericarditis, bacterial pneumonia, and gastrointestinal tract bleeding with hemorrhage) finalized in the CY 2011 ESRD PPS final rule (75 FR 49100) due to predicted short term increased facility costs when furnishing dialysis services. Specifically, the costs were identified with increased utilization of ESAs and other services. The payment adjustments are applied to the ESRD PPS base rate for 4 months following an appropriate diagnosis reported on the facility monthly claim. In the CY 2011 ESRD PPS final rule, we finalized payment variables as indicated in Table 2below.

TABLE 2: ACUTE COMORBIDITY CATEGORIES RECOGNIZED FOR A PAYMENT ADJUSTMENT UNDER THE ESRD PPS

Acute Comorbidity Category	CY 2011 Payment Multiplier	CY 2016 Payment Multiplier
Pericarditis	1.114	1.040
Bacterial Pneumonia	1.135	--
Gastrointestinal Tract Bleeding w/Hemorrhage	1.183	1.082

In the CY 2016 ESRD PPS proposed rule (80 FR 37817), we explain that analysis of CYs 2012 and 2013 claims data for the regression analysis continues to demonstrate significant facility resources when furnishing dialysis services to ESRD patients with these acute comorbidities. However, in accordance with section 632(c) of ATRA and in response to stakeholders' public comments and requests for the elimination of all of the comorbid payment adjustments, we have compared the frequency of how often these conditions were indicated on the facility monthly bill type with how often a corroborating claim in another Medicare setting is identified in a 4-month look back period. We were unable to corroborate the diagnoses of bacterial pneumonia on ESRD facility claims with the presence of a diagnosis on claims from other Medicare settings, leading us to the conclusion that this comorbidity is significantly under-reported by ESRD facilities.

In order for the bacterial pneumonia comorbid payment adjustment to apply, we require three specific sources of documentation: an X-ray, a sputum culture, and a provider assessment. Since 2011, facilities have expressed concern regarding these documentation requirements. Specifically, facilities cite a documentation burden in that they are unable to obtain hospital or other discharge information for the patients in their care, and are therefore unable to submit the diagnosis on the claim form necessary to receive a payment adjustment. In addition, stakeholders have indicated that our requirements are out of step with the assessments used by many physicians and Medicare providers to make the diagnosis. For example, many providers

will diagnose bacterial pneumonia simply by patient assessment and would not consider the X-ray or the sputum culture necessary to their diagnosis.

Because in the opinion of stakeholders, the ESRD PPS comorbidity payment adjustments often go unpaid, facilities have encouraged CMS to eliminate these adjustments through the authority granted in section 632(c) of ATRA. However, we find that all of the acute comorbid payment adjustors continue to be strong predictors of cost variation among ESRD patients based on the updated regression analysis. Accordingly, we continue to believe it is appropriate to apply a comorbidity payment adjustment for the acute comorbidities of pericarditis and gastrointestinal tract bleeding with hemorrhage. However, in consideration of stakeholder concerns about the burden associated with meeting the documentation requirements for bacterial pneumonia, we proposed to eliminate the case-mix payment adjustment for the comorbidity category of bacterial pneumonia beginning in CY 2016. Based upon the regression analysis of CY 2012 through 2013 Medicare claims and cost report data, where comorbidities are measured only on ESRD facility claims, the proposed payment adjustment for pericarditis would be 1.040 and the adjustment for gastrointestinal tract bleeding with hemorrhage would be 1.082.

Chronic Comorbidity Categories

There are three chronic comorbidity categories (hereditary hemolytic and sickle cell anemias, myelodysplastic syndrome, and monoclonal gammopathy), which were finalized as payment adjustors in the CY 2011 ESRD PPS final rule (75 FR 49100) due to a demonstrated prediction of increased facility costs when furnishing dialysis services. In addition, these conditions have demonstrated a persistent effect on costs over time; that is, once the condition is diagnosed for a patient, the condition is likely to persist. For this reason, the payment adjustments are paid continuously when an appropriate diagnosis code is reported on the

facility's monthly claim. In the CY 2011 ESRD PPS final rule, we finalized payment variables as indicated in Table 3 below for chronic comorbidities, effective January 1, 2011.

TABLE 3: CHRONIC COMORBIDITY CATEGORIES RECOGNIZED FOR A PAYMENT ADJUSTMENT UNDER THE ESRD PPS

Chronic Comorbidity Category	CY 2011 Payment Multiplier	CY 2016 Payment Multiplier
Hereditary Hemolytic or Sickle Cell Anemias	1.072	1.192
Myelodysplastic Syndrome	1.099	1.095
Monoclonal Gammopathy	1.024	--

In the CY 2016 ESRD PPS proposed rule (80 FR 37818), we explain that analysis of CY 2012 through 2013 claims and cost report data for the purposes of regression analysis has continued to demonstrate that significant facility resources are used when furnishing dialysis services to ESRD patients with these chronic comorbidities. However, in accordance with section 632(c) of ATRA and in response to stakeholders' public comments and requests for the elimination of all of the comorbid payment adjustments, we compared the frequency of how often these conditions were reported on the facility monthly bills with how often a corroborating claim is reported in another Medicare setting in a 12-month look back period. This analysis demonstrated significant differences in the reporting of monoclonal gammopathy by ESRD facilities and in other treatment settings.

In order for the monoclonal gammopathy comorbidity payment adjustment to apply, Medicare requires a positive serum test and a bone marrow biopsy test. We believe that billing inconsistency may result from the variation in diagnostic assessment for the condition. We believe that some facilities may report the diagnosis based upon only the positive serum test, and forgo the bone marrow biopsy, while other facilities may view the bone marrow biopsy as excessive for what is often an asymptomatic condition and forgo the payment adjustment

altogether.

CMS has historically required the bone marrow biopsy for confirmation of a diagnosis of monoclonal gammopathy because often it is a laboratory-defined disorder, where the disease has no symptoms but where the patient is identified to be at considerable risk for the development of multiple myeloma. Because many ESRD patients suffer from anemic conditions due to their dialysis, they can test false positive for monoclonal gammopathy. We considered modifying our documentation policies for requiring the bone marrow biopsy when making the payment adjustment. However, we are concerned that we will be unable to confirm the diagnosis without a bone marrow test.

Based on the regression analysis conducted using CY 2012 and 2013 ESRD PPS claims and cost report data, we find that all of the chronic comorbid payment adjustors continue to be strong predictors of cost variation among ESRD patients and accordingly, we proposed to continue to make a payment adjustment for the chronic comorbid conditions of hereditary hemolytic and sickle cell anemias and myelodysplastic syndrome. However, in consideration of stakeholders' concerns about the excessive burden of meeting the documentation requirements for monoclonal gammopathy, due to variation in patient assessment, we proposed to eliminate the case-mix payment adjustment for the comorbid condition of monoclonal gammopathy beginning in CY 2016. Based upon the regression analysis of CY 2012 through 2013 ESRD facility claims and cost report data, the updated payment adjustment for hereditary hemolytic and sickle cell anemias would be 1.192 and for myelodysplastic syndrome the payment adjustment would be 1.095.

The comments we received and our responses are set forth below:

Comment: MedPAC expressed support for the proposal to eliminate bacterial pneumonia

and monoclonal gammopathy as payment adjustments under the ESRD PPS. In addition, they recommend that CMS consider removing all comorbidity payment adjustments because they may result in undue burden on patients required to undergo additional diagnostic procedures, are poorly identified on dialysis claims, and reflect only differences in the cost of separately billable services. They note that to the extent that these conditions result in high costs, these costs are addressed through the outlier policy.

Many national dialysis organizations representing small, medium and large dialysis organizations, nursing associations, and a professional association also supported our proposal to eliminate two of the comorbidity category adjustments. Several organizations pointed out that comorbidities such as these are not generally diagnosed in the ESRD facility or by physicians associated with the facility. Regardless of the fact that comorbid conditions may be indicative of higher patient ESA utilization and thus higher ESRD treatment costs, the commenters claim that the policy rationale of these adjusters is not being met. Due to the burdensome requirements related to documentation and diagnosis coding requirements needed for clinical comorbidity adjustments, dialysis providers are not able to receive this adjustment for many patients' comorbidities because of incomplete patient medical histories, as well as a lack of availability of specialty and primary care health records.

The national dialysis organizations agreed with MedPAC's assertion that the outlier payment policy is sufficient for the purpose of reimbursing dialysis providers for treating patients with pericarditis, gastrointestinal bleeding, hereditary, hemolytic, or sickle cell anemia, and myelodysplastic syndrome. For these reasons, they recommended that we eliminate all of the remaining comorbidity adjustments and rely upon the outlier policy to fine-tune the payment to facilities caring for the small number of beneficiaries who may incur higher costs due to

comorbidities.

Several other organizations representing mostly SDOs and independent ESRD facilities commented that the frequency of reporting of codes for the comorbidity adjustments remains significantly below CMS's estimates because dialysis facilities continue to face challenges in getting the required documentation in order to report specific diagnosis codes and obtain the comorbidity payment adjustments. The organization states that there are many dialysis patients who have GI bleeding and are even hospitalized multiple times without there ever being a confirmed diagnosis by their GI specialist. Yet, the dialysis unit bears the burden of the higher costs associated with this condition. An MDO commented that a more fair and reasonable change to the comorbid condition payment multipliers would be to either change or decrease the documentation requirements for bacterial pneumonia and monoclonal gammopathy so more providers qualify for the adjustments. Another organization of SDOs agreed, noting similar problems with obtaining the required documentation for the GI bleeding with hemorrhage comorbidity and suggested that CMS exercise its discretion to further limit, if not withdraw completely, the comorbidities included in the current case-mix adjustments.

Response: In response to the suggestion that we change or decrease the documentation requirements for bacterial pneumonia and monoclonal gammopathy rather than remove the comorbidity categories, we believe removing these comorbidities is more appropriate. As we stated in the CY 2016 ESRD PPS proposed rule (80 FR 37817), in order for the bacterial pneumonia comorbid payment adjustment to apply, we require three specific sources of documentation: An x-ray, a sputum culture, and a provider assessment. Due to the variation in diagnostic assessment, we find that the condition is underreported on facility claims and that we

are unable to confirm a positive diagnosis without the additional burden of documenting an X-ray or sputum culture.

For monoclonal gammopathy, in the CY 2016 ESRD PPS proposed rule (80 FR 37818), we stated that CMS has historically required documentation of a bone marrow biopsy to confirm a diagnosis of monoclonal gammopathy because often it is a laboratory-defined disorder, where the disease has no symptoms but where the patient is identified to be at considerable risk for the development of multiple myeloma. Because many ESRD patients suffer from anemic conditions due to their dialysis, they can test false positive for monoclonal gammopathy. We considered modifying our documentation policies for requiring the bone marrow biopsy when making the payment adjustment. However, we are concerned that we will be unable to confirm the diagnosis without a bone marrow test. Based on our concern regarding the variation in diagnostic testing, we proposed to delete monoclonal gammopathy as a payment adjustment. Because of the patient and facility burden associated with these conditions, we continue to believe it is appropriate to delete bacterial pneumonia and monoclonal gammopathy as payment adjustments under the ESRD PPS.

With regard to the problems organizations described in obtaining the documentation needed to report a comorbidity, we did not intend that ESRD facilities would actually order additional tests or procedures in order to document a comorbidity. Rather, our assumption was that the patient's nephrologist or primary care physician would be aware if their patient had any of the two chronic conditions and would provide the documentation. If there is nothing in the medical record, then the facility would be unable to claim a comorbidity adjustment for that patient and would have to seek payment through the outlier mechanism.

With regard to the acute comorbidity categories, we do not understand how ESRD

facilities are unable to obtain confirmatory documentation for most ESRD patients with gastrointestinal tract bleeding with hemorrhage and pericarditis. Considering the ICD-10-CM codes that are available for reporting these conditions under the ESRD PPS, we believe in most cases these patients would be evaluated and treated in an acute care setting such as an emergency room or hospital and, as a result, it should not be burdensome or difficult for ESRD facilities to obtain the documentation. We believe that if a patient has one of the comorbidities, a physician must have done a clinical work up to make the diagnosis. Diagnoses are based on clinical signs and symptoms as well as diagnostic tests and these findings are included in the medical record.

Obtaining the medical documentation necessary to obtain payments for the comorbidities we proposed to retain should not be complicated or burdensome; and is important for care coordination purposes. Once the patient signs a medical release form (which could be done while the patient is in the dialysis facility) and it is faxed to either the hospital or the physician office, the records should be released. In situations where the patient's medical record is incomplete so the ESRD facility is unable to obtain the documentation needed to report the comorbidity diagnosis, we would expect the facility to include the cost for all outlier-eligible services on the claim and qualify for an outlier payment when the cost exceeds the outlier fixed dollar loss threshold. This approach supports access to dialysis for high cost patients. We will continue to monitor the extent to which the comorbidities are reported for future refinement.

MedPAC also made a comment regarding the comorbidity payment adjustment reflecting only differences in the cost of separately billable services. We note that accurate multipliers for uncommon conditions could not be derived from the facility-level model. If we were to use the facility-level model and link those comorbidities with composite rate costs in addition to drugs, we would not have been able to detect that with any reasonable level of statistical precision.

Therefore, we believe that it is appropriate to derive the comorbidity payment adjustments from the separately billable model.

With regard to the comments concerning the comorbidity payment adjustment not being paid out as we had anticipated in CY 2011, we note that prior to the implementation of the expanded bundle in 2011, comorbidities were rarely reported on dialysis claims. Therefore, the 2011 model predicted the prevalence of comorbidity adjusters using Medicare claims from other settings (except for laboratory claims). That predicted prevalence was used in the calculation of the case-mix adjustment budget-neutrality factor. Actual reporting on dialysis claims during the first year of the expanded bundle fell short of the levels expected based on diagnoses reported on claims from other care settings. It was not known at that time whether such underreporting would become persistent or if reporting would rise as providers became more familiar with the requirements of the new payment system. Since there are now several years of data that have demonstrated continued reporting below expected levels, we have come to agree with the comment that the comorbidities are less frequently documented on ESRD facility claims compared to the reporting on claims in other care settings. However, rather than eliminate the comorbidities as several commenters suggest, we have revised the predicted prevalence of comorbidity adjusters in our calculation of the refinement budget-neutrality adjustment factor to be based on actual reporting in the dialysis setting. Specifically, the 2016 model refinement is based on comorbidities identified for payment on dialysis claims only, that is, for this final rule we have reset our assumptions to reflect the actual prevalence of the comorbidity adjusters in the ESRD population. The budget-neutrality adjustment accounts for the elimination of monoclonal gammopathy and bacterial pneumonia as well as the actual prevalence of reported comorbidities on dialysis claims.

We anticipate going forward, the reduction in the base rate to fund comorbidity adjusters will be in balance with actual payments made for those adjusters. This is demonstrated by comparing the amount of the estimate of the direct reduction in the base rate due to the comorbidities provided in column 3 of Table 4, which shows the value for the CY 2011 model, with that in column 7 of Table 4, which shows the value for the CY 2016 model. Specifically, if all other variables are held constant, in the CY 2011 model 0.8 percent of the base rate was held to fund the comorbidity payment adjustments, whereas in the CY 2016 model 0.1 percent of the base rate will be held to fund the comorbidity payment adjustments.

We agree with MedPAC and other commenters that in the absence of case-mix adjusters for comorbidities, it would be more likely that facilities would receive outlier payments. However, this would only partially compensate facilities for the higher costs associated with the comorbidity. If the costs for these patients are higher but do not reach the outlier fixed dollar loss threshold, facilities would not receive outlier compensation. Even if the outlier threshold is met, facilities would only receive compensation for costs above the threshold. Therefore, we believe it is appropriate to retain four of the comorbidity payment adjusters in order to ensure that ESRD facilities receive additional payment for these costly patients and preserve access to care for patients with these conditions.

Comment: A large health plan requested that we reconsider our proposal to delete the comorbidity category of bacterial pneumonia. They pointed out that when a patient has bacterial pneumonia, additional costs are incurred by ESRD facilities for antibiotic treatment, pulmonary destabilization secondary to pneumonia, and tests such as X-rays for fluid buildup. The plan encouraged us to provide adequate reimbursement for this condition.

Response: Under the ESRD PPS, ESRD facilities are responsible only for furnishing

renal dialysis services, which are defined in 42 CFR 413.171. Payment adjustments are made to ESRD facilities for comorbidities to reflect the increased utilization and cost of ESAs and other renal dialysis services drugs and laboratory testing furnished to patients with these comorbidities. The ESRD facilities are not responsible for the costs related to treatment of the comorbidity, such as antibiotic treatment and x-rays in the case of bacterial pneumonia, but rather only for the cost of the renal dialysis services they are required to furnish.

Comment: An MDO disagreed with the decrease in the payment multipliers for pericarditis (from 1.114 to 1.040) and gastrointestinal bleeding (from 1.183 to 1.082) and stated that removing an entire payment multiplier for a comorbid condition and also decreasing the others will be detrimental to providers. They noted that the other comorbidity payment multipliers for hereditary hemolytic or sickle cell anemia (from 1.072 to 1.192) and mylodysplastic syndrome (from 1.099 to 1.095) appear to be acceptable.

Response: The reduction in the payment multipliers for many of the adjustments under the ESRD PPS is due to the decrease in utilization of renal dialysis service drugs and biologicals, especially ESAs reflected in the updated regression analysis. In light of the reduction in utilization and facility costs for renal dialysis service drugs and biologicals, the new payment multipliers reflect facility cost on average and therefore should not be detrimental to ESRD facilities.

After consideration of public comments, effective January 1, 2016, we are adopting the proposed comorbidity category payment multipliers provided in Table 2 for the acute comorbidity categories of pericarditis and gastrointestinal tract bleeding with hemorrhage and Table 3 for the chronic comorbidity categories of hereditary hemolytic or sickle cell anemias and myelodysplastic syndrome of the CY 2016 ESRD PPS proposed rule (80 FR 37817 and 80 FR

37818, respectively) as final. The multipliersare presented below in Table 4. We are also finalizing removal of monoclonal gammopathy and bacterial pneumonia from the comorbidities eligible for payment adjustments.

4) Onset of Dialysis

Section 1881(b)(14)(D)(i) of the Act required the ESRD PPS to include a payment adjustment based on case-mix that may take into account a patient's length of time on dialysis. For the CY 2011 ESRD PPS final rule (75 FR 49090), we analyzed the length of time beneficiaries have been receiving dialysis and found that patients who are in their first 4 months of dialysis have higher costs and noted that there was a drop in the separately billable payment amounts after the first 4 months of dialysis. Based upon this analysis, we proposed and finalized the definition of onset of dialysis as beginning on the first date of reported dialysis on CMS Form 2728 through the first 4 months a patient is receiving dialysis. We finalized a 1.510 onset of dialysis payment adjustment for both home and in-facility patients (75 FR 49092). In addition, we acknowledged that there may be patients whose first 4 months of dialysis occur when they are in the coordination of benefits period and not yet eligible for the Medicare ESRD benefit. We explained that in these circumstances, no onset of dialysis adjustment would be made (75 FR 49090).

Most commenters supported inclusion of an onset of dialysis patient-level adjustment and noted that the higher costs for new patients are due to the stabilization of the health status of the patient and dialysis training. Because the Medicare onset of dialysis payment adjustment reflects the costs associated with all of the renal dialysis services furnished to a Medicare beneficiary in the first 4 months of dialysis, additional payment adjustments are not made for comorbidities or training during the months in which the onset of dialysis payment adjustment is made. We

discussed and finalized this payment adjustment in the CY 2011 ESRD PPS final rule (75 FR 49092 through 49094).

Based on the regression analysis conducted for the refinement, we found that the onset of dialysis continues to be a strong predictor of cost variation among ESRD patients and proposed an updated payment adjustment of 1.327.

The comments we received and our responses are set forth below:

Comment: One large health plan expressed concern about the drop in the onset of dialysis payment multiplier. They stated that new patients require a significant amount of resources as many have been hospitalized, and require frequent medication adjustments, higher dosing regimens of ESAs and more frequent lab testing. They recommend we review the analysis to ensure adequate payment is made for new patients. Another organization noted that CMS did not offer a rationale for the reduction of the multiplier for onset of dialysis. They are concerned that the practical effect of the proposal to lower the multiplier would be lower payments for the treatment of patients in this critical stage. They requested that we reevaluate this proposal and make its policy rationales for any changes available to the dialysis community.

Response: The proposed onset of dialysis payment adjustment was derived from a regression analysis of CY 2012 and 2013 claims and cost report data and reflects decreased use of renal dialysis service drugs and laboratory testing, particularly ESAs. We believe it is important for Medicare payment to reflect the changes in practice that have occurred with implementation of the bundled payment system in 2011 and believe that the proposed revised adjuster value captures of the cost of the onset of dialysis under the ESRD PPS.

Comment: A dialysis supply manufacturer was also concerned about the reduction in the onset of dialysis payment adjustment and the unintended effect it could have on training for

home hemodialysis (HHD). This is because when an ESRD facility is receiving the onset of dialysis adjustment for a patient, training add-on payments are not made. Thus, the commenter is concerned that a reduced onset of dialysis adjustment factor may lead to less HHD training.

Response: For HHD, most of the reported training treatments occur after the first four months when the onset of dialysis adjustment no longer applies; 83 percent of Medicare HHD training treatments occur after the first four months (based on 2014 claims). Data in the June 2014 claims indicates 492 patient months where the patient qualified for the onset of dialysis adjustment and was in HHD training. That number would equate to approximately 50 to 100 patients in a year and represents 0.24 percent of all patients months qualifying for the onset of dialysis adjustment (that total is 202,687).

It appears to be common for patients do in-facility hemodialysis first (with the facility receiving the onset of dialysis adjustment), and then the patient receives HHD training (with the facility receiving the training adjustment). The reasons for this could be legitimate, such as a patient not receiving modality education before starting, so the decision to do HHD is made after starting in-facility. Sometimes patients decide to do HHD before needing dialysis, but when they start, they are too uremic to do training, and so a period of in-facility hemodialysis to attain stability comes first, and then training follows. Less legitimate would be if facilities are focused on the payments rather than the patient. Then they simply have the patient do in-center HD first, collect the onset adjustment, and then train them on HHD. They get both payments. In the scenario where a patient both identifies that they want to do HHD, and are well enough to start off right away with training, we believe they have had better than average pre-ESRD care and/or are healthier than the average patient starting HHD, and so may not have the same costs during the four-month onset of dialysis period as the average onset patient (for example, starting with an

AVF, better anemia management, etc).

After consideration of the public comments, effective January 1, 2016, we are adopting the proposed payment multiplier of 1.327 for the onset of dialysis adjustment. The finalized payment adjustment is in Table 4 below.

In summary, we are finalizing the adult case-mix payment adjustments as provided in Table 4 below. In addition, this table also reflects the facility-level payment adjustments addressed in the next section.

Table 4: CY 2016 Adult Case-Mix and Facility-Level Payment Adjustments

Variable	EB Multipliers for CY2011	Estimate of the direct reduction in base rate due to this factor, for CY2011	CR Multipliers for CY2016	SB Multipliers for CY2016	EB Multipliers for CY2016	Estimate of the direct reduction in base rate due to this factor, for CY2016
Age						
18-44	1.171		1.308	1.044	1.257	
45-59	1.013	3.1%	1.084	1.000	1.068	
60-69	1.000		1.086	1.005	1.070	8.400%
70-79	1.011		1.000	1.000	1.000	
80+	1.016		1.145	0.961	1.109	
Body surface area (per 0.1 m^2)	1.020	0.0%	1.039	1.000	1.032	0.000%
Underweight (BMI < 18.5)	1.025	0.1%	1.000	1.090	1.017	0.058%
Time since onset of renal dialysis < 4 months	1.510	2.5%	1.307	1.409	1.327	1.307%
Facility low volume status	1.189	0.3%	1.368	0.955	1.239	0.410%
Comorbidities						
Pericarditis (acute)	1.114	0.0%	1.000	1.209	1.040	0.005%
Gastro-intestinal tract bleeding (acute)	1.183	0.2%	1.000	1.426	1.082	0.040%
Bacterial pneumonia (acute)	1.135	0.3%	---	---	---	---
Hereditary hemolytic or sickle cell anemia (chronic)	1.072	0.1%	1.000	1.999	1.192	0.022%
Myelodysplastic syndrome (chronic)	1.099	0.2%	1.000	1.494	1.095	0.028%
Monoclonal gammopathy (chronic)	1.024	0.0%	---	---	---	---
Rural	---	---	1.015	0.978	1.008	0.118%

d. Refinement of Facility-Level Adjustments

i. Low-Volume Payment Adjustment

Section 1881(b)(14)(D)(iii) of the Act requires a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. As required by this provision, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities that meet the definition of a low-volume facility. A background discussion on the low-volume payment adjustment (LVPA) and a proposal regarding the LVPA eligibility criteria is provided below.

The current amount of the LVPA is 18.9 percent. In the CY 2011 ESRD PPS final rule (75 FR 49125), we indicated that this increase to the base rate is an appropriate adjustment that will encourage small facilities to continue to provide access to care. With regard to the magnitude of the payment adjustment for low-volume facilities, we stated that it is more appropriate to use the regression-driven adjustment rather than the 10 percent minimum adjustment mentioned in the statute because it is based on empirical evidence and allows us to implement a payment adjustment that is a more accurate depiction of higher costs.

For the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed those ESRD facilities that met the definition of a low-volume facility as specified in 42 CFR 413.232(b) as part of the updated regression analysis. We found that the cost per treatment for these facilities is still high compared to other facilities. With regard to the magnitude of the payment adjustment for low-volume facilities, we continue to believe that it is appropriate to use the regression-

driven adjustment because it is based on empirical evidence and allows us to implement a payment adjustment that is a more accurate depiction of higher costs. In the proposed rule, we stated that the regression analysis of CY 2012 and 2013 low-volume facility claims and cost report data indicated a payment multiplier of 1.239 percent. Accordingly, we proposed an updated LVPA adjustment factor of 23.9 percent for CY 2016 and future years.

ii. CY 2016 Proposals for the Low-Volume Payment Adjustment (LVPA)

1) Background

As required by section 1881(b)(14)(D)(iii) of the Act, the ESRD PPS provides a facility-level payment adjustment of 18.9 percent to ESRD facilities that meet the definition of a low-volume facility. Under 42 CFR 413.232(b), a low-volume facility is an ESRD facility that, based on the documentation submitted pursuant to 42 CFR 413.232(h): (1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. Under 42 CFR 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership and 25 road miles or less from the ESRD facility in question. Our regulation at 42 CFR 413.232(d) exempts facilities that were in existence and Medicare-certified prior to January 1, 2011 from the 25-mile geographic proximity criterion, thereby grandfathering them into the LVPA.

For purposes of determining eligibility for the LVPA, "treatments" means total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis (PD) patients, one week of PD is considered equivalent to 3 HD treatments. In the CY 2012 ESRD PPS final rule (76 FR 70236), we clarified that we base eligibility on the three years preceding the payment year and those years are based on cost reporting periods. We further clarified that the ESRD facility's cost reports for the periods ending in the three years preceding the payment year must report costs for 12-consecutive months (76 FR 70237).

In the CY 2015 ESRD PPS final rule (79 FR 66152 through 66153), we clarified that hospital-based ESRD facilities' eligibility for the LVPA should be determined at an individual facility level and their total treatment counts should not be aggregated with other ESRD facilities that are affiliated with the hospital unless the affiliated facilities are commonly owned and within 25 miles of each other. Therefore, the MAC can consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports, such as the individual facility's total treatment counts, to verify the number of treatments that were furnished by the individual hospital-based facility that is seeking the adjustment.

In the CY 2015 ESRD PPS final rule (79 FR 66153), with regards to the cost reporting periods used for eligibility, we clarified that when there is a change of ownership that does not result in a new Medicare Provider Transaction Access Number but creates two non-standard cost reporting periods (that is, periods that are shorter or longer than 12 months) the MAC is either to add the two non-standard cost reporting periods together where combined they would equal 12-consecutive months or prorate the data when they would exceed 12-consecutive months to determine the total treatments furnished for a full 12-month cost reporting period as if there had not been a CHOW.

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its MAC confirming that it meets all of the requirements specified at 42 CFR 413.232 and qualifies as a low-volume ESRD facility. In the CY 2012 ESRD PPS final rule (76 FR 70236), we finalized a yearly November 1 deadline for attestation submission and we revised the regulation at §413.232(f) to reflect this date. We noted that this timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria. In the CY 2015 ESRD PPS final rule (79 FR 66153 through 66154), we amended §413.232(f) to accommodate the timing of the policy clarifications finalized for that rule. Specifically, we extended the deadline for the CY 2015 LVPA attestations until December 31, 2014 to allow ESRD facilities time to assess their eligibility based on the policy clarifications for prior years under the ESRD PPS and apply for the LVPA for CY 2015. Further information regarding the administration of the LVPA is provided in the Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 11, section 60.B.1.

2) The United States Government Accountability Office Study on the LVPA

In the CY 2015 ESRD PPS final rule (79 FR 66151 through 66152), we discussed the study that the United States Government Accountability Office (the GAO) conducted on the LVPA. We also provided a summary of the GAO's main findings and recommendations. We stated that the GAO found that many of the facilities eligible for the LVPA were located near other facilities, indicating that they may not have been necessary to ensure sufficient access to dialysis care. They also identified certain facilities with relatively low volume that were not eligible for the LVPA, but had above-average costs and appeared to be necessary for ensuring access to care. Lastly, the GAO stated the design of the LVPA provides facilities with an adverse incentive to restrict their service provision to avoid reaching the 4,000 treatment

threshold.

In the conclusion of their study, the GAO provided the Congress with the following recommendations: 1) To more effectively target facilities necessary for ensuring access to care, the Administrator of CMS should consider restricting the LVPA to low-volume facilities that are isolated; 2) To reduce the incentive for facilities to restrict their service provision to avoid reaching the LVPA treatment threshold, the Administrator of CMS should consider revisions such as changing the LVPA to a tiered adjustment; 3) To ensure that future LVPA payments are made only to eligible facilities and to rectify past overpayments, the Administrator of CMS should take the following four actions: (i) require Medicare contractors to promptly recoup 2011 LVPA payments that were made in error; (ii) investigate any errors that contributed to eligible facilities not consistently receiving the 2011 LVPA and ensure that such errors are corrected; (iii) take steps to ensure that CMS regulations and guidance regarding the LVPA are clear, timely, and effectively disseminated to both dialysis facilities and Medicare contractors; and (iv) improve the timeliness and efficacy of CMS's monitoring regarding the extent to which Medicare contractors are determining LVPA eligibility correctly and promptly re-determining eligibility when all necessary data become available.

As we explained in the CY 2015 ESRD PPS final rule (79 FR 66152), we concurred with the need to ensure that the LVPA is targeted effectively at low-volume high-cost facilities in areas where beneficiaries may lack dialysis care options. We also agreed to take action to ensure appropriate payment is made in the following ways: 1) evaluating our policy guidance and contractor instructions to ensure appropriate application of the LVPA; 2) using multiple methods of communication to MACs and ESRD facilities to deliver clear and timely guidance; and 3) improving our monitoring of MACs and considering measures that can provide specific

expectations.

3) Addressing GAO's Recommendations

As discussed above, in the CY 2015 ESRD PPS final rule (79 FR 66152), we made two clarifications of the LVPA eligibility criteria that were responsive to stakeholder concerns and GAO's concern that the LVPA should effectively target low-volume, high-cost facilities. However, we explained that we did not make changes to the adjustment factor or significant changes to the eligibility criteria because of the interaction of the LVPA with other payment adjustments under the ESRD PPS. Instead, we stated that in accordance with section 632(c) of ATRA, for CY 2016 we would assess facility-level adjustments and address necessary LVPA policy changes when we would use updated data in a regression analysis similar to the analysis that is discussed in the CY 2011 ESRD PPS final rule (75 FR 49083).

For CY 2016, because we are refining the ESRD PPS, we reviewed the LVPA eligibility criteria and proposed changes that we believe address the GAO recommendation to effectively target the LVPA to ESRD facilities necessary for ensuring access to care.

4) Elimination of the Grandfathering Provision

In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49119), we expressed concern about potential misuse of the LVPA. Specifically, our concern was that the LVPA could incentivize dialysis companies to establish small ESRD facilities in close geographic proximity to other ESRD facilities in order to obtain the LVPA, thereby leading to unnecessary inefficiencies. To address this concern, we finalized that for the purposes of determining the number of treatments under the definition of a low-volume facility, the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments furnished by the ESRD facility and other ESRD facilities that are both: (i) under common

ownership with; and (ii) 25 road miles or less from the ESRD facility in question. However, we finalized the grandfathering of those commonly owned ESRD facilities that were certified for Medicare participation on or before December 31, 2010, thereby exempting them from the geographic proximity restriction.

We established the grandfathering policy in 2011 in an effort to support low-volume facilities and avoid disruptions in access to essential renal dialysis services while the ESRD PPS was being implemented. However, now that the ESRD PPS transition is over and facilities have adjusted to the ESRD PPS payments and incentives, we believe it is appropriate to eliminate the grandfathering provision. Because we are doing a refinement of the payment adjustments under the ESRD PPS for CY 2016, the timing is appropriate for eliminating the grandfathering policy so that this change can be assessed along with other proposed changes to the ESRD PPS resulting from the regression analysis.

In the CY 2016 ESRD PPS proposed rule (80 FR 37820), we proposed that for the purposes of determining the number of treatments under the definition of a low-volume facility, beginning in CY 2016, the number of treatments considered furnished by any ESRD facility regardless of when it came into existence and was Medicare certified would be equal to the aggregate number of treatments actually furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both: (i) under common ownership with; and (ii) 5 road miles or less from the ESRD facility in question. The proposed 5 road mile geographic proximity mileage criterion is discussed below. We proposed to amend the regulation text by removing paragraph (d) in 42 CFR 413.232 to reflect that the geographic proximity provision described in paragraph (c) and discussed below is applicable to any ESRD facility that is Medicare certified to furnish outpatient maintenance dialysis. We solicited comment on the

proposed change to remove the grandfathering provision by deleting paragraph (d) from our regulation at 42 CFR 413.232.

5) Geographic Proximity Mileage Criterion

In GAO's report, they stated that the LVPA did not effectively target low-volume facilities that had high costs and appeared necessary for ensuring access to care. The GAO stated that nearly 30 percent of LVPA-eligible facilities were located within 1 mile of another facility in 2011, and about 54 percent were within 5 miles, which indicated to them that these facilities might not have been necessary for ensuring access to care. Furthermore, the GAO indicated that in many cases, the LVPA-eligible facilities were located near high-volume facilities. The GAO explained in the report that providers that furnish a low volume of services may incur higher costs of care because they cannot achieve the economies of scale that are possible for larger providers. They also stated that low-volume providers in areas where other care options are limited may warrant higher payments because, if Medicare's payment methods did not account for these providers' higher cost of care, beneficiary access to care could be reduced if these providers were unable to continue operating. They further explained that in contrast, low-volume providers that are in close proximity to other providers may not warrant an adjustment because beneficiaries have other care options nearby.

We agree with the GAO's assertion that it may not be appropriate to provide additional payment to an ESRD facility that is located in close proximity to another ESRD facility when the facilities are commonly owned. The purpose of the LVPA is to recognize high cost, low-volume facilities that are unable to achieve the economies of scale that are possible for larger providers such as large dialysis organizations (LDO) and medium dialysis organizations (MDO). In addition, we note that under the current LVPA eligibility criteria, approximately half of low-

volume facilities are LDO and MDO facilities that have the support of their parent companies in controlling their cost of care.

In the proposed rule (80 FR 37821), we explained that we analyzed the ESRD facilities receiving payment under Medicare for furnishing renal dialysis services in CY 2013 for purposes of simulating different eligibility scenarios for the LVPA. The CY 2013 claims and cost report data was the best data available. We stated in the proposed rule that the CY 2014 cost reports would be available later in the year. For this final rule we still do not have complete cost report data for CY 2014 and therefore could not update our analysis.

For the analysis we simulated the MAC's verification process in order to determine LVPA eligibility. Our analysis considered the treatment counts on cost reporting periods ending in 2010 through 2012, the corresponding CY 2013 LVPA eligibility criteria defined at 42 CFR 413.232, and the location of low-volume facilities to assess the impact of various potential geographic proximity criteria. Because we used the CY 2013 claims and attestations, our analysis did not match the facilities currently receiving the LVPA because we were unable to analyze 2014 cost reports of LVPA facilities at that time. However, this analysis allowed us to test various geographic proximity mileage amounts to determine whether facilities eligible for the LVPA in 2013 would continue to be eligible for the LVPA as well as allowing us to determine the existence of any other ESRD facilities in those areas.

Initially, we applied the low-volume eligibility criteria (without grandfathering) and the current 25 road mile criterion and categorized facilities by urban/rural location, type of ownership, and other factors, and determined that out of the total of 434 low-volume facilities, 38 percent of LVPA facilities would lose low-volume status, including 19 percent in rural areas. For those determined to meet the LVPA criteria, we also assessed the extent to which there were

other ESRD facilities (in the same chain or other chain), located within 5 road miles and 10 road miles from the LVPA facilities. Based on our concern that too many rural and independent facilities would lose low-volume status if we used the 25 road mile geographic proximity criterion, we then analyzed 1 road mile, 5 road miles, 10 road miles, 15 road miles, and 20 road miles in order to determine a mileage criterion that protected rural facilities while supporting access to renal dialysis services in rural areas. We believe that ESRD facilities located in rural areas are necessary for access to care and we would not want to limit LVPA eligibility for rural providers.

Based on this analysis, we proposed to reduce the geographic proximity criterion from 25 road miles to 5 road miles because our analysis showed that no rural facilities would lose LVPA eligibility due to the proposed 5 road mile geographic proximity criterion. This policy would discourage ESRD organizations from inefficiently operating two ESRD facilities within close proximity of each other. This policy would also allow ESRD facilities that are commonly owned to be considered individually when they are more than 5 miles from another facility that is under common ownership. We proposed to amend the regulation text by revising paragraph (c)(2) in 42 CFR 413.232 to reflect the change in the mileage for the geographic proximity provision. We solicited comments on the proposed change to 42 CFR 413.232(c)(2). We note that our analysis indicated that approximately 30 facilities that are part of LDOs and MDOs would lose the LVPA due to the 5 mile proximity change and the elimination of grandfathering, which caused many facilities to exceed 4000 treatments. For this reason, we stated that we considered whether a transition would be appropriate and requested public comments.

iii. Geographic Payment Adjustment for ESRD Facilities Located in Rural Areas

1) Background

Section 1881(b)(14)(D)(iv)(III) of the Act provides that the ESRD PPS may include such payment adjustments as the Secretary determines appropriate, such as a payment adjustment for ESRD facilities located in rural areas. Accordingly, in the CY 2011 ESRD PPS proposed rule we analyzed rural status as part of the regression analysis used to develop the payment adjustments under the ESRD PPS. In the CY 2011 ESRD PPS proposed rule (74 FR 49978), we discuss our analysis of rural status as part of the regression analysis and explained that to decrease distortion among independent variables, rural facilities were considered control variables rather than payment variables. We indicated that based on our impact analysis, rural facilities would be adequately reimbursed under the proposed ESRD PPS. Therefore, we did not propose a facility-level adjustment based on rural location and we invited public comments on our proposal.

In the CY 2011 ESRD PPS final rule (75 FR 49125 through 49126), we addressed commenters' concerns regarding not having a facility-level adjustment based on rural location. Some of the commenters provided an explanation of the unique situations that exist for rural areas and the associated costs. Specifically, the commenters identified several factors that contribute to higher costs including higher recruitment costs to secure qualified staff; a limited ability to offset costs through economies of scale; and decreased negotiating power in contractual arrangements for medications, laboratory services, and equipment maintenance. The commenters were concerned about a negative impact on beneficiary access to care that may result from insufficient payment to cover these costs. In addition, the commenters further noted that rural ESRD facilities have lower revenues because they serve a smaller volume of patients of which a larger proportion are indigent and lack insurance, and a smaller proportion have higher paying private insurance.

In response to the comments discussed above, we indicated that according to our impact analysis for the CY 2011 ESRD PPS final rule, rural facilities, as a group, were projected to receive less of a reduction in payments as a result of implementation of the ESRD PPS than urban facilities and many other subgroups of ESRD facilities and, therefore, we did not implement a facility-level payment adjustment that is based on rural location. However, we stated our intention to monitor how rural ESRD facilities fared under the ESRD PPS and consider other options if access to renal dialysis services in rural areas is compromised under the ESRD PPS.

2) Determining a Facility-Level Payment Adjustment for ESRD Facilities Located in Rural Areas Beginning in CY 2016

Since implementing the ESRD PPS, we have heard from industry stakeholders that rural facilities continue to have the unique difficulties described above when furnishing renal dialysis services that cause low to negative Medicare margins. Because we are committed to promoting beneficiary access to renal dialysis services, especially in rural areas, we analyzed rural location as a payment variable in the regression analysis conducted for the CY 2016 ESRD PPS proposed rule.

Including rural areas as a payment variable in the regression analysis showed that this facility characteristic was a significant predictor of higher costs among ESRD facilities and we proposed a payment multiplier of 1.008. The adjustment would be applied to the ESRD PPS base rate for all ESRD facilities that are located in a rural area. In the CY 2011 ESRD PPS final rule (75 FR 49126), we finalized the definition of rural areas in 42 CFR 413.231(b)(2) as any area outside an urban area. We defined urban area in 42 CFR 413.231(b)(1) as a Metropolitan Statistical Area or a Metropolitan division (in the case where Metropolitan Statistical Area is

divided into Metropolitan Divisions). We proposed to add a new section to our regulations at §413.233 to provide that the base rate will be adjusted for facilities that are located in rural areas, as defined in §413.231(b)(2).

The rural facility adjustment would also apply in situations where a facility is eligible to receive the low-volume payment adjustment. In other words, a facility could be eligible to receive both the rural and low-volume payment adjustments. Low-volume and rural areas are two independent variables in the regression analysis. The low-volume variable measures costs facilities incur as a result of furnishing a small number of treatments whereas the rural area variable measures the costs associated with locality. The regression analysis indicated that being in a rural area – regardless of treatments furnished – explains an increase in costs for furnishing dialysis compared to urban areas. Since low-volume and rural areas are independent variables in the regression, we believe that a low-volume facility located in a rural area would be eligible for both adjustments. We believe that while the magnitude of the payment multiplier is small, rural facilities would still benefit from the adjustment. Therefore, we proposed a 1.008 facility-level payment multiplier under the ESRD PPS for rural areas and solicited comment on this proposal.

3) Further Investigation into Targeting High-Cost Rural ESRD Facilities

Section 3127 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) required that the Medicare Payment Advisory Commission (MedPAC) study and report to Congress on: 1) adjustments in payments to providers of services and suppliers that furnish items and services in rural areas; 2) access by Medicare beneficiaries' to items and services in rural areas; 3) the adequacy of payments to providers of services and suppliers that furnish items and services in rural areas; and 4) the quality of care furnished in rural areas. The report required by section 3127(b) of the Affordable Care Act was published in the MedPAC

June 2012 Report to Congress: Medicare and the Health Care Delivery System (hereinafter referred to as June 2012 Report to Congress), which is available at http://www.medpac.gov/documents/reports/jun12_entirereport.pdf. In addition to the findings presented on each of the four topics, this report presented a set of principles designed to guide expectations and policies with respect to rural access, quality, and payments for all sectors, which can be used to guide Medicare payment policy. For purposes of the proposed rule, we were most interested in the principles of payment adequacy and special payments to rural providers.

In the June 2012 Report to Congress, MedPAC explained that providers in rural areas often have a low volume of patients and in some cases, this lack of scale increases costs and puts the provider at risk of closure. MedPAC stated that to maintain access in these cases, Medicare may need to make higher payments to low-volume providers that cannot achieve the economies of scale available to urban providers. However, they explained that low volume alone is not a sufficient measure to assess whether higher payments are warranted and that Medicare should not pay higher rates to two competing low-volume providers in close proximity. They stated that these payments may deter small neighboring providers from consolidating care in one facility, which results in poorly targeted payments and can contribute to poorer outcomes for the types of care where there is a volume–outcome relationship. MedPAC further explained that to target special payments when warranted, Medicare should direct these payments to providers that are uniquely essential for maintaining access to care in a given community. The payments need to be structured in a way that encourages efficient delivery of healthcare services.

MedPAC presented three principles guiding special payments that will allow beneficiaries' needs to be met efficiently: 1) Payments should be targeted toward low-volume

isolated providers—that is, providers that have low patient volume and are at a distance from other providers. Distance is required because supporting two neighboring providers who both struggle with low-volume can discourage mergers that could lead to lower cost and higher quality care; 2) the magnitude of special rural payment adjustments should be empirically justified, that is, the payments should increase to the extent that factors beyond the providers' control increase their costs; and 3) rural payment adjustments should be designed in ways that encourage cost control on the part of providers.

We were interested in the information that MedPAC provided in their report regarding services furnished to Medicare beneficiaries in rural areas. We believe that the adjustment that we proposed, which we arrived at through a regression analysis, is consistent with principle two above, which states that the magnitude of special rural payment adjustments should be empirically justified. We considered alternatives to deriving the adjustment from the regression analysis in an effort to increase the value of the adjustment. For example, we could establish a larger adjustment independent of the regression and offset it by a reduction to the base rate. We also considered analyzing different subsets of rural areas and designating those areas as the payment variable in our model. Because we were able to determine through the regression analysis that rural location is a predictor of cost variation among ESRD facilities, we are planning to analyze the facilities that are located in rural areas to see if there are subsets of rural providers that experience higher costs. We are also planning to explore potential policies to target areas that are isolated or identify where there is a need for health care services, such as, for example, the frontier counties (that is, counties with a population density of six or fewer people per square mile) and we would also consider the use of Health Professional Shortage Area (HPSA) designations managed by the Health Resources and Services Administration (HRSA).

Information regarding HPSAs can be found on the HRSA website:http://bhpr.hrsa.gov/shortage/hpsas/designationcriteria/.

We believe that this type of analysis would be consistent with the June 2012 Report to Congress's principle that special payments should target the low-volume facilities that are isolated. We solicited comments on establishing a larger payment adjustment outside of the regression analysis. We noted that such an adjustment would need to be offset by a further reduction to the base rate. For example, we could compare the average cost per treatment reported on the cost report of ESRD facilities located in rural areas with ESRD facilities located in urban areas and develop a methodology to derive the magnitude of the adjustment. In addition, we solicited comments on targeting subsets of rural areas for purposes of using those facilities located in those areas for analysis as payment variables in the regression analysis used to develop the payment multipliers for the refinement for CY 2016.

As most of the commenters combined their views on the low-volume and rural adjustments, we present these comments and responses followed by specific comments and responses on each adjustment.

Comment: MedPAC expressed concern that neither the low-volume adjustment nor the rural adjustment targets facilities that are critical to beneficiary access. They recommend a single adjustment that targets low-volume isolated providers in place of the two separate adjustments we proposed. In addition, MedPAC expressed support for the GAO recommendation that we avoid giving facilities an incentive to limit services to avoid reaching the low volume treatment threshold (the so-called cliff effect). They suggest that a payment approach that decreases the payment adjustment as facility volume increases might reduce this incentive.

Several dialysis organizations and a national patient organization recommended that we

rely upon a two-tiered low-volume adjuster policy with the current LVPA (as modified by CMS in the proposed rule) as tier 1. Rather than adopting a rural adjuster and using the dollars allocated for the rural adjuster, CMS could create a second low-volume adjustment. The tier-2 adjustment would apply to rural facilities that furnish between 4001-6000 treatments per year. Other professional associations expressed support for this tiered approach.

One organization suggested that CMS consider using a tiered LVPA that would pay higher for rural facilities that are also low-volume, while still applying an adjustment (although of a lesser amount) to low-volume facilities that may be in closer proximity to other commonly owned dialysis facilities. Since rural status for facilities may be associated with higher costs independent of the number of treatments they provide, CMS should consider adding a tier of the LVPA that would provide a payment adjustment for a higher range of treatments delivered for facilities with a rural designation. A simplified example of this tiered approach may look like the following:

1. Rural + <4,000 treatments 75 percent of the LVPA adjuster value
2. Rural + 4,001 – 6,000 treatments 50 percent of the LVPA adjuster value
3. <4,000 treatments 25 percent of the LVPA adjuster value

They noted that the geographic proximity rules may still be necessary with this approach, which could serve as an interim solution until such a time that CMS is able to conduct further analysis to better identify facilities that are geographically isolated.

Another organization suggested that CMS expand the low-volume adjuster to include a second tier for facility volume rather than applying a rural adjuster that is less representative of real facility costs. Their proposed second tier, medium volume classification would include those facilities administering between 4,001 and 7,000 treatments annually. They indicated that these

facilities, in aggregate, have lower margins than rural facilities. Combining the dollars from the proposed rural adjuster and the increase in the current low-volume adjuster would result in a new adjuster of approximately 1.025 for all treatments at medium volume facilities. They indicate that reimbursement based on volume is superior to reimbursement based on geography due to proper alignment with the costs of care.

Response: We appreciate the useful suggestions for refining the LVPA from the commenters. However, significant changes to the eligibility criteria would need to be proposed to provide the opportunity for public input. We believe that the proposed policy changes represent improvement in the targeting of the payment adjustment. We will certainly consider these suggestions for future refinement as our analyses of low-volume and rural ESRD facilities continue.

Comment: An LDO organization commented that, in their experience, the primary challenge facing rural facilities is access to more patients and that most LVPA facilities are rural. However, rural facilities with a high volume of patients may be financially viable. In their view, rural and low-volume are not necessarily independent variables. Another LDO commented that the proposed rural adjustment is inappropriate because it would be applied to all facilities at the same rate regardless of need. In their experience operating numerous rural facilities, they note that size is the driving factor in total facility cost rather than geographic location of the facility. Their analysis showed that high-volume rural facilities performed similarly to urban facilities with comparable data.

Response: As we explained above, low volume and rural areas are two independent variables in the regression analysis. The low-volume variable measures costs facilities incur as a result of furnishing a small number of treatments whereas the rural area variable measures the

costs associated with locality. Consistent with the comment from the LDO, CMS' analysis found that low volume is associated with higher cost for both urban and rural facilities. CMS analysis also found that being in a rural area, regardless of the number of treatments furnished, explains an increase in costs for furnishing dialysis compared to urban areas. With regard to the commenter's impression that LVPA facilities are mostly rural, we note that in our analysis of CY 2014 claims data for the 419 facilities receiving the LVPA, the distribution is 227 urban and 192 rural.

Comment: An organization representing small and medium dialysis facilities and a large health plan expressed support for the update to the LVPA adjustment and appreciated our efforts to address the inherently high cost of low volume and rural facilities. They noted that while some facilities would lose the adjustment under the proposed changes, many of the facilities gaining the adjustment are independent, hospital-based, or part of a small dialysis organization. They believe this is an appropriate targeting of the LVPA and agree with the proposed changes.

A patient group also expressed support for the proposed changes to the LVPA and the proposed rural adjustment because they believe these adjustments will maintain payment levels at roughly their current levels. They also described the current lack of access to dialysis services in International Falls, Minnesota. While they indicate that resources have been found to fund startup costs, the commenter was disheartened that the Medicare payment apparently does not suffice to attract a for-profit LDO, as those organizations have greater access to capital and economy of scale in purchasing and other overhead costs. The commenters stated that CMS must remain vigilant to ensure that Medicare payments are sufficient to support the nationwide kidney care infrastructure that Congress intended Medicare coverage of ESRD to foster.

An organization representing small and medium dialysis facilities applauds CMS for proposing a rural adjustment. Although they agree with MedPAC that low-volume ESRD facilities that are necessary to maintain beneficiary access to care should receive enhanced payment, they disagree with MedPAC's recommendation to remove the rural adjustment. They noted several issues that create special circumstances for rural facilities, including increased salary and benefit costs and the costs associated with water quality issues and serving the needs of patients in remote areas.

Response: We thank these commenters for their support of the LVPA changes and the rural adjustment. With regard to the point that CMS must ensure that Medicare payments are sufficient to support the nationwide kidney care infrastructure, we believe the ESRD PPS is based on a sound and stable methodology, that the base rate covers dialysis treatment costs on average and that the outlier policy provides additional payment and ensures access for high-cost patients.

Comment: An organization representing small and medium dialysis facilities recommended that we make the rural adjustment an add-on payment rather than a multiplier of the base rate to allow rural facilities to realize the true value of the adjuster, and not subject them to a lower adjustment due to the effects of the rural wage index on the base rate.

Response: The model we have developed and implemented for the ESRD PPS in 2011 is multiplicative and as a result, an additive adjuster cannot be directly estimated from the model. That is, the regression was set up to produce multiplicative factors and as a result cannot produce an additive adjustment for one variable. However, if the extra resources required by patients receiving a case-mix adjustment partially involve labor, it is not clear why a multiplicative adjustment would not be appropriate because the added labor effort incurred by facilities in

lower wage areas would also be paid at the lower wage. The rationale for the additive training adjuster in 2011 was that training treatments are such a small share of the total that a reliable adjuster could not be estimated from the model and, therefore, external assumptions about training costs were used to derive the additive adjustment. However, the rural multiplier can and should be estimated from the model, and serves to account for factors increasing costs in rural areas, after accounting for the wage index.

Comment: An organization urged CMS to establish a process for facilities to find resolution when their MACs have incorrect data. For example, some facilities may be eligible for the rural adjuster, but may not be receiving it due to incorrect data at the MAC. In these circumstances, the organization believes facilities should be able to appeal directly to CMS to ensure the MAC's data is correct and the facility is receiving the payment it is entitled to.

Response: We agree facilities should receive the low volume and the rural adjustments if they are eligible. The commenter did not provide specific examples of the types of data issues they were experiencing, however, we note that in order to receive the LVPA, MACs verify that the facilities' total treatments reported on their cost reports are under 4,000 and that the other LVPA criteria are met. Rural status is more straightforward to establish, but in both cases the MAC has to enter correct information in the Outpatient Provider Specific File (OPSF) so that the payment adjustments are applied to the claim. For this reason, we are planning to send out sub-regulatory guidance about the importance of keeping the information in the OPSF up-to-date and to address issues regarding incorrect data for the LVPA and rural adjustments.

Comment: A national patient organization also expressed concern that even with the proposed changes to the LVPA, the incentive still remains for facilities that have common ownership to maintain low-volume status while having two or more facilities serving in close

proximity to a facility that has different ownership. For example, two facilities under common ownership could sit 10 miles from one another, but on either side of a facility that has different ownership causing all three facilities to potentially be low-volume facilities.

Response: The proposed LVPA adjustment is the first step toward improving the eligibility for payment. Our goal with this proposal was to minimize the impact on rural facilities. We have and are continuing to perform additional analysis in order to better target benefit distribution to those facilities serving the access needs of those in remote locations.

Comment: An SDO expressed support for the GAO's finding that too many closely located facilities are receiving the LVPA, stating that the focus needs to be placed on ensuring access to care. Consequently, they fully support the elimination of the grandfathering provision. However, they recommend that we maintain the current geographic mileage proximity criterion of 25 road miles. Other organizations indicated that the rural payment adjustment should only be available to a clinic if there is not any outpatient dialysis clinic within five miles of the clinic.

Response: We appreciate the commenter's support of the removal of the grandfathering provision. The five mile geographic mileage proximity criterion was chosen for two reasons: 1) it eliminated the LVPA adjustment for those commonly-owned facilities with several facilities within a five mile radius with treatment counts just under 4000, and 2) it spared the impact on the rural facilities with geographic and topographical challenges. We plan on examining the impact of a future geographic facility adjustment applicable to all facilities, not just those that are commonly-owned.

Comment: An MDO also pointed out that under provider enrollment instructions a change of ownership (CHOW) typically occurs when a Medicare provider has been purchased or leased by another organization. The CHOW results in the transfer of the old owner's Medicare

Identification Number and provider agreement (including any outstanding Medicare debt of the old owner) to the new owner. The regulatory citation for CHOWs can be found at 42 CFR 489.18. If the purchaser (or lessee) elects not to accept a transfer of the provider agreement, then the old agreement should be terminated and the purchaser or lessee is considered a new applicant. The commenter points out that the instructions fail to account for the rare instances when a provider does accept the agreement but ownership changed from hospital-based to independent, requiring a new provider number in the independent ESRD facility range of provider numbers. The commenter asked that CMS consider providers in these situations eligible for the LVPA for CY 2016 and future years and perhaps retroactively as well.

Response: We appreciate the commenter pointing out this scenario and we will examine options for addressing this concern.

Comment: An organization of nonprofit SDOs expressed support for the proposed change to the geographic proximity criterion and for the increase in the LVPA multiplier in recognition of the higher costs borne by low-volume facilities. However, they noted CMS could improve its proposal by providing that continuation of LVPA status be based on a three year rolling average, rather than the current one-year eligibility period, reducing the incentive to hold down the number of patients served in any given year for fear of exceeding the cap.

Response: We appreciate the commenter's support of the proposed change for the LVPA adjustment. We will consider the suggestion of a three-year rolling average for eligibility for the LVPA for future rulemaking.

Comment: Two nonprofit dialysis organizations expressed support for the rural adjustment and recommend the following conditions: (1) The rural adjustment should only be available for clinics that are not receiving the LVPA, that is, once a facility that benefits from the

rural adjustment satisfies the LVPA criteria, it should have to choose which to forego; and (2) The rural adjustment should not be available to a clinic that provided more than 6000 treatments or 7000 treatments in the prior calendar year. An SDO also expressed support for the rural adjustment, but suggested that we consider limiting the rural adjustment to only those facilities located in a medically underserved area.

Response: As we explained above, the low-volume variable measures costs facilities incur as a result of furnishing a small number of treatments, whereas the rural area variable measures the costs associated with locality. The regression analysis indicated that being in a rural area, regardless of the number of treatments furnished, explains an increase in costs for furnishing dialysis compared to urban areas. Because low-volume and rural areas are independent variables in the regression, we believe that a low-volume facility located in a rural area would be eligible for both adjustments due to their high costs associated with both their location and their low patient volume.

Comment: A professional association also supports the rural adjustment, but notes that the proposed multiplier of 1.008 seems to be based on limited data. They expressed concern about the lack of accounting for SRR and other QIP measures. An SDO disagreed with our proposal to increase the LVPA multiplier from 18.9 percent to 23.9 percent and urged CMS to allocate the additional funds to the rural facility adjustment. They believe that based on the GAO study, it would appear that some LVPA funds could be allocated to funding the rural adjustment rather than further decreasing the base rate to fund the increase.

Response: The rural adjuster was based on the same data as the other adjusters. We are not aware of additional, national data that could be used to establish an adjuster. It is not clear why and how SRR and other QIP measures should be used as payment adjusters.

With respect to the commenters concern regarding the increase in the magnitude of the LVPA, CMS analyses found that both low volume facilities and rural facilities have higher costs than average, with the magnitudes reflected in the payment adjusters. A targeted reallocation of funds from facilities that could be eligible for the LVPA to rural facilities would not reflect estimates of the separate effect of rural location and low-volume on the cost of providing dialysis care.

Comment: In response to CMS requests for comments regarding developing a subset of rural providers to potentially establish a high payment adjustment, a professional association recommends that CMS postpone this measure until additional data can be generated. Another industry stakeholder recommended that we focus the rural adjuster on a smaller subset of rural facilities and provide them with a higher adjustment. They suggested we consider an approach based on population density that is similar to how CMS defines super rural.

Response: As we explain above, we are very interested in analyzing subsets of rural providers, such as facilities located in HPSA and frontier areas in order to better target facilities necessary to ensure access to care.

Comment: An MDO questioned how rural status is defined for the purpose of obtaining the rural adjustment. They asked if a facility would be considered rural where it is assigned a rural CBSA code-- one with a 2 digit State CBSA – as opposed to the 5-digit urban CBSA code. An LDO indicated that the definition of rural, "not in an urban area," is not suitable for use in a payment adjuster as it is too broad and does not address the specific issue.

Response: The rural adjustment would be paid to facilities that are not in a CBSA, that is, facilities that are assigned a two-digit State code. As we continue our analysis of subsets of rural providers, we will update the definition in 42 CFR 413.231.

Comment: Several professional associations recommended a transition period prior to implementation of the new geographic proximity criterion for the 30 facilities that will lose the LVPA. One association strongly recommends that CMS work closely with the parent networks to evaluate the impact of any closures on patient access to care.

Response: We do not anticipate that facilities will close because the LVPA will target facilities with truly high costs because of low patient volume. Analysis of the 2013 return code data shows that 3 facilities would be expected to receive the LVPA that were not previously grandfathered, and of these 3, none are expected to lose their LVPA adjustment. Of the 392 facilities that were grandfathered in 2013, 121(78 urban and 43 rural) are expected to lose the LVPA adjustment using the new LVPA eligibility criteria. Of the 43 rural facilities, all of them are expected to lose their LVPA eligibility because their treatment counts exceeded the 4000 treatment limit. None are expected to lose it due to the 5-mile geographic eligibility criterion. Of the 78 urban facilities that are expected to lose their LVPA adjustment, 45 have treatment counts that exceed the 4000 treatment limit, and 33 do not meet the 5-mile radius criterion.

Of note, there is at least one other dialysis facility within 5 miles for each one of the 33 dialysis facilities expected to lose their LVPA eligibility due to the 5-mile radius. Of the 33 facilities, 30 are LDOs and 27 out of the 33 facilities have multiple facilities within the 5 mile radius (two or more alternative facilities). Based on this analysis, we are not implementing a transition for facilities that will lose LVPA status at this time.

The LVPA adjustment was implemented to ensure facility availability for ESRD patients. Those facilities that are providing lower levels of treatments in a given year are supplemented with this adjustment to ensure their business survival and the continued availability of their services to the patients they serve. We believe we have made significant progress in targeting

this population of dialysis facilities.

In summary, with respect to the LVPA, we are finalizing the proposed revisions to the eligibility criteria, that is, the removal of grandfathering and change in the geographic proximity criterion. Specifically, for the purposes of determining the number of treatments under the definition of a low-volume facility, beginning CY2016, the number of treatments considered furnished by any ESRD facility regardless of when it came into existence and was Medicare certified will be equal to the aggregate number of treatments actually furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both: (i) under common ownership with; and (ii) 5 road miles or less from the ESRD facility in question. We are finalizing this provision by amending the regulation text by removing paragraph (d) in §413.232, and revising the geographic proximity provision described in paragraph (c). ESRD facilities that meet the LVPA eligibility criteria at §413.232 are eligible for the 23.9 percent increase to their ESRD PPS base rate as illustrated on Table 4.

We would like to note that we inadvertently failed to propose changes to the regulation text that pertains to the attestation deadline, in order to accommodate the timing of the policy changes finalized in this rule. Specifically, we are finalizing the extension of the attestation deadline for the CY 2016 LVPA attestations until December 31, 2015 to allow ESRD facilities time to assess their eligibility based on the policy changes to the LVPA for CY 2016 and, if appropriate, submit an attestation. Therefore, we are finalizing a revision to the newly redesignated §413.232(e) to reflect this date.

In addition, we are finalizing the implementation of a rural payment adjustment of 0.8 percent. Specifically, this payment adjustment would be applied to the ESRD PPS base rate for all ESRD facilities that are located in a rural area. We are also finalizing the addition of

§413.233 to the regulation text to reflect this new adjustment.

e. Refinement of the Case-Mix Adjustments for Pediatric Patients

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made for renal dialysis services. This provision does not distinguish between services furnished to adult and pediatric patients. Therefore, we developed a methodology that used the ESRD PPS base rate for pediatric patients and finalized pediatric payment adjusters in our CY 2011 ESRD PPS final rule at 75 FR 49131 through 49134. Specifically, the methodology for calculating the pediatric payment adjusters reflects case-mix adjustments for age and modality. We noted in our CY 2011 ESRD PPS final rule that the payment adjustments applicable to composite rate services for pediatric patients were obtained from the facility level model of composite rate costs for patients less than 18 years of age and yielded a regression-based multiplier of 1.199. However, based upon public comments received expressing concern that the payment multiplier was inadequate for pediatric care, we revised our methodology and we finalized pediatric payment adjusters that reflected the overall difference in average payments per treatment between pediatric and adult dialysis patients for composite rate (CR) services and separately billable (SB) items in CY 2007 based on the 872 pediatric dialysis patients reflected in the data.

We indicated in the CY 2011 ESRD PPS final rule (75 FR 49131 through 49134), that the average CY 2007 Medicare Allowable Payment (MAP) for composite rate services for pediatric dialysis patients was $216.46, compared to$156.12 for adult patients. The difference in composite rate payment is reflected in the overall adjustment for pediatric patients as calculated using the variables of (1) age less than 13 years, or 13 through 17 years; (2) dialysis modality, that is, peritoneal dialysis (PD) or hemodialysis (HD). While the composite rate MAP for

pediatric patients was higher than that for adult patients ($216.46 versus $156.12), the separately billable MAP was lower for pediatric patients ($48.09versus $83.27), in CY 2007. There are fewer separately billable items in the pediatric model, largely because of the predominance of the PD modality for younger patients and the smaller body size of pediatric patients. The overall difference in the CY 2007 MAP between adult and pediatric dialysis patients was computed at 10.5 percent or $216.46 + $48.09 = $264.55 and $156.12 + $83.27 = $239.39. $264.55/$239.39 = 1.105.

For CY 2016, we explained in the CY 2016 ESRD PPS proposed rule (80 FR 37823), that for purposes of regression analysis, we did not propose any changes to the formula used to establish the pediatric payment multipliers and will continue to apply the computations of Mult*EB*= P * C * (W*CR* + W*SB* * Mult*SB*),where P is the ratio of the average MAP per session for pediatric patients to the average MAP per session for adult patients as shown below, C is the average payment multiplier for adult patients (1.1151), WCR (0.798) and WSB (0.202) are the proportion of MAP for CR and SB services, respectively, among pediatric patients, and MultSB represents the SB model multipliers. We are using updated values for P, C, WCR, and WSB along with the updated SB multipliers to calculate the updated EB multipliers. The overall difference in the CY 2013 MAP between adult and pediatric dialysis patients was computed at 8.2 percent (P = $283.42/$ 261.91= 1.082).

The regression analysis for a new pediatric payment model for Medicare pediatric ESRD patients for CY 2016 will use the same methodology that was used for the CY2011 ESRD PPS final rule, except for the use of more recent data years (2012 through 2013) and in the method of obtaining payment data. Specifically, we used the projected total expanded bundle MAP based on 2013 claims to calculate the ratio of pediatric total MAP per session to adult total MAP per

session. The projected MAP was calculated by pricing out utilization of SBs based on line items in the claims, rather than using actual payments from the claims as in the pre-2011 data. These adjustment factors reflected a proposed 8.21 percent increase to account for the overall difference in average payments per treatment for pediatric patients. For this final rule, we did not make changes to the pediatric model and are therefore finalizing the updated pediatric SB and EB multipliers as shown below in Table 5.

TABLE 5: CY 2016 PEDIATRIC CASE-MIX PAYMENT ADJUSTMENTS

Cell	Patient Characteristics		CY 2016 Final Rule (based on 2012 and 2013 data)		
	Age	Modality	Population%	Separately Billable Multiplier	Expanded Bundle Payment Multiplier
1	<13	PD	27.62%	0.410	1.063
2	<13	HD	19.23%	1.406	1.306
3	13-17	PD	20.19%	0.569	1.102
4	13-17	HD	32.96%	1.494	1.327

The comments we received and our responses are set forth below.

Comment: Two professional associations support the 8 percent increase in the pediatric case-mix adjusters, however, they expressed concern that it is inadequate to cover the actual cost of dialyzing children. They suggested that ongoing updates to the pediatric case-mix adjusters are warranted because without adequate reimbursement, it becomes difficult for facilities to maintain the specially trained staff to deliver quality care to pediatric patients. They state that our mutual goal should be to ensure that reimbursement is commensurate with actual cost so that pediatric facilities can continue to provide high quality care. They requested that CMS allow pediatric facilities to apply for an exception to the ESRD composite rate as it has in the past when a facility‘s cost reports showed that the actual cost per treatment was higher than the composite rate.

Response: We agree with the commenters that the ESRD pediatric patient population is unique because it represents a very small percentage of the overall dialysis population but has high utilization of renal dialysis services that are not as prevalent in the adult population. While our goal is to align reimbursement with costs, we continue to believe that our methodology described above will provide sufficient payment to ESRD facilities that treat pediatric ESRD patients as we discuss in the CY 2011 ESRD PPS final rule (75 FR 49128 through 49134). In addition, we have an existing outlier policy that can be utilized in the event the cost of a pediatric patient is excessive.

With regard to the request that we provide an exceptions process such as the one we provided under the composite rate payment system, under which Medicare paid a composite rate based on an individual facility's cost per treatment, we do not have the statutory authority to pay a different base rate from that applied to other ESRD facilities. Section 1881(b)(14)(A)(i) requires the Secretary to implement a payment system under which a single payment is made to a provider of services or renal dialysis facility for renal dialysis services in lieu of any other payment. We do not believe the statute gives us authority to utilize an exceptions process under the ESRD PPS.

As we indicated in the CY 2011 ESRD PPS final rule (75 FR 49178), pursuant to section 1881(b)(14) of the Act, we created an ESRD prospective payment system in lieu of payments under previous ESRD payment systems. Given that these payment exceptions pertained to the prior composite rate payment systems under sections 1881(b)(7) and(b)(12) of the Act, we do not believe that such exceptions would carry forward or be appropriate under the ESRD PPS. Because the ESRD PPS transition has concluded, no portion of the ESRD PPS payments are

based on the composite rate, and as a result, it is not appropriate to resume composite rate exception payments.

Comment: One organization urged CMS to continue to reevaluate and regularly update the pediatric payment adjuster by utilizing the most recent data from Medicare cost reports and CROWNWeb.

Response: We agree it is important that the ESRD PPS payment adjustments are updated and refined so that the system reflects current clinical practice. Although we do not reevaluate and update the payment multipliers each year, we assess the impact of the changes we make to the ESRD PPS by simulating payments using the most recent year of ESRD facility claims and estimating the impact on facilities. For ESRD facilities that treat pediatric patients, we estimate the impact separately for facilities that treat less than 2 percent, between 2 and 19 percent, between 20 and 49 percent, and over 50 percent and publish the impacts in the annual ESRD PPS proposed and final rules.

f. The Home and Self-Dialysis Training Add-On Payment Adjustment

We received many comments from patients, patient advocacy groups, a dialysis supply manufacturer, national dialysis associations, and ESRD facilities concerning the adequacy of the home and self-dialysis training add-on payment adjustment. Although we did not make any proposals regarding the training add-on payment, we are addressing the commenters' concerns here.

Comment: Many commenters expressed concern about the adequacy of payment to ESRD facilities for training home and self-dialysis patients. Specifically, commenters expressed concern that the combination of inadequate payment and increasing costs to provide education for home therapies, especially home hemodialysis (HHD), could prevent patients from choosing

home dialysis. Commenters asked us to consider changes to the training add-on payment adjustment, explaining that nursing time and quality training are essential to ensure patients are successful in taking care of themselves at home. The commenter asked CMS to ensure that the training add-on payment adjustment accurately reflects costs and sufficient staff time to thoroughly train patients and families, limiting the number of patients who return to receiving in-facility dialysis.

Two other patient advocacy organizations reiterated their support for expanded patient access to home dialysis, pointing out that the percentage of patients using HHD remains low at just under 2 percent. The organizations noted that the upfront costs of beginning a home program may be one barrier to growth. They encouraged CMS to monitor patient access to home dialysis and ensure that the payment for home training covers the costs of the nursing time involved. They also expressed concern that any necessary increases to the training add-on payment adjustment should not come at the expense of funds from the ESRD PPS base rate, which those organizations believe are necessary to care for patients who chose to receive dialysis in-center.

A dialysis supply manufacturer provided an analysis indicating that adequate reimbursement of HHD training costs would require an additional $240 per treatment for each of the 25 training treatments allowed. They explained that 5 hours of one-on-one nursing time per HHD training treatment was necessary, rather than the 1.5 hours per treatment paid for by the current home dialysis training add-on payment adjustment. The $240 per treatment for each of the 25 training treatments allowed would compensate ESRD facilities for 5 hours of one-on-one nursing time per HHD training treatment.

A national dialysis association noted that their respective ESRD facilities do not observe an access barrier to HHD and indicated that they are not turning eligible patients or beneficiaries away from this modality. They stated that the ESRD PPS provides modality choice for beneficiaries that meet the clinical and practical requirements to dialyze at home. They noted that for many beneficiaries home dialysis is not a feasible option. The commenter noted that the beneficiary's home needs to be large enough to accommodate the equipment and supplies and be sufficiently sanitary to deliver dialysis that would otherwise be furnished under highly regulated conditions (that is, in-facility). In addition, while noting the unique challenges for both beneficiaries and providers, the commenter stated that some HHD machines are designed in such a way that the patient must dialyze more frequently than the three time per week schedule that has been the standard for achieving adequate therapy results. The commenter urged CMS and those in the kidney community to view home dialysis holistically and in the context of the broader ESRD PPS. The commenter suggested that if CMS wished to support home dialysis beneficiaries, then CMS should look at ways to restore funds to the ESRD PPS base rate for the care of all patients.

Response: We appreciate the commenters' suggestions regarding the evaluation of the home and self-dialysis training add-on payment adjustment. Access to care and the well-being of Medicare beneficiaries has always been our primary concern, and we agree that HHD is an important treatment option for patients that can appropriately use this modality. Additionally, we recognize the point raised by commenters that home dialysis is not a feasible option for all patients.

Home and self-dialysis training are programs that educate ESRD patients and/or other individuals to assist the patient in performing self-dialysis or home dialysis with little or no

professional assistance. In the context of this response, since the commenters are specifically discussing training for hemodialysis to be completed by a patient and/or caregiver in the home, we refer to the add-on as the home dialysis training add-on adjustment. Under our current policy, ESRD facilities are entitled to bill a maximum of 25 training sessions per patient for HHD training. This provides ESRD facilities with payment for 37.5 total hours of training (that is, $1,881.00) for this dialysis modality through the home dialysis training add-on payment adjustment in addition to the training costs that are included in the ESRD PPS bundled payment rate. We believe this provides an adequate opportunity for training of ESRD beneficiaries. In fact, as we note below, the use of home dialysis has increased in the ESRD population since the implementation of the ESRD PPS.

While we have heard from the commenters that we should increase the home dialysis training add-on payment adjustment so that more ESRD patients can receive the benefit of HHD, we have also heard from LDOs that the current training add-on is sufficient. In addition to these differing viewpoints, we've also received information in public comments that indicate a wide variance in training times and the duration of training sessions. While we have heard different things from stakeholders about whether or not the home dialysis training add-on payment adjustment is adequate, we are not in a position this year to address the commenters' concerns. We are, however, committed to conducting further analysis of the home dialysis training add-on payment adjustment and will consider making appropriate changes to the adjustment in future rulemaking.

As described below, the regulatory history of the training add-on payment adjustment demonstrates recognition of the importance of preserving access to all modalities of dialysis treatment and a commitment to adequate payment for home hemodialysis. Beginning in the mid-

1980s, we paid for home or self-dialysis training through a training add-on payment of $20 per treatment for 25 HHD treatments, $20 per treatment for 15 CCPD treatments, and $12 per treatment for 15 CAPD treatments. In the CY 2011 ESRD PPS proposed rule, we proposed that the cost for all home dialysis services would be included in the bundled payment (74 FR 49930). We noted that because we were proposing that training costs under the ESRD PPS would be treated no differently than any other overhead expense, an explicit adjustment to the bundled payment amount for HD and PD training expenditures would not be necessary (74 FR 49931). We also explained in the proposed rule that we were proposing modality neutral payments, because PD, the predominant modality for home dialysis at that time, is less costly than HD, and we believed that estimating a prospective rate that is higher for PD than it would otherwise be would encourage home dialysis for PD patients (74 FR 49967).

In the CY 2011 ESRD PPS final rule, we explained that we received comments encouraging us to consider utilizing an add-on payment adjustment to pay for the costs of home dialysis training. In response to those comments, we explained that although we were continuing to include training payments in computing the ESRD PPS base rate, we agreed with commenters that we should treat training as an adjustment under the ESRD PPS. Thus, we finalized the home dialysis training add-on payment adjustment of $33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either hemodialysis or peritoneal dialysis training and retraining (75 FR 49063). We chose to calculate a home dialysis training add-on payment adjustment based on one hour of nursing time because it was similar to the existing training add-on payments under the basic case-mix payment system (75 FR 49062). The amount we finalized for the adjustment – $33.44 per training treatment – was updated from the previous adjustment amount of $20 per hour and was

based on the national average hourly wage for nurses from Bureau of Labor Statistics data updated to 2011 (75 FR 49063). We noted that because nursing salaries differ greatly based on geographic location, we would adjust the training add-on payment by the geographic area wage index applicable to the ESRD facility. Based on the amount of the home dialysis training add-on payment adjustment that was finalized in 2011, facilities that furnished 25 HHD training treatments would receive around $500 in the form of home dialysis training add-on adjustment payments in addition to the dollars included in the base rate to account for training costs.

We clarified our policy on payment for home dialysis training again in the CY 2013 ESRD PPS final rule in which we stated that training costs are included in the ESRD PPS base rate, however, we also provide an add-on adjustment for each training treatment furnished by a Medicare-certified home dialysis training facility (77 FR 67468). As such, we explained that it is not the intent of the add-on treatment to reimburse a facility for all of the training costs furnished during training treatments. Rather, the single ESRD PPS base rate, all applicable case-mix and facility-level adjustments, as well as the add-on payment should be considered the Medicare payment for each training treatment and not the training add-on payment alone. We noted that the fact that the add-on payment for training accounts for one hour of training time per treatment is not intended to imply that it only takes one hour per training session to properly educate a beneficiary to perform home dialysis.

Then in the CY 2014 ESRD PPS final rule (78 FR 72183), we concluded in response to public comments that the training add-on, which represented 1 hour of nursing time, did not adequately represent the staff time required to ensure that a patient is able to perform home dialysis safely. We had received numerous comments on the home dialysis training add-on payment adjustment raising concerns about access to home dialysis and identifying training

elements that were not contemplated in 2011, such as self-cannulation and certain aspects of operating an HHD machine. As a result, we recomputed the add-on based upon 1.5 hours of nursing time per training treatment, which amounted to a 50 percent payment increase of $16.72 per training treatment in addition to the training treatment costs included in the base rate. Therefore, the add-on payment rose from $33.44 to $50.16. We noted that the finalized per training treatment add-on payment amount of $50.16 was in line with the costs reported on the 2010 ESRD facility cost reports, which indicated an average facility training cost of $53.00 per training treatment.

Thus, as stated above, current policies allows ESRD facilities to bill a maximum of 25 training sessions per patient for HHD training. This provides ESRD facilities with payment for 37.5 total hours of training (that is, $1,881.00) for this dialysis modality through the home dialysis training add-on payment adjustment in addition to the training costs that are included in the ESRD PPS bundled payment rate. We believe this provides an adequate opportunity for training of ESRD beneficiaries.

While we have heard from the commenters that we should increase the add-on so that more ESRD patients can receive the benefit of HHD, we have also heard from LDOs that the current training add-on is sufficient. In addition to these differing viewpoints, we've also received information in public comments that indicate a wide variance in training times and the duration of training sessions. In the CY 2014 ESRD PPS final rule, we noted that patient and caregiver commenters indicated a training time for home dialysis training of 2 to 6 weeks in length, with face-to-face nursing time of 2 to 6 hours per training day (78 FR 72184). Commenters also acknowledged that many of the training days took place in the training facility, in a group setting, and not in the patient's home. In addition, some commenters reported that

nursing staff were not present for the final week of training, as the patient had achieved total independent self-care (78 FR 72185). We explained that while we believed that an increase in the amount of the home dialysis training add-on payment was appropriate, we were concerned that training services furnished to Medicare beneficiaries appeared inconsistent across training facilities.

Access to care and the well-being of Medicare beneficiaries has always been our primary concern, and we agree that HHD is an important treatment option for patients that can appropriately use this modality. As reflected through the past policies of continuing increased reimbursement through the base rate and the add-on adjustments, we believe we have enhanced, not prevented, access to HHD. In fact, patient use of this treatment modality has increased since the introduction of the ESRD PPS in 2011, according to our monitoring data. We monitor the utilization of home dialysis and provide a quarterly public use file with this information, which is available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Spotlight.html. Given the widely varying information we've received about utilization of home dialysis services as well as the differing perspectives on the adequacy of the home dialysis training adjustment, we are committed to conducting further analysis of the this adjustment and will consider making appropriate changes to the adjustment in future rulemaking.

2. Final CY 2016 ESRD PPS Update

a. ESRD Bundled Market Basket

i. Overview and Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the

ESRD payment amounts are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

Section 1881(b)(14)(F)(i)(I) of the Act, as added by section 217(b)(2)(A) of PAMA, provides that in order to accomplish the purposes of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the market basket percentage increase factor for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1 percentage point for 2018. Accordingly, for CY 2016, we will reduce the final amount of the market basket percentage increase factor by 1.25 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, and will further reduce it by the productivity adjustment.

ii. Market Basket Update Increase Factor and Labor-Related Share for ESRD Facilities for CY 2016

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRDB input price index (75 FR 49151 through 49162) and subsequently revised and rebased the ESRDB input price index in the CY 2015 ESRD final rule (79 FR 66129 through 66136). Although ‘‘market basket’’ technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket.

Accordingly, the term ‘‘ESRDB market basket,’’ as used in this document, refers to the ESRDB input price index.

We proposed to use the CY 2012-based ESRDB market basket to compute the CY 2016 ESRDB market basket increase factor and labor-related share. We proposed an ESRDB market basket update of 2.0 percent, based on the IHS Global Insight 1st quarter 2015 forecast (with historical data through the 4th quarter of 2014). Also, as required by section 1881(b)(14)(F)(I)(i) of the Act as amended by section 217(b)(2)(A) of PAMA, we proposed to reduce the amount of the market basket increase factor by 1.25 percent, resulting in a proposed CY 2016 ESRDB market basket percentage increase factor of 0.75 percent.

For the CY 2016 ESRD payment update, we proposed to continue using a labor-related share of 50.673 percent for the ESRD PPS payment, which was finalized in the CY 2015 ESRD final rule (79 FR 66136). We implemented the new labor-related share using a 2-year transition of 46.205 percent for CY 2015 and 50.673 percent for CY 2016 (79 FR 66142).

We did not receive any comments on our proposed market basket update. Therefore, based on the most recent forecast available, we are finalizing a CY 2016 ESRDB market basket update of 1.8 percent, based on the IHS Global Insight 3rd quarter 2015 forecast (with historical data through the 2nd quarter 2015). We are also further reducing the 1.8 percent ESRDB market basket update by 1.25 percent as required by section 217(b)(2)(A) of PAMA. Therefore the CY 2016 market basket percentage increase factor is 0.55 percent.

iii. Productivity Adjustment

The productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as 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 fiscal year, year, cost reporting period, or other annual period) (the ‘‘MFP adjustment’’).

The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see http://www.bls.gov/mfp to obtain 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. As described in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504), to generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the CY 2012 ESRD 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.

We proposed that beginning in CY 2016, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs (for details see 80 FR 37825). To summarize the proposed change, 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 proposed to use IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the CY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on our Web site at http://www.cms.gov/ Research-Statistics-Data-and-Systems/ Statistics-Trends-and-Reports/ Medicare Program Rates Stats/ MarketBasketResearch.html. We

also proposed that in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

The proposed CY 2016 MFP adjustment was 0.6 percent based on IGI's 1st quarter 2015 forecast (with historical data through the 4th quarter 2014). We invited comments on the MFP proposal.

Comment: One commenter stated that, using IGI's first quarter 2015 forecast, the MFP adjustment for CY 2016 (the 10 year moving average of MFP for the period ending CY 2016) is projected to be 0.6 percent. The commenter asked what other firms suggest for projected MFP and why are we basing the MFP solely on a single quarter's forecast.

Response: IHS Global Insight (IGI), Inc. is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets and multifactor productivity (MFP). We do not purchase additional forecasts of MFP or other economic series from separate consulting firms.

The MFP adjustment is based on the 40 quarter (or 10-year) moving average of changes in economy-wide private non-farm MFP. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be aligned with the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period). Therefore, the commenter is incorrect that the MFP is based solely on a single quarter's forecast because, in actuality, the MFP adjustment reflects 40 quarters worth of data through the 4th quarter of 2016.

We did not receive any comments related to our proposal to change the capital input series in the MFP formula. Therefore, based on the most recent forecast available, we are finalizing a CY 2016 MFP adjustment of 0.4 percent, based on the IHS Global Insight 3rd quarter 2015 forecast (this reflects historical MFP data through 2014).

iv. Calculation of the ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2016

As required by section 1881(b)(14)(F) of the Act, which requires the ESRD PPS to be updated by the market basket reduced by the MFP adjustment, as well as section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, which requires a 1.25 percentage point reduction to the ESRDB market basket increase factor, the proposed CY 2016 ESRD market basket increase was 0.15 percent (2.0 percent market basket update less 1.25 percent PAMA reduction, less 0.6 percentage point MFP update). We also noted that if more recent data is subsequently available we would use such data to determine the final CY 2016 market basket update and MFP adjustment in the ESRD PPS final rule.

Therefore, using the most recent data available, the final CY 2016 ESRDB market basket less MFP update is 0.15 percent. This is based on a 1.8 percent market basket update, less a 1.25 percent adjustment as required by section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, and further reduced by a 0.4 percent MFP update. The CY 2016 ESRDB market basket update and MFP adjustment are based on the IHS Global Insight 3rd quarter 2015 forecast with historical data through the 2nd quarter 2015.

b. The Final CY 2016 ESRD PPS Wage Indices

i. Annual Update of the Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the use of the Office of Management and Budget's (OMB) Core-Based Statistical Areas (CBSAs)-based geographic area designations to define

urban and rural areas and their corresponding wage index values.

In the CY 2016 ESRD PPS proposed rule (80 FR 37825), we stated that we would continue to use the same methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49117) for determining the wage indices for ESRD facilities. Specifically, we are updating the wage indices for CY 2016 to account for updated wage levels in areas in which ESRD facilities are located. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient prospective payment system. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The final CY 2016 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the final CY 2016 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

In the CY 2011 and CY 2012 ESRD PPS final rules (75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively), we also discussed and finalized the methodologies we use to calculate wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area.

For CY 2016, we are applying this criteria to American Samoa and the Northern Mariana Islands, where we apply the wage index for Guam as established in the CY 2014 ESRD PPS

final rule (78 FR 72172)(0.9611), and Hinesville-Fort Stewart, Georgia, where we apply the statewide urban average based on the average of all urban areas within the state (78 FR 72173) (0.8666).We note that if hospital data becomes available for these areas, we will use that data for the appropriate CBSAs instead of the proxy.

A wage index floor value has been used in lieu of the calculated wage index values below the floor in making payment for renal dialysis services under the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized that we would continue to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition. In the CY 2012 ESRD PPS final rule (76 FR 70241), we finalized the 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively. We continued to apply and to reduce the wage index floor by 0.05 in the CY 2013 ESRD PPS final rule (77 FR 67459 through 67461). Although our intention initially was to provide a wage index floor only through the 4-year transition to 100 percent implementation of the ERSD PPS (75 FR 49116 through 49117; 76 FR 70240 through 70241), in the CY 2014 ESRD PPS final rule (78 FR 72173), we continued to apply the wage index floor and continued to reduce the floor by 0.05 per year for CY 2014 and for CY 2015.

For CY 2016, we proposed to continue to apply the CY 2015 wage index floor, that is, 0.4000, to areas with wage index values below the floor but we did not propose to reduce the wage index floor for CY 2016. Our review of the wage indices show that CBSAs in Puerto Rico continue to be the only areas with wage index values that would benefit from a wage index floor because they are so low. Therefore, we believe that we need more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor and leave it at 0.4000. Because the wage index floor is only applicable to a small number

of CBSAs, the impact to the base rate through the wage index budget-neutrality factor is insignificant. To the extent other geographical areas fall below the floor in CY 2016 or beyond, we believe they should have the benefit of the 0.4000 wage index floor as well. We will continue to review wage index values and the appropriateness of a wage index floor in the future.

ii. Implementation of New Labor Market Delineations

As noted earlier in this section, in the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized for the ESRD PPS the use of the CBSA-based geographic area designations described in OMB bulletin 03-04, issued June 6, 2003, as the basis for revising the urban and rural areas and their corresponding wage index values. This bulletin, as well as subsequent bulletins, is available online at http://www.whitehouse.gov/omb/bulletins_index2003-2005.

OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. In accordance with our established methodology, we have historically adopted via rulemaking CBSA changes that are published in the latest OMB bulletin. 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 may be obtained at http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf. According to OMB, "[t]his 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." When referencing the new OMB geographic boundaries of statistical areas, we use the term "*delineations*" rather than the term "*definitions*" that we have used in the past,

consistent with OMB's use of the terms (75 FR 37249). 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, we were unable to undertake such a lengthy process before publication of the FY 2014 IPPS/LTCH PPS proposed rule and, thus, did not implement changes to the hospital wage index for FY 2014 based on these new CBSA delineations.

For the same reasons, the CY 2014 ESRD PPS wage index (based upon the pre-floor, pre-reclassified hospital wage data, which is unadjusted for occupational mix) also did not reflect the new CBSA delineations. In the FY 2015 IPPS/LTCH PPS final rule, we implemented the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13-01, beginning with the FY 2015 IPPS wage index (79 FR 49951 through 49963). Similarly, in the CY 2015 ESRD PPS final rule (79 FR 66137 through 66142), we implemented the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13-01, beginning with the CY 2015 ESRD PPS wage index.

In order to implement these changes for the ESRD PPS, we identified the new labor market area delineation for each county and facility in the country and determined that there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. In the CY 2015 final rule (79 FR 66137 and 66138), we provided tables that showed the CBSA delineations and wage index values for CY 2014 and the CY 2015 CBSA delineations, wage index values, and the percentage change in these values for those counties that changed from rural to urban, from urban to rural, and from one urban area to another and also showed the changes to the statewide rural wage index.

While we believe that the new CBSA delineations result in wage index values that are more representative of the actual costs of labor in a given area, we recognized that use of the new CBSA delineations results in reduced payments to some facilities. For this reason, we implemented the new CBSA delineations using a 2-year transition with a 50/50 blended wage index value for all facilities in CY 2015 and 100 percent of the wage index based on the new CBSA delineations in CY 2016. Therefore, for CY 2016, we are completing the transition and will apply 100 percent of the wage index based on the new CBSA delineations and the most recent hospital wage data.

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized a policy to use the labor-related share of 41.737 percent for the ESRD PPS which was based on the ESRDB market basket finalized in that rule. In the CY 2015 ESRD PPS final rule (79 FR 66136), we finalized a new labor-related share of 50.673 percent, which was based on the rebased and revised ESRDB market basket finalized in that rule, and transitioned the new labor-related share over a 2-year period. For CY 2015, the labor-related share is based 50 percent on the old labor-related share and 50 percent on the new labor-related share, and the labor-related share in CY 2016 is based 100 percent on the new labor-related share.

The comments we received on wage index issues and our responses are set forth below.

Comment: A large health plan requested that we develop a wage index specific to ESRD facilities. They pointed out that ESRD staffing is inherently different than hospital staffing and that tying the ESRD wage index to hospital wage and staffing patterns does not reflect the true costs of operating an ESRD facility.

Response: We are unable to implement a wage index based on ESRD wage data for CY 2016 as we did not propose to make this change and we do not have sufficient data on ESRD facility wages at this time. In future refinements to the ESRD PPS we will certainly consider the feasibility of this recommendation. However, we note that efforts to develop provider-specific wage indices for other Medicare providers have been unsuccessful from both CMS' and the providers' viewpoints. As a result, we do not intend to consider an ESRD-specific wage index until we can demonstrate that such an index would be more reflective of the wages and salaries paid, that it would significantly improve our ability to determine payment for ESRD facilities, and that we can justify the resources required to collect the data, as well as the increased burden on providers.

Comment: An organization representing small and medium dialysis facilities urged CMS to examine the impact of the wage index on the case-mix adjusters and their value to dialysis facilities. For facilities located in areas where the wage index is below one, the practical effect of the wage index is a lower base rate. In addition, because the case-mix adjusters are calculated as multipliers to the base rate, facilities located in areas where the wage index is below one are receiving less value from the adjusters. Thus, the low wage area facilities are hit twice for the lower wage index. If CMS increases the weight of the case-mix adjusters in the payment formula, the disparities between high wage area and low wage area facilities is further exacerbated.

Response: The case-mix adjusters are estimated controlling for the urban versus rural location of the facilities where labor costs play a significant role in the cost. The case- mix adjusters in the CR part of the model reflect the costs of providing basic dialysis services to patients. These costs, which are largely labor costs, are expected to be lower for facilities in

areas with low wage indices. Therefore, it is appropriate that the incremental cost of caring for a patient in the young or very old age category should be proportionately smaller in areas with lower wages. The case-mix adjusters, other than age, apply mainly in the SB equation part of the model. The SB part of the model is not adjusted for wages.

As to the concern that rural facilities are not receiving the full case-mix adjustments, we understand the commenter's concern and intend to continue to examine the impact of the wage index on the case-mix adjusters and the payments made to ESRD facilities, particularly facilities located in areas where the wage index is below one.

Comment: A national dialysis organization expressed support for the wage index proposals and the continued application of the wage index floor where applicable. An organization representing small and medium dialysis facilities asked CMS to implement a freeze in the wage floor to prevent further hardship for rural facilities.

A health plan commented that the proposed 4 percent decrease to the base rate due to refinement will be detrimental to ESRD facilities located in Puerto Rico and urged CMS to re-establish a fair and meaningful wage index floor to substitute for the low wage index values that result from hospital wage data reported in Puerto Rico.

The commenter provided several alternative wage indexes for Puerto Rico for the CY 2016 ESRD PPS final rule: (1) apply our policies for areas that do not have reliable hospital data, and apply the wage index for Guam as we did in implementing the ESRD PPS in the Northern Marianas and American Samoa, (2) use the U.S. Virgin Islands as a proxy for Puerto Rico given the geographic proximity and its "non-mainland" or "island" nature, or (3) re-establish the wage index floor in effect in 2010 when Puerto Rico became the only wage areas subject to the floor, that is, 0.65. Finally, the commenter requests that we delay the increase in the labor-related

share to which to the wage index is applied for facilities in Puerto Rico because increases in the labor-related share lowers payments for low wage index areas.

Response: For CY 2016, we proposed to continue to apply the CY 2015 wage index floor, that is, 0.4000, to areas with wage index values below the floor, rather than reduce the floor by 0.05 as we have done over the last 10 years. We stated that we need more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor. The commenter has provided useful suggestions that we plan to consider in proposing updates to the wage index policies under the ESRD PPS for CY 2017, so that we may review all options in the future rulemaking, which will allow for public comments.

With regard to delaying implementation of the labor-related share for facilities in Puerto Rico, we believe it is important that we apply the labor-related share derived from the latest update to the ESRDB market basket. We do not believe it would be appropriate to delay implementation longer or to apply the new labor-related share in a non-uniform manner. In addition, a change to the labor-related share does not address the primary issue the commenter identified, which is the comparatively lower wages reported by hospitals in Puerto Rico. For these reasons, we are not making any changes to the labor-related share finalized in the CY 2015 ESRD PPS final rule.

Comment: An MDO requested that we provide them the wage index in an Excel format so that they have access to the county names.

Response: We provide a file that includes the county names with each rule that is issued. The link to the ESRD PPS rules webpage is https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-

Notices.html. The file with county names was available when the CY 2016 ESRD PPS proposed rule was published.

After considering the public comments submitted, we are finalizing the CY 2016 wage index policies as proposed and implementing the CBSA designations based on the latest hospital wage data. In addition, we are maintaining a wage index floor of 0.4000 and continuing our current policies for wage areas with no hospital data.

c. CY 2016 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, comorbidities such as cancer, and possibly race and gender. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy in our regulations at 42 CFR 413.237, which provide that ESRD outlier services are the following items and services that are included in the ESRD PPS bundle: (i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) medical/surgical supplies, including syringes, used to administer ESRD-related drugs, that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (iv) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding oral-only drugs used in the treatment of ESRD.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of

determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item on the monthly claim. Renal dialysis service drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Our regulations at 42 CFR 413.237 specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the

ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed-dollar loss amount. In accordance with §413.237(c) of the regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule, using 2007 data, we established the outlier percentage at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the fixed-dollar loss amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and fixed-dollar loss amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For the CY 2016 outlier policy, we proposed to use the existing methodology for determining outlier payments by applying outlier services payment multipliers that resulted from the updated regression analyses. The updated outlier services payment multipliers are represented by the updated separately billable payment multipliers presented in Table 7 for patients age 18 years and older. We used these updated outlier services payment multipliers to calculate the predicted outlier service MAP amounts and projected outlier payments for CY 2016.

In the CY 2016 ESRD PPS proposed rule (80 FR 37827), we proposed that the outlier

services MAP amounts and fixed-dollar loss amounts would be derived from claims data from CY 2014. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we proposed that the outlier thresholds for CY 2016 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2014. We stated that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and fixed-dollar loss amounts every year under the ESRD PPS. However, we believe for the first time since the implementation of the ESRD PPS that data for CY 2014 reflects relatively stable ESA use. We have included Table 6 below to demonstrate the leveling off of the decline in ESA utilization.

TABLE 6: TOTAL MEDICARE ESA UTILIZATION IN THE ESRD POPULATION

	2009	2010	2011	2012	2013	2014[1]
Total ESA Utilization						
Epogen (x100,000)	2,083,893	2,075,217	1,655,778	1,319,383	1,262,186	1,143,405
Darbepoetin (x100,000)	533	496	379	280	242	291
ESA Utilization per Session						
Epogen	5,404	5,171	3,995	3,078	2,895	2,858
Darbepoetin	1.38	1.24	0.91	0.65	0.55	0.73

[1]2014 based on December 2014 claims

i. CY 2016 Update to the Outlier Services MAP Amounts and Fixed-Dollar Loss Amounts

For CY 2016, we did not propose any changes to the methodology used to compute the MAP or fixed-dollar loss amounts. Rather, the proposed rule updated the outlier services MAP amounts and fixed-dollar loss amounts to reflect the utilization of outlier services reported on 2014 claims using the December 2014 claims file. For this final rule, the outlier services MAP amounts and fixed dollar loss amounts were updated using the 2014 claims from the June 2015

claims file. The impact of this update is shown in Table 7, which compares the outlier services MAP amounts and fixed-dollar loss amounts used for the outlier policy in CY 2015 with the updated estimates for this rule. The estimates for the final CY 2016 outlier policy, which are included in Column II of Table 7, were inflation adjusted to reflect projected 2016 prices for outlier services.

TABLE 7– OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I **Final outlier policy for CY 2015 (based on 2013 data price inflated to 2015)***		**Column II** **Final outlier policy for CY 2016 (based on 2014 data price inflated to 2016)***	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**
Average outlier services MAP amount per treatment	$39.89	$52.98	$40.20	$53.29
Adjustments				
Standardization for outlier services	1.1145	0.9878	0.9951	0.9729
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$43.57	$51.29	$39.20	$50.81
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$54.35	$86.19	$62.19	$86.97
Patient months qualifying for outlier payment	6.3%	6.3%	5.8%	6.5%

As demonstrated in Table 7, the estimated fixed-dollar loss amount per treatment that determines the CY 2016 outlier threshold amount for adults (Column II; $86.97) is slightly higher than that used for the CY 2015 outlier policy (Column I; $86.19). The lower threshold is accompanied by a decline in the adjusted average MAP for outlier services from $51.29 to $50.81. For pediatric patients, the fixed dollar loss increased from $54.35 to $62.19. Likewise, the adjusted average MAP for outlier services fell from $43.57 to $39.20.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2016 will be 6.5 percent for adult patients and 5.8 percent for pediatric patients, based on the 2014 claims data. The pediatric outlier MAP and fixed-dollar loss amounts continue to be lower

for pediatric patients than adults due to the lower use of outlier services (ESAs and other injectable drugs) in the pediatric population.

ii. Outlier Policy Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081), in accordance with 42 CFR 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments. Based on the 2014 claims from the June 2015 claims file, outlier payments represent approximately 0.8 percent of total payments, slightly below the 1 percent target due to small declines in the use of outlier services. Recalibration of the thresholds using 2014 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2016. We believe the update to the outlier MAP and fixed-dollar loss amounts for CY 2016 will increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier target. We note that the recalibration of the fixed-dollar loss amounts that are being finalized in this rule will result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but will increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would also increase for renal dialysis services eligible for outlier payments.

In the CY 2016 ESRD PPS proposed rule (80 FR 37828), we noted that many industry stakeholder associations and renal facilities have expressed disappointment that the outlier target percentage has not been achieved under the ESRD PPS and have asked that CMS eliminate the outlier policy. We further stated that with regard to the suggestion that we eliminate the outlier adjustment altogether, under section 1881(b)(14)(D)(ii) of the Act, the ESRD PPS must include a

payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of ESAs necessary for anemia management. We believe that the ESRD PPS is required to include an outlier adjustment in order to comply with section 1881(b)(14)(D)(ii) of the Act.

In addition, we believe that the ESRD PPS base rate captures the cost for the average renal patient, and to the extent data analysis continues to show that certain patients, including certain racial and ethnic groups, receive more ESAs than the average ESRD patient, we believe an outlier policy, even a small one, is an important payment adjustment to provide under the ESRD PPS. We did not propose to modify the 1 percent outlier percentage for CY 2016 because we believe that the regression analysis continues to demonstrate high cost patients and that the elimination of the comorbidity categories of bacterial pneumonia and monoclonal gammopathy and other regression updates would assist facilities in receiving outlier payments in CY 2016 that are 1.0 percent of total ESRD PPS payments.

In the proposed rule (80 FR 37829), we further stated that we understand the industry's frustration that payments under the outlier policy have not reached 1.0 percent of total ESRD PPS payments since the implementation of the payment system. As we explained in the CY 2014 ESRD PPS final rule (78 FR 72165), each year we simulate payments under the ESRD PPS in order to set the outlier fixed-dollar loss and MAP amounts for adult and pediatric patients to try to achieve the 1.0 percent outlier policy. We would not increase the base rate to account for years where outlier payments were less than 1.0 percent of total ESRD PPS payments, nor would we reduce the base rate if the outlier payments exceed 1 percent of total ESRD PPS payments.

We believe the 1.0 percent outlier percentage has not been reached under the payment system due to the significant drop, over 25 percent, in the utilization of high cost drugs such as

Epogen since the implementation of the payment system. In other words, the shortfall in outlier payments is likely to arise precisely because facilities are incurring lower costs than they did in the historical data used to set the base rate. However, we have learned in our discussions with ESRD facilities that some facilities might not report outlier services on the ESRD facility monthly claim form as they do not believe that they will reach the outlier threshold. We issued sub-regulatory guidance for CY 2015 that instructs ESRD facilities to include all composite rate drugs and biologicals furnished to the beneficiary on the monthly claim form (Change Request 8978, issued December 2, 2014). In CY 2015 ESRD PPS final rule (79 FR 66149 through 66150), we discussed the drug categories that we consider to be used for the treatment of ESRD with the expectation that all of those drugs and biologicals would be reported on the claim. In addition to this guidance, we also have included a clarification for how facilities are to report laboratory services and drugs and biologicals on the monthly claim form. We believe these steps will lead to an increase in outlier payments in CY 2016.

The comments we received on the outlier policy update for CY 2016 and our responses are set forth below.

Comment: An organization representing small and medium dialysis facilities stated that if CMS is unable to distribute the entire one percent of the holdback, the amount of the outlier holdback should be lowered. An organization of nonprofit SDOs agreed, indicating that the outlier factor should be reduced to 0.5 percent, which is closer to the actual rate of outlier payments that have been made since 2011.A nonprofit dialysis organization would prefer that the outlier provision be removed from the bundled payment system, but at a minimum, the outlier target percentage should be reduced from 1.0 percent to 0.5 percent. A large national dialysis

organization expressed support for the outlier policy as an alternative to the comorbidity adjustments. A professional association also expressed support for the outlier policy.

An MDO pointed out that the ESRD PPS paid 0.9 percent of the 1.0 percent outlier target and asked what the dollar amount difference was and how many Medicare claims in 2014 received an outlier payment. They commented that this amount could be added back to the base rate for CY 2016 because they believe the fact that the full outlier holdback was not paid out means ESRD facilities essentially lost out on this money. A professional association supports the concept of an outlier policy to sufficiently reimburse dialysis facilities for high-cost patients. However, they are concerned that the current policy is flawed based on the low percentage of facilities that qualify for outlier payments. They suggest one of two options to ensure disbursement of this withholding: (1) an annual adjustment of the threshold for outlier payments to fully expend the withholding; or (2) an annual adjustment of the withholding based on the running average of the expenditure from the prior 3 years, with the total withholding not to exceed 1.0 percent. Another organization urged CMS to examine whether outlier payments are being received by the facilities that truly need them.

Response: We appreciate the commenters' support for the outlier policy. As we explained in the proposed rule and above, our analysis of ESRD PPS claims show that outlier payments reached 0.8 percent of the l.0 percent outlier target in 2014. Specifically, outlier payments were made for 185,293 patient months, totaling $71,325,656 ($89,157,069 when including patient or secondary insurer obligations). For these patient months, outlier payments represented 16.2 percent of total Medicare payments. 5,992 facilities received at least one outlier payment. Twenty percent of outlier payments in dollars were received by independent facilities and another 13 percent were received by facilities that were part of a multi-facility organization

other than the three largest chains. Outlier payments are particularly important for small dialysis organizations and independent dialysis facilities because they often lack the volume of patients necessary to offset the high cost of certain patients. With regard to the comment that the outlier policy is flawed based on the low percentage of facilities that qualify for outlier payments, we note that 94 percent of facilities received outlier payments. Further, the 1.0 percent outlier target is small compared to outlier policies in other Medicare payment systems and was not designed to cover a large number of claims. As indicated in Table 7, we estimate that the percentage of patient months qualifying for outlier payments in CY 2016 will be 6.5 percent for adult patients and 5.8 percent for pediatric patients, based on the 2014claims data.

We acknowledge that the l.0 percent target has not been achieved since 2011 primarily because our annual update of the fixed-dollar loss amounts and MAP amounts could not keep up with the continued decline in the use of outlier services (primarily ESAs). That is, facilities incurred lower costs than anticipated, and those savings accrued to facilities more than offsetting the extent to which the consequent outlier payments fell short of the 1.0 percent target. However, as we stated in the proposed rule and above, we now believe that decline is leveling off, which will make our projections of outlier payments more accurate. In addition, because we are deleting two comorbidity category adjustments (bacterial pneumonia and monoclonal gammopathy) for CY 2016, we believe it is important to maintain the current 1.0 percent outlier policy. By doing so, the ESRD PPS protects patient access by providing additional payment for patients whose care requires more outlier services than the average patient.

With regard to the suggestion that we annually adjust the withholding based on the running average of the expenditure from the prior three years, with the total withholding not to exceed 1.0 percent, as we explain above, each year we simulate payments under the ESRD PPS

in order to set the outlier fixed-dollar loss and MAP amounts for adult and pediatric patients to try to achieve the 1.0 percent outlier policy. We would not increase the base rate to account for years where outlier payments were less than 1.0 percent of total ESRD PPS payments and, more importantly we would not reduce the base rate if the outlier payments exceed 1.0 percent of total ESRD PPS payments. Rather than increasing and decreasing the base rate, we re-estimate the fixed-dollar loss threshold and MAP amounts so that outlier payments in the following year are 1.0 percent of total ESRD PPS payments. This is the approach used in other Medicare payment systems that include an outlier policy, such as the Inpatient Psychiatric Facility PPS. As we have done since 2011, we will continue to monitor outlier payments and assess annually the extent to which adjustments need to be made in the fixed-dollar loss and MAP amounts in order to achieve outlier payments that are 1.0 percent of total ESRD PPS payments.

d. Annual Updates and Policy Changes to the CY 2016 ESRD PPS

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we discussed the implementation of the ESRD PPS per treatment base rate that is codified in the Medicare regulations at §413.220 and §413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate, outlier payments, and geographic wage index budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims, that is, the lowest per patient utilization year from the 2006 through2008 time period, as required by section 1881(b)(14)(A)(ii) of the Act, updated to CY 2011, and represented the average per treatment MAP for renal dialysis services. The payment system is

updated annually by the ESRDB market basket less the productivity adjustment which is discussed in section II.B.2.of this final rule.

ii. Annual Payment Rate Update for CY 2016

We proposed an ESRD PPS base rate for CY 2016 of $230.20. This update reflected several factors, described in more detail below.

Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2016 projection for the ESRDB market basket was 2.0 percent. In CY 2016, this amount must be reduced by 1.25 percentage points as required by section 1881(b)(14)(F)(i)(I), as amended by section 217(b)(2)(A) of PAMA, which is calculated as 2.0 – 1.25 = 0.75. This amount is then further reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as required by section 1881(b)(14)(F)(i)(II) of the Act. The proposed multi-factor productivity adjustment for the CY 2016 proposed rule was 0.6, yielding a proposed update to the base rate of 0.15 percent for CY 2016 (0.75 – 0.6 = 0.15 percent).

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2016, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in CY 2014 ESRD PPS final rule (78 FR 72174). The CY 2016 proposed wage index budget-neutrality adjustment factor was 1.000332.

Refinement Budget-Neutrality Adjustment Factor: In order to implement the refinement in a budget-neutral manner, we proposed to adjust the ESRD PPS base rate by a budget-neutrality adjustment factor. In CY 2011, we standardized the base rate to account for the overall effects of

the ESRD PPS adjustment factors by making a 5.93 percent reduction to the base rate. To account for the overall effects of the refinement (that is, to not increase Medicare spending), we proposed a negative 4 percent adjustment (that is, a factor of 0.959703) to the ESRD PPS base rate to account for the additional dollars paid to facilities through the payment adjustments. While the per-treatment base rate would be reduced, we believe that this refinement improves payment accuracy and we would expect payments to be better targeted to those characteristics that increase costs for facilities. Notably, a significant portion of the downward effect on the base rate is due to the higher payments resulting from changes in the age adjustments. However other changes, such as using the prevalence of comorbidities on the ESRD facility claim, has an upward effect on the refinement budget-neutrality adjustment factor.

In summary, we proposed a CY 2016 ESRD PPS base rate of $230.20. This reflects a market basket increase of 0.15 percent, the CY 2016 wage index budget-neutrality adjustment factor of 1.000332, and the refinement budget-neutrality adjustment of 0.959703.

The comments and our responses are set forth below.

Comment: Several dialysis organizations recommended that the standardization factor applied to the base rate be updated annually to reflect the actual prevalence of the payment adjustors. The organizations pointed out that between 2011 and 2014, the ESRD PPS underpaid providers by more than $844 million relative to CMS' projections in the ESRD PPS final rules for those years. They stated that the underpayments are the direct result of CMS' policies and methodological flaws in calculating the payment adjusters and the outlier pool.

An organization representing small and medium dialysis facilities sponsored an analysis that found that from 2012 to 2013, providers were underpaid by an estimated $33 million, or $.019 per treatment because the actual prevalence of the case-mix adjusters did not align with

CMS' assumptions. The organization pointed out that the estimates of the prevalence of comorbid conditions in the 2016 refinement is well below the estimate made in 2011. A nonprofit dialysis organization pointed out that because of the burden associated with comorbidity adjustments, providers are not able to report comorbidities to the extent predicted by CMS. As a result, CMS is paying less per treatment than anticipated. They urged CMS to update the standardization factor. The organizations stated that since the original base rate was set assuming a much higher prevalence of these conditions, it would appear that the ESRD PPS did not achieve budget neutrality with the prior payment system. The organization believes CMS should re-estimate the original standardization factor to account for the lower prevalence of the comorbidity adjustments and use this base rate as the starting point for any changes in 2016. This will ensure that overall budget neutrality is ensured within the ESRD PPS and prevent CMS from locking in the underpayments from the last several years into perpetuity. Going forward, they urged CMS to monitor the impact of the case-mix adjusters to ensure that actual prevalence of the adjusters is keeping pace with the original estimates and that the expected levels of payment are being realized.

Response: The refinement budget-neutrality adjustment supplements the standardization factor. This is because the value of the adjusters following the 2016 refinement has increased. As such, it would be inappropriate to recalibrate the standardization adjustment because the value of this adjustment together with the 4 percent refinement budget-neutrality adjustment is equal to the updated adjuster values calculated using updated data. The 4 percent increase, primarily the result of the updated age adjusters, is expected to be paid out to ESRD facilities because they are based on information required to be included on every claim (the patients' birth date) and therefore, there is no documentation burden.

With respect to the suggestion that we update the budget-neutrality adjustment factor annually to reflect the actual prevalence of the payment adjustors, we do not believe this is the best approach. We would not want to increase or decrease the base rate based on the prevalence of the payment adjusters in one year. Instead, as we have done since 2011, we intend to monitor the prevalence of the case-mix adjusters to ensure that actual prevalence of the adjusters is keeping pace with the original estimates.

Comment: Several dialysis organizations commented that they are deeply concerned by the reduction of the base rate for CY 2016. They indicated that the proposed rule does not contain sufficient information to determine the relationship between the standardization factor applied to the base rate in 2011 and the refinement budget-neutrality adjustment factor. For example, they note it is not possible from the preamble to determine whether the contractor used the actual frequency of adjusters applied to the 2013 claims to derive a standardization factor that is the sum of the previous standardization factor and the refinement budget-neutrality adjustment factor. The indicated that it appears that the significant reduction in the base rate is due to the inappropriate increase in the age adjuster. They request that we recompute the standardization factor and refinement budget-neutrality adjustment factor based on their recommended changes in the model and provide sufficient information in the final rule to allow stakeholders to understand the interaction of the two budget-neutrality factors.

Response: As discussed above, the refinement budget-neutrality adjustment accounts for the increase in the value of the adjusters above the value already accounted for by the standardization adjustment. Thus, the total value of the revised adjusters is represented by the standardization factor plus the refinement budget-neutrality adjustment. In other words, the standardization adjustment reflected the adjuster values as calculated in 2011 and when we used

updated data to calculate the values for 2016, we needed to determine the extent to which the new values diverged from the values that were accounted for in the standardization adjustment when the ESRD PPS was implemented. Because the values increased in the refinement, we needed a further reduction to the base rate in addition to the standardization adjustment, which was applied in the form of the refinement budget-neutrality adjustment.

In terms of the commenters' point about the age adjustment, as discussed above, we believe the methodology for our regression was sound and we do not believe the increased value of the age adjusters is inappropriate. Moreover, we believe the increased value of the age adjusters is beneficial to ESRD facilities because they will always be paid out. This is because patient age is already captured on ESRD facility claims. As long as the patient is in one of the age categories for which we have a payment adjustment, the ESRD facility will always receive the adjustment without any added burden to document the patient's age.

We used the data from CY 2012 and CY 2013 to set the adjustment factors and then applied those factors to the CY 2014 claims to determine the budget-neutrality factor associated with this refinement. The final refinement budget-neutrality adjustment factor is not the sum of the standardization factor computed for the CY 2011 rule and the budget-neutrality factor associated with the refinement. Rather, we used the CY2014 claims to estimate payments under the PPS for CY2016 both when applying the original payment adjustment factors that have been used since CY2011 and when applying the modified payment adjustment factors that were developed for this refinement. The refinement budget-neutrality factor was then calculated as the ratio of these two total estimated payment amounts. Note that neither of these total estimated payment amounts included the estimated outlier payments because they are added separately in determining the total payment for each claim.

The calculation described above resulted in a factor of 0.959703 that was applied as a reduction to the base rate amount in the proposed rule due to the overall larger payment adjustments to be made under the PPS due to the proposed refinement. The commenter is correct that this reduction in the base rate resulted primarily from the change in the age multipliers estimated using 2012 through 2013 data compared to those estimated for the 2011 model using 2006 through 2008 data. Concerns about the age multipliers are addressed in responses to other comments in section II.B.1.c.i of this final rule. Notably, the prevalence of comorbidities for this refinement was assessed based only on comorbidities reported on CY2014 dialysis facility claims for payment as case-mix adjusters. This decreased the estimated prevalence of those case-mix adjusters relative to the process used for the CY2011 final rule, which based prevalence estimates on multiple claims types from other providers.

Comorbidities represent less of the total value of the adjusters than they did before the refinement and age represents much more of the value of the adjusters than they did before the refinement. We believe this will be a positive change for facilities because the age adjustment should pay out in full without any added documentation burden. When repeating the calculation described above with updated CY2014 claims data, we are finalizing an updated refinement budget-neutrality factor of 0.960319.

With regard to the reduction to the base rate for CY 2016, the refinement modeling which relies on ESRD facility claims and cost reports shifts the emphasis away from comorbidities (which proved difficult for facilities to obtain and now have less of an impact on the refinement budget-neutrality adjustment factor) to the age adjustments, which should be paid out. While the base rate has been further reduced by 4 percent to account for the increased value of the payment

adjusters following the refinement, maintaining five age categories makes it more likely that ESRD facilities will receive sufficient payment to offset the reduction to the base rate.

Comment: An MDO stated that they do not support the refinement budget-neutrality adjustment factor because it is forcing the base rate to be less than it could be. They indicated that the base rate should not be decreasing on an annual basis. An organization representing small and medium dialysis facilities commented that it is necessary and appropriate for the ESRD PPS to contain case-mix adjustments, however, the proposal to reduce the base rate to allow for the increased value of some case-mix adjusters will create greater payment risk for dialysis facilities and add further complexity to an already complicated payment system. The organization suggests that rather than increasing the value of the case-mix adjusters, CMS should increase the value of the base rate. Ensuring an adequate base rate will minimize loss in payment to providers due to flaws in the case-mix adjustment formula. An SDO recommended that CMS avoid placing so much emphasis on payment adjusters that the ESRD PPS base rate is reduced to $230.20.

Response: The refinement budget-neutrality adjustment factor is applied to pay for the increased value of the payment adjustments provided under the ESRD PPS following our updated regression analysis. In complying with the ATRA requirement to revise the case-mix adjustments in CY 2016, we had to apply a refinement budget-neutrality factor so that the refinement did not increase Medicare spending. We believe, however, that the adjustment values are more accurate and will be paid out more easily and therefore, although the base rate is reduced, ESRD facilities should receive additional payments through the payment adjustments. With regard to the comment that the base rate should not be decreasing on an annual basis, the reductions to the base rate were required by section 1881(b)(14)(F)(i)(I) of the Act, as amended

by section 217(b)(2)(A) of PAMA) and are applied in lieu of the drug utilization adjustment implemented in the CY 2014 ESRD PPS final rule (78 FR 72161).

In summary, for CY 2016 we are finalizing a base rate of $230.39. For this rule, the latest projection for the ESRDB market is 1.8 percent. As we stated above, in accordance with section 1881(b)(14)(F)(i)(I) of the Act, for CY 2016 this amount is reduced by 1.25 percent, which is calculated as 1.8 – 1.25 = 0.55. This amount is further reduced by the final CY 2016 multifactor productivity adjustment of 0.4, thus yielding a final update to the base rate of 0.15 percent for CY 2016 (0.55 – 0.4 = 0.15). Therefore, the CY 2015 ESRD PPS base rate of $239.43 is updated to $239.79 ($239.43 x 1.0015 = $239.79). Next, we applied the final wage index budget-neutrality adjustment factor of 1.000495 to yield a wage-adjusted base rate of $239.91 ($239.79 x 1.000495 = $239.91). Our last step in setting the base rate for CY 2016 is to apply the refinement budget-neutrality adjustment factor of 0.960319. The final CY 2016 ESRD PPS base rate is $230.39 ($239.91 x 0.960319 = $230.39).

3. Section 217(c) of PAMA and the ESRD PPS Drug Designation Process

As part of the CY 2016 ESRD PPS rulemaking, section 217(c) of PAMA requires the Secretary to implement a drug designation process for –

(1) Determining when a product is no longer an oral-only drug; and

(2) Including new injectable and intravenous products into the bundled payment under such system.

In accordance with section 217(c) of PAMA, we proposed a process that would allow us to recognize when an oral-only renal dialysis service drug or biological is no longer oral only and to include new injectable and intravenous products into the ESRD PPS bundled payment, and, when appropriate, to modify the ESRD PPS payment amount to reflect the costs of furnishing a

new injectable or intravenous renal dialysis service drug or biological that is not bundled in the ESRD PPS payment amount. We believe that this process, which we refer to as the drug designation process under the ESRD PPS, will provide a systematic method for including new injectable and intravenous drugs and biologicals that are designated as renal dialysis services in the ESRD PPS bundled payment.

a. Background

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement the ESRD PPS, under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The renal dialysis services that are included in the ESRD PPS bundle are described in section 1881(b)(14)(B) of the Act and include: (i) items and services included in the composite rate for renal dialysis services as of December 31, 2010; (ii) erythropoiesis stimulating agents (ESAs) and any oral form of such agents that are furnished to individuals for the treatment of ESRD; (iii) other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately under Title XVIII of the Act, and any oral equivalent form of such drug or biological; and (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of ESRD.

We implemented the ESRD PPS in the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214) and codified the definition of renal dialysis services at 42 CFR 413.171. In addition to former composite rate items and services and ESAs, we defined renal dialysis services at 42 CFR 413.171 as including other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral

form). In the CY 2011 ESRD PPS final rule (75 FR 49037 through 49053), we discussed the other drugs and biologicals referenced in paragraph (3) of the definition "Renal dialysis services" at 42 CFR 413.171 and finalized how they were included in the ESRD PPS. We explained that we interpreted clause (iii) as encompassing not only injectable drugs and biologicals (other than ESAs) used for the treatment of ESRD, but also all non-injectable drugs furnished under Title XVIII of the Act (75 FR 49039). Under this interpretation, the *any oral equivalent form of such drug or biological* language pertains to the oral versions of injectable drugs other than ESAs. In addition, as we discussed in section II.B.4 of the final rule (75 FR 49040), we concluded that, to the extent oral-only drugs and biologicals that are used for the treatment of ESRD do not fall within clause (iii) of the statutory definition of renal dialysis services, such drugs would fall under clause (iv).

In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), we explained that to identify drugs and biologicals that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biologicals billed on ESRD claims and evaluated each drug and biologicals to identify its category by indication or mode of action. We also explained that categorizing drugs and biological on the basis of drug action would allow us to determine which categories (and therefore, the drugs and biologicals within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

Using this approach, in our CY 2011 ESRD PPS final rule we established categories of drugs and biologicals that are <u>not</u> considered used for the treatment of ESRD (75 FR 49049-49051), categories of drugs and biologicals that are <u>always</u> considered used for the treatment of ESRD, and categories of drugs and biologicals that <u>may be</u> used for the treatment of ESRD but

are also commonly used to treat other conditions. Those drugs and biologicals that were identified as not used for the treatment of ESRD were not considered renal dialysis services and were not included in computing the base rate. The categories of drugs and biologicals that were always considered used for the treatment of ESRD were identified as access management, anemia management, anti-infectives (specifically vancomycin and daptomycin used to treat access site infections), bone and mineral metabolism, and cellular management (75 FR 49050). As we noted in the CY 2016 ESRD PPS proposed rule (80 FR 37830), we removed anti-infectives from the list of categories of drugs and biologicals that are included in the ESRD PPS base rate and not separately payable in the CY 2015 ESRD PPS final rule (79 FR 66149 through 66150). The categories of drugs that were always considered used for the treatment of ESRD have otherwise remained unchanged since we finalized them in the CY 2011 ESRD PPS final rule. The current categories of drugs that are included in the ESRD PPS base rate and that may be used for the treatment of ESRD but are also commonly used to treat other conditions are antiemetics, anti-infectives, antipruritics, anxiolytics, drugs used for excess fluid management, drugs used for fluid and electrolyte management including volume expanders, and pain management (analgesics) (79 FR 66150).

In the CY 2011 ESRD PPS final rule (75 FR 49050), we explained that for those categories of drugs and biologicals that are always considered used for the treatment of ESRD we used the payments for the drugs included in the category in computing the ESRD PPS base rate, that is, the injectable forms (previously covered under Part B) and oral or other forms of administration (covered under Part D). For purposes of the inclusion of payments related to the oral or other forms of administration for those drugs that are always considered used for the treatment of ESRD, we stated that based on our determination at the time of the final rule, there

were oral or other forms of injectable drugs only for the bone and mineral metabolism and cellular management categories. Therefore, we included the payments under Part D for oral vitamin D (calcitrol, doxercalcitrol and paracalcitrol) and oral levocarnitine in our computation of the base rate (75 FR 49042).

In response to a commenter's request to provide a specific list of ESRD-only drugs in the CY 2011 ESRD PPS final rule, we explained that we chose to identify ESRD drugs and biologicals by category rather than in a specific list because using categories of drugs and biologicals allows us to respond to changes in drug therapies over time based upon many factors including new developments, evidence-based medicine, and patient outcomes (75 FR 49050). By categorizing drugs and biologicals based on drug action, we can account for other drugs and biologicals that may be used for those same actions in the future under the ESRD PPS. We further explained that, while we have included drugs and biologicals used in 2007 in the final ESRD base rate, we recognize that these may change. Because there are many drugs and biologicals that have many uses and because new drugs and biologicals are being developed, we stated that we did not believe that a drug-specific list would be beneficial (75 FR 49050).

Rather than specifying the specific drugs and biologicals used for the treatment of ESRD, we identified drugs and biologicals based on the mechanism of action. We stated that we did not finalize a specific list of the drugs and biologicals because we did not want to inadvertently exclude drugs that may be substitutes for drugs identified and we wanted the ability to reflect new drugs and biologicals as they become available. We did, however, provide a list of the specific Part B drugs and biologicals that were included in the proposed and final ESRD PPS base rate in Table C in the Appendix to the CY 2011 ESRD PPS final rule (75 FR 49205 through 49209) and a list of the former Part D drugs that were bundled in the ESRD PPS in Table D in

the Appendix to that rule (75 FR 49210). We emphasized that drugs or biologicals furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management and bone and mineral metabolism will be considered a renal dialysis service under the ESRD PPS and will not be eligible for separate payment. We also noted that any ESRD drugs or biologicals developed in the future that are administered by a route of administration other than injection or oral would be considered renal dialysis services and would be in the ESRD PPS bundled base rate. We also stated that any drug or biological used as a substitute for a drug or biological that was included in the ESRD PPS bundled base rate would also be a renal dialysis service and would not be eligible for separate payment (75 FR 49050).

In the CY 2011 ESRD PPS final rule (75 FR 49050 through 49051), we explained that for categories of drugs and biologicals that may be used for the treatment of ESRD but are also commonly used to treat other conditions, we used the payments made under Part B in 2007 for these drugs in computing the ESRD PPS base rate, which only included payments made for the injectable forms of the drugs. We excluded the Part D payments for the oral (or other form of administration) substitutes for the drugs and biologicals described above because they were not furnished or billed by ESRD facilities or furnished in conjunction with dialysis treatments (75 FR 49051). For those reasons, we presumed that these drugs and biologicals that were paid under Part D were prescribed for reasons other than for the treatment of ESRD. However, we noted that if these drugs and biologicals currently paid under Part D are furnished by an ESRD facility for the treatment of ESRD, they would be considered renal dialysis services and we would not provide separate payment.

In the CY 2011 ESRD PPS final rule (75 FR 49075), we included in Table 19 the Medicare allowable payments for all of the components of the ESRD PPS base rate for CY 2007

inflated to CY 2009, including payments for drugs and biologicals and the amount each contributed to the base rate, except for the oral-only renal dialysis drugs where payment under the ESRD PPS has been delayed. In the CY 2016 ESRD PPS proposed rule (80 FR 37832), we reiterated that we grouped the injectable and intravenous drugs and biologicals by action, or more specifically, into functional categories for the purpose of adding new drugs or biologicals with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We also stated that in past rules we referred to these categories as *drug categories* but we believe the term *functional categories* is more precise and better reflects how we have used the categories. We discuss the proposal and the finalized definition of this term in 42 CFR 413.234(a) later in this discussion.

In the proposed rule (80 FR 37833), we explained that since the ESRD PPS CY 2011 final rule was published, the base rate has been updated by the ESRDB market basket, discussed in section II.B.2. of this final rule, which reflects changes in the drug price indices. In addition, we stated that we designated several new drugs and biologicals as renal dialysis services because they fit within the functional categories captured in the base rate and no adjustment to the base rate has been made, consistent with the CY 2011 ESRD PPS final rule. We proposed that this approach of considering drugs and biologicals as included in the ESRD PPS base rate if they fit within one of our functional categories would continue as part of the drug designation process described below.

b. Final Drug Designation Process

i. Inclusion of New Injectable and Intravenous Products in the ESRD PPS Bundled Payment

In the CY 2016 ESRD PPS proposed rule (80 FR 37831), in accordance with section

217(c)(2) of PAMA, we proposed to include new injectable and intravenous products in the ESRD PPS bundled payment by first determining whether the new injectable or intravenous products are reflected currently in the ESRD PPS. We proposed to make this determination by assessing whether the product can be used to treat or manage a condition for which there is an ESRD PPS functional category. We stated that under our proposed regulation at 42 CFR 413.234(b)(1), if the new injectable or intravenous product can be used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product would be considered reflected in the ESRD PPS bundled payment and no separate payment would be available. Specifically, any new drug, biosimilar, or biologic that fits into one of the ESRD functional categories would be considered to be included in the ESRD PPS. We stated that these drugs and biologicals would count toward the calculation of an outlier payment. In the calculation of the outlier payment, we price drugs using the ASP pricing methodology, which is generally ASP+6 percent. We believe that this step in our process codifies in regulation our existing policy of using the functional categories to add drugs to the bundled payment, which we finalized in the CY 2011 ESRD PPS final rule (75 FR 49047 through 49052).

Also, we proposed that if the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product would not be considered included in the ESRD PPS bundled payment, and we proposed to take the following steps as described in our proposed regulation at §413.234(b)(2): (i) revise an existing ESRD PPS functional category or add a new ESRD PPS functional category for the condition that the new injectable or intravenous product is used to treat or manage; (ii) pay for the new injectable or intravenous product using the transitional drug add-on payment adjustment discussed below; and (iii) add the new injectable or intravenous

product to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

For purposes of the drug designation process, we proposed to define a new injectable or intravenous product in our regulation at §413.234(a) as an injectable or intravenous product that is approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, assigned a Healthcare Common Procedure Coding System (HCPCS) code, and designated by CMS as a renal dialysis service under §413.171. In the proposed rule (80 FR 37832), we explained that following FDA approval, injectable or intravenous drugs then go through a process to establish a billing code, specifically a HCPCS code. Information regarding the HCPCS process is available on the CMS website at https://www.cms.gov/medicare/coding/MedHCPCSGenInfo/Application_Form_and_Instructions.html. We stated that we would designate injectable and intravenous products as renal dialysis services under the ESRD PPS by analyzing the information in the FDA-approved labeling, the HCPCS application information, including studies submitted as part of these two standardized processes. We indicated that a change request would be issued that will provide notice that the drug is included in the ESRD PPS bundle and is available for use, allowing patients to have access to the new drug.

We proposed to codify the term ESRD PPS functional category at §413.234(a) as a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. We explained that we would codify this definition in regulation text to formalize the approach we adopted in CY 2011 because the drug designation process is dependent on the functional categories. In the

proposed rule (80 FR 37832), we listed the 11 functional categories that are used to treat or manage conditions associated with ESRD, which are displayed in Table 8A below.

TABLE 8A: ESRD PPS FUNCTIONAL CATEGORIES

Category	**Rationale for Association**
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	Used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications and are included for their action to treat itching secondary to dialysis.
Anxiolytic	Drugs in this classification have multiple actions but are included for the treatment of restless leg syndrome secondary to dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat graft site pain and to treat pain medication overdose.

We proposed to determine whether a new injectable or intravenous product falls into one of our existing functional categories by assessing whether the product is used to treat or manage the condition for which we have created a category. We believe that this approach to determining whether a new drug falls into one of our existing drug categories is consistent with

the policy we finalized in the CY 2011 ESRD PPS final rule (75 FR 49047 through 49052).

The comments we received and our responses are below.

Comment: A national organization of dialysis organizations, an organization of kidney care providers, manufacturers, and patient advocates, and an LDO commented that CMS does not have the statutory authority to add new renal dialysis services to the ESRD PPS bundle. The commenters believe that section 217(c) of PAMA only permits CMS to develop a process for adding new drugs to the bundle, which they contend is fundamentally different than permitting CMS to actually add new drugs to the bundle. One commenter stated that, in contradicting the plain meaning of section 217(c)(2) of PAMA, the proposed rule renders it meaningless.

One commenter asserted that section 217(c)(2) of PAMA cannot be read in isolation of section 1881(b)(14)(B) of the Act as the sole authority to add new drugs to the bundle; rather, section 217(c)(2) must be read in concert with section 1881(b)(14)(B), which does not permit new injectable or intravenous drugs to be added to the bundle. Other commenters stated that CMS seems to assume, incorrectly, that the existing statutory definition of renal dialysis services can accommodate new injectable or intravenous drugs. A number of commenters echoed this contention, asserting that the text, structure, and purpose of section 1881(b)(14)(B) of the Act show clear congressional intent not to allow CMS to add new injectable or intravenous drugs into any of the four articulated categories of renal dialysis services. The commenters explained that PAMA did not amend the definition of renal dialysis services in section 1881(b)(14)(B) of the Act, and therefore CMS is not authorized to add new ESRD drugs to the ESRD PPS bundled payment. Specifically, section 1881(b)(14)(B)(i) includes only items and services being paid for under the previous composite rate payment system as of December 31, 2010. They further explained that section 1881(b)(14)(B)(ii) refers only to ESAs and any oral form of ESAs

furnished for ESRD treatment, and the plain language of this provision excludes non-ESAs. With respect to section 1881(b)(14)(B)(iii), the commenters stated that this category excludes new injectable or intravenous drugs because, even if a new injectable or intravenous drug is being furnished to individuals for the treatment of ESRD, it would not have been separately paid for under the Act prior to January 1, 2011, and therefore, for CMS to read section 1881(b)(14)(B)(iv) as allowing the addition of new injectable or intravenous products to the bundle, renders category (iii) meaningless. Some commenters stated that section 1881(b)(14)(B) of the Act is clear and unambiguous. Another commenter stated that the proposed process violates step one under Chevron v. NRDC, 467 U.S. 837 (1984) because the statute's language is clear and unambiguous.

Response: We believe we have the authority to add new renal dialysis services to the bundle under both sections 1881(b)(14)(B) of the Act and 217(c)(2) of PAMA. First, we read section 1881(b)(14)(B)(iii) as requiring the inclusion of a specific category of drugs in the bundle—that is, drugs and biologicals, including those with only an oral form, furnished to individuals for the treatment of ESRD and for which separate payment was made prior to January 1, 2011. We also read section 1881(b)(14)(B)(iv) as specifying a different category of items that must be included in the bundle—that is, items and services, which includes drugs and biologicals, not specified by sections 1881(b)(14)(B)(i), (ii), or (iii). Second, we read the language of section 217(c)(2) of PAMA—"the Secretary of Health and Human Services . . . shall establish a process for . . . including new injectable and intravenous products into the bundled payment system"—as more than a directive to simply develop an inoperative scheme. We believe the provision requires us to both define and implement a drug designation process for including new injectable and intravenous products into the bundle.

Comment: As several commenters noted that the Administrative Procedure Act (APA) precludes CMS from assuming that new injectable or intravenous drugs can constitute renal dialysis services because the application of that assumption constitutes CMS adopting a policy without going through notice- and -comment rulemaking. Several commenters further indicated that all new drugs should be added to the bundle only through notice-and-comment rulemaking. Specifically, when CMS is determining that a drug or biological (whether it is substantially the same as a drug or biological currently in the bundle or not) should be added to the bundle, all data should be presented and the process should be complete and transparent to allow interested stakeholders to evaluate the proposals before they are finalized. While they acknowledge that there would be a gap between launch of the new product and publication of a proposed and final rule, they strongly recommend that CMS use an interim rulemaking process or guidance to allow the product to be paid for separately outside the bundle until the rulemaking process can be completed. They do not believe such substantive changes in policy and payment rates should be adopted through sub-regulatory guidance. Other commenters pointed out that the proposed rule does not specify any public process for adding a new drug to an existing category or creating a new category, which is problematic given that serious APA concerns are raised if a regulated party is not given an opportunity to comment on a policy that affects settled legal rights.

A national dialysis organization strongly urged CMS to adopt the same process for all new drugs and biologicals unless they are substantially the same as drugs or biologicals currently paid for under the ESRD PPS payment rate. For new drugs or biologicals that are substantially the same as drugs or biologicals currently paid under the ESRD PPS, the organization supported incorporating them into the PPS on a case-by-case basis using notice-and-comment rulemaking and foregoing the transition period if it can be shown that the PPS rate is adequate to cover the

cost of the drug or biological. If the rate is inadequate to cover the cost of the new drug, the transitional drug add-on payment adjustment should apply.

Finally, another commenter stated that the proposed rule does not specify any public process for adding a new drug to an existing category or creating a new category, which the commenter believes raises serious APA concerns. They urged CMS to utilize notice-and-comment rulemaking to add new drugs to the ESRD PPS.

Response: As stated above, the functional categories and our process for adding new drugs to the bundled payment when they fit into those functional categories was adopted in response to public comments in the CY 2011 ESRD PPS final rule and has been our policy since the inception of the ESRD PPS. We've added new drugs to the ESRD PPS bundled payment consistent with this policy in the years since the ESRD PPS was implemented and announced those additions using change requests. These decisions have not been controversial because the drugs were substantially the same as other drugs in the functional category. However, in response to commenters' request for the opportunity to provide input for determinations in the future that may be controversial, we will consider in future rulemaking establishing an informal process for obtaining public input when new injectable or intravenous products are added to an existing functional category.

We do not believe it is necessary to add injectable and intravenous products to the bundled payment using notice-and-comment rulemaking because we have already included dollars in the base rate to account for products used to treat or manage conditions associated with ESRD for which we have adopted functional categories – consistent with the process we adopted through notice-and-comment rulemaking – and we believe that new drugs used to treat or manage the same conditions will be adequately accounted for by those categories. We also

believe that our process of reviewing the FDA labeling data and information, reviewing the information presented for obtaining a HCPCS code, and CMS internal medical review following the announcement of the FDA and HCPCS decision, allows new drugs to be added to the bundled payment as quickly as possible, whereas subjecting these additions to notice-and-comment rulemaking would significantly delay inclusion of new drugs in the PPS, even though there are already dollars in the base rate to account for those products and the process for adding these products to the bundle has been in place since 2011. For new renal dialysis service drugs or biologicals that do not fit within one of our existing categories, however, we will revise or adopt a new functional category, pay a transitional add-on payment adjustment for the new product, and make any necessary changes to the base rate to account for the new product, and all of those steps will be subject to notice-and-comment rulemaking.

Comment: An LDO objected to the proposed definition of functional category as a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. They believe the definition expands the statutory definition of renal dialysis services by implying that the categories now may include any drugs associated with ESRD, without regard to whether those drugs are actually essential to the delivery of maintenance dialysis. A national dialysis organization requested that CMS affirmatively state that the bundled drugs must be renal dialysis services for the treatment of ESRD and connected to/contemporaneous with the dialysis procedure. The commenters suggested changes to the descriptions of some of the functional categories to more precisely define the drugs that would fit into the categories. In particular, the commenters suggested changes to the anti-infective, pain management, and anxiolytic functional categories to better describe how each of the categories relate to the treatment of ESRD in

accordance with the statute. The organization suggested that language be removed from the description of the antiemetic functional category to eliminate drugs used to treat nausea caused by the use of oral-only drugs because these drugs are paid outside the bundle and are covered under a separate benefit category.

An organization of home dialysis patients also requested that CMS put a policy in place to ensure that the drugs included in the bundle relate to dialysis care only and not overall care. The commenter gave the example of when oral-only transplant medications would be added to the bundle. They noted that some patients need to stay on their transplant medications even when the kidney no longer functions well because the drugs help prevent rejection of the kidney and the increase of more antibodies. The commenter stated that they understand the need to control costs, but they believed the proposed drug designation process was excessive and could hinder innovation and prevent new treatment options from entering the marketplace.

Response: We did not intend to expand the functional categories beyond the drugs and biologicals used in the treatment of ESRD, and we do not believe our definition of ESRD PPS functional category in the regulations at 42 CFR 413.234 does that. With regard to limiting renal dialysis services to those that are essential to the delivery of maintenance dialysis, we note that we believe the drugs that are and will be included in the ESRD PPS bundled payment are limited to those that are essential to the delivery of maintenance dialysis. In particular, we believe all drugs that fit into our existing functional categories (which have been revised slightly as described below) are essential to the delivery of maintenance dialysis because they are necessary to treat or manage conditions associated with the beneficiary's ESRD, and thus, they enable the beneficiary to remain sufficiently healthy to continue receiving maintenance dialysis.

With regard to the concern about bundling oral-only transplant medications into the ESRD PPS, we note that immunosuppressive drugs are covered under Part B under a separate benefit category and those drugs do not fit into the functional categories under the ESRD PPS.

Regarding the commenter's concerns about overly broad definitions for the anti-infective, pain management, and anxiolytic categories, we note that we moved the anti-infective functional group from the always used for the treatment of ESRD list to the may be used for the treatment of ESRD list for precisely the reasons given by the commenter. We recognize that there could be medical situations in which the beneficiary requires an anti-infective that has nothing to do with ESRD and access site infections or peritonitis. Therefore, when ESRD facilities furnish drugs or biologicals that are identified on Table 8B as those that may be used for the treatment of ESRD (for example, the pain management and anxiolytic functional categories) for reasons other than the treatment of ESRD, they can receive separate payment for the drug when it is reported with the AY modifier on the claim. Appending the AY modifier to the line item drug or biological on the claim is an attestation that the item or service is not being furnished for the treatment of ESRD.

We have carefully reviewed the commenters' recommendations regarding narrowing the functional categories to describe how the category relates to the treatment of ESRD. Many of the commenters' recommendations are consistent with how we believe the categories should be defined and help to ensure that the drugs that fall into them are those that are essential for the delivery of maintenance dialysis. Therefore, we are adopting several of them. The final functional categories as revised with suggestions from commenters are included in Table 8B, with the commenters' suggestions italicized.

TABLE 8B: ESRD PPS FUNCTIONAL CATEGORIES

Category	Rationale for Association
DRUGS ALWAYS CONSIDERED USED FOR THE TREATMENT OF ESRD	
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
DRUGS THAT MAY BE USED FOR THE TREATMENT OF ESRD	
Antiemetic	Used to prevent or treat nausea and vomiting *related to* dialysis. Excludes antiemetics *used for purposes unrelated to dialysis, such as those* used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat *vascular access-related and peritonitis* infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications. *Use within an ESRD functional category* includes treatment for itching *related to* dialysis.
Anxiolytic	Drugs in this classification have multiple actions. *Use within an ESRD functional category* include treatment of restless leg syndrome *related to* dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat *vascular access* site pain and to treat pain medication overdose, *when the overdose is related to medication provided to treat vascular access site pain.*

We did not incorporate the commenters' recommended language that would remove from the antiemetic functional category drugs used to treat nausea resulting from oral-only drugs that are currently paid for outside the bundle. The commenter's rationale was that the oral-only drugs are covered under a separate benefit category. We believe, however, that if the oral-only drugs

are being given for the treatment of ESRD and they cause nausea, then the drug used for treatment of that nausea falls within the antiemetic functional group covered by the ESRD PPS. Specifically, if drugs are used to treat nausea caused by the oral-only drugs designated as renal dialysis services (calcimimetics and phosphate binders), then the drug used for the treatment of the nausea falls within the functional group covered by the ESRD PPS. However, when other Part D oral-only drugs are prescribed to treat non-ESRD conditions and those drugs cause nausea, then the drugs used to treat the nausea would also be separately covered.

Finally, with respect to the comment that the drug designation process would hinder innovation, we note that for novel drugs that are used to treat or manage a condition for which we do not have a functional category, we will revise an existing category or adopt a new category to cover the drug and pay a transitional drug add-on payment adjustment for at least 2 years. For drugs that are used to treat or manage a condition for which we have a functional category, we note that we have not encountered high cost drugs that we believe would not be accounted for by the existing functional categories. We do, however, appreciate the commenters' concerns and we anticipate addressing the possibility of the unique situations they have identified in future rulemaking.

Comment: One national dialysis organization stated that adding new drugs or biologicals to existing functional categories presumes that CMS can exercise clinical judgment as to what drugs will be related to the treatment of ESRD before the majority of clinical professionals have had the opportunity to use them.

Response: We define a new injectable or intravenous product in our regulation at §413.234(a) as an injectable or intravenous product that is approved by the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service

Act, commercially available, assigned a Healthcare Common Procedure Coding System (HCPCS) code, and designated by CMS as a renal dialysis service under §413.171. In the proposed rule (80 FR 37832), we explained that following the clinical trials intended to support FDA approval, and after FDA approves the drugs for use in ESRD patients, injectable or intravenous drugs then go through a process to establish a billing code, that is, the HCPCS code process. The HCPCS process involves the input of physicians and stakeholders. Additionally, if a drug will be used for both the treatment of ESRD and for the treatment of non-ESRD conditions, it would receive two HCPCS codes. We stated that we would designate injectable and intravenous products as renal dialysis services under the ESRD PPS by analyzing the information in the FDA-approved labeling, the HCPCS application information, and a review by CMS medical officers and medical personnel, in addition to reviewing clinical studies submitted. In all three of these steps, physicians assist in the determination as to whether a new drug is a renal dialysis service as well as whether the new drug fits into one of the functional categories. We believe the information provided for the FDA approval, HCPCS coding process, and the CMS internal review by medical professionals will provide sufficient information over a period of time for CMS to determine the following: 1) Whether a product is a new injectable or intravenous drug; 2) whether the drug is a renal dialysis service; and 3) whether the drug fits into an existing functional category. If a new drug is not considered to be a renal dialysis service, then it will not be a part of the ESRD PPS bundle.

Comment: One professional association suggested that when new agents are newly introduced and have a role either similar to or identical to existing agents and are not associated with better outcomes, they should be included in the current PPS without additional payment.

Response: We agree with the commenter's suggestion for adding new drugs whose role

is either similar or identical to existing agents to the existing functional categories. We believe that the drug designation process finalized at 42 CFR 413.234 addresses the commenter's concern.

Comment: A large dialysis organization commented that the proposal does not conform to the PAMA directive to establish a process for including new injectable and intravenous products into the ESRD PPS bundled payment, but instead established a regulatory process for including only new functional categories of drugs within the ESRD PPS bundled payment. Only if a new drug also represents a new *functional category* would the proposed transitional drug add-on payment adjustment apply. The organization believes the proposed rule requires an extremely broad notion of functional categories of drugs included in the ESRD PPS that expands the ESRD PPS in a manner outside of the statutory construct. With respect to the process for including new injectable or intravenous drugs into the PPS and the use of the functional categories of ESRD drugs and biologicals, commenters expressed concern about the overly broad definitions of the functional categories and the proposal to categorize injectable and intravenous drugs and biologicals as within the bundle if they seem to fit into one of the functional categories. The commenters stated that it is even more concerning that new categories will be added if the current broadly-defined categories do not incorporate new injectable or intravenous drugs or biologicals. The organization believes that these policy choices would result in no such drug or biological being defined as new, which is inconsistent with the congressional interest in establishing a process for including new injectable and intravenous products into the bundled payment.

A dialysis organization and a professional association asked that CMS consider a pass-through payment for all new drugs that are considered truly new. They recommend a rate of 106

percent of ASP, minus the portion of the ESRD PPS base rate that CMS determines is attributable to the category of drugs that corresponds to a truly new drug.

Response: In accordance with section 217(c) of PAMA, we proposed a process that would allow us to include new injectable and intravenous products into the ESRD PPS bundled payment, and, when appropriate, to modify the ESRD PPS payment amount to reflect the costs of furnishing a new injectable or intravenous renal dialysis service drug or biological that is not bundled in the ESRD PPS payment amount. We believe the proposal conforms to the PAMA directive to establish a process for including new injectable and intravenous products into the ESRD PPS bundled payment. The commenter seems to be concerned not with the process of adding new drugs to existing functional categories as described in the CY 2011 final rule, but with payment of those new injectable and intravenous drugs that fit into the functional categories. As indicated in the CY 2011 final rule, the current ESRD PPS has dollars built into the base rate for drugs within the functional categories. If a new drug is available, a determination is made as to whether it is a renal dialysis service drug. This is determined through reviewing the publicly-available data and information underlying the FDA approval process, approved labeling, and the information provided during the HCPCS review process and following an internal CMS medical review process. Next, a determination is made as to whether the drug fits into one of the functional categories. The proposed transitional drug add-on payment adjustment is only made for new injectable and intravenous drugs used for the treatment of ESRD for which there is no current functional category because we've included dollars in the base rate to account for drugs used to treat or manage conditions associated with ESRD for which we have a functional category. However, as there is nothing in the base rate to account for drugs in a new functional group, those drugs would be paid using the pricing methodologies

specified under section 1847A of the Act (which could include ASP + 6 percent) for a minimum of 2 years. With respect to the commenters' concern that the functional categories are too broad, we note that we adopted several of the commenters' suggested changes to the descriptions of the functional categories above.

Comment: An LDO and a drug manufacturer stated that the ESRD statute requires budget neutrality apply only in 2011; they do not believe the Congress intended for CMS to add new items or services to the bundle without increasing the overall Medicare spending for ESRD. In other words, the Congress has not required CMS to reduce spending on currently bundled items and services when it adds new items or services to the bundle. A national dialysis organization indicated that CMS must ensure that limited conceptual views of budget neutrality will not jeopardize good policy decisions and ensure that reimbursement resources are adequate to provide necessary products and services to beneficiaries.

Response: We agree with the commenter with respect to new drugs that do not fit within one of the functional categories. Where appropriate, dollars will be added to the base rate to account for those drugs that fall within the new functional categories and this would increase ESRD expenditures. However, for drugs that are used to treat or manage conditions associated with ESRD for which we have existing functional categories, we do not believe it would be appropriate to increase Medicare expenditures by providing additional payment beyond the ESRD PPS base rate. We note that the ESRD bundled (ESRDB) market basket updates the PPS base rate annually for input price changes for providing renal dialysis services as specified by the bundle. The ESRDB market basket update accounts for price changes of the drugs and biologicals that are reflected in the ESRD PPS base rate. For example, the market basket includes price indices, published by the Bureau of Labor Statistics, such as the PPI Biological

Products for Human Use and the PPI Vitamin, Nutrient, and Hematinic Preparations. The ESRDB market basket is discussed in section II.B.2 of this final rule and the cost weight and price proxies are discussed in detail in the CY 2015 final rule 79 FR 66129 through 66133. We appreciate the commenters' concerns regarding the cost of new drugs that fall within the existing functional categories and we anticipate addressing the possibility of the unique situations they have identified in future rulemaking.

Comment: For new drugs, one organization proposes a different process adapted largely from the hospital OPPS mechanism for incorporating new drugs into its ambulatory payment classification (APC) system, which is a reasonable and known method to incorporate new drugs into an existing PPS. The OPPS mechanism provides additional payment (pass-through payment) for a limited time period (2 to 3 years) to account for the cost of new drugs before the cost is able to be fully reflected in the applicable APC. Two drug industry groups and three drug manufacturers commented that the proposed eligibility criteria for obtaining the transitional drug add-on payment are overly restrictive and will prevent this policy from motivating the provision of high-quality, efficient, and effective care. They agree that we should decouple the transitional drug add-on from the functional categories and provide the additional payment for all new injectable and intravenous drugs and biologicals and oral equivalents for 2 to 3 years, similar to the IPPS or the OPPS. A professional association recommends that when a new product for dialysis care becomes available, new money should be allocated to pay for the new product.

One of the drug manufacturers believes that these new renal dialysis service drugs should meet similar newness criteria as those that CMS applies in the IPPS for the New Technology Add-On Payment. Under that program, a specific medical service or technology is considered new for purposes of new technology add-on payments until such time as Medicare data are

available to fully reflect the cost of the technology and the system is recalibrated.

Response: If a new drug is determined to be a renal dialysis service and it does not fit into a current functional category, then no dollars have been included in the base rate for the functional category. A new functional category will be proposed through notice-and-comment rulemaking and the drug will be paid for using a transitional drug-add on payment adjustment for at least 2 years while utilization data are collected. We understand the commenters' recommendation that CMS should make pass-through payments for all new drugs, including both those that fit into current functional groups and those that do not in a manner similar to the OPPS pass-through payments process. We note that while the OPPS pass-through policy provides additional payment for new drugs, those payments are made in a budget-neutral manner. If we were to provide additional payment for new drugs that fit into an existing functional category, we would similarly want to make such a policy budget-neutral because we have already accounted for those drugs in the PPS base rate. We believe our process is preferable because it would not involve reducing the base rate to fund additional payments for new drugs that fit into an existing functional category.

Under the new technology add-on payment (NTAP) policy, additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. Importantly, not all new technologies or medical services for which an application is submitted to CMS are determined to be eligible for the NTAP.

We believe the drug designation process will allow us to pay the transitional drug add-on

payment adjustment for more new products than if we utilized a policy similar to the NTAP. This is because under our drug designation process, all new injectable and intravenous renal dialysis service products that do not fit into an existing functional category will be paid for using the transitional drug add-on payment adjustment for a minimum of 2 years and the products will not need to meet clinical improvement or cost criteria. In addition, the transitional drug add-on payment adjustment is calculated using the pricing methodologies specified in section 1847A of the Act. We believe payment for these drugs using those pricing methodologies will capture the cost of expensive new injectable or intravenous products and be consistent with how drugs and biologicals are paid under Part B.

Comment: A large dialysis organization stated that defining new drugs requires special consideration of cost. They suggested that rather than comparing the cost of the new drug to the ESRD PPS base rate, we should compare it to the cost of the existing drugs in the same CMS-defined "mode of action" category. In such a case, a drug might qualify for payment of the transitional drug add-on payment adjustment on the basis that its cost per unit or dosage exceeds a specified percentage (for example 150 percent) of the average cost per unit or dosage of the top three most common drugs in the same category (based on utilization data). This comparison would demonstrate that the amount allocated to that category in the ESRD PPS base rate is insufficient to cover the cost of the new drug. An LDO stated that by failing to account for the costs of new drugs that enter the market, the proposed rule represents a severe departure from the fundamental cost basis of the ESRD PPS. An organization representing small and medium dialysis facilities and an MDO expressed concern that many drugs would be automatically included in the bundle without any evaluation of the drug's cost or whether it should be considered the standard of care for dialysis patients.

A drug manufacturer believes the transitional drug add-on payment adjustment should apply to all new drugs and, in particular, drugs designated as priorities by the FDA under the Generating Antibiotics Incentives Now (GAIN) Act or the Qualified Infectious Disease Product (QIDP) Act, not just those drugs that are used to treat or manage a condition for which we have not adopted a functional category, in order to promote access to new therapies and encourage innovation in ESRD care. They pointed out that the functional categories are very comprehensive and capture every known condition related to ESRD. They indicated that under the proposed approach CMS would make no additional payment regardless of whether the drug has a novel mechanism of action, new FDA approval, or other distinguishing characteristics. The commenter believes the CMS proposal sends conflicting messages to manufacturers about the importance of developing new treatments for this underserved patient population.

An organization of nonprofit SDOs commented that CMS should provide additional payment for drugs and biologicals that would fall within an existing functional category that represent a significant clinical improvement and may warrant a higher payment. The commenter noted that utilizing the outlier policy to address these high costs ultimately comes at the expense of the bundled base rate and would not cover the full cost of the new drug or biologic.

Response: We appreciate the commenters' suggestion to compare the cost of new drugs to the cost of existing drugs in the same functional categories and to utilize the transitional drug add-on payment adjustment for all new drugs. Our intent in adopting the functional categories in the CY 2011 ESRD PPS final rule was to be as comprehensive as possible with regard to the drugs used in the treatment of ESRD at the time the rule was written. We are concerned that comparing the cost of new drugs and biologicals to the existing drugs in a category would impact drug manufacturers' drug pricing strategy and marketing and lead to higher prices for all new

drugs. Because our intent is to better align ESRD PPS payment with resource utilization, including the utilization of new drugs that would fit into the current functional groups and those that would fit into a new functional category, we will consider in future rulemaking how to address these unique situations. The commenters' suggestions, including a review of the drugs designated as priorities by the FDA under the Generating Antibiotics Incentives Now (GAIN) Act or the Qualified Infectious Disease Product (QIDP) Act, are the type of input we would seek from stakeholders if such a process were to be implemented. In future rulemaking, we plan to address these unique situations by considering ESRD facility resource use, supporting novel therapies for ESRD patients, and balancing the risk of including new drugs for both CMS and the dialysis facilities.

We agree with the commenter who noted that while the outlier policy was included to mitigate the risk of high-cost patients, by design, it would not cover the full cost of a new drug or biologic because outlier payments are made only for costs above the fixed dollar loss ratio. In response to the concern that drugs would be automatically included in the bundle without any evaluation of whether they should be included in a dialysis patient's standard of care, we note that a new drug that would potentially be considered a renal dialysis service drug would only be included in a current functional category if the FDA indicated the drug was for treatment of ESRD patients, it obtained a HCPCS code, and a review performed by CMS medical officers and subject matter experts confirms that the new drug is a renal dialysis service and covered under a current functional category. This review will take into account reports of efficacy, adverse events and utilization patterns. Also, we note that the inclusion of a new drug in the ESRD PPS bundled payment does not require that it be prescribed to a particular beneficiary. Rather, the patient and their nephrologist should determine the patient's plan of care.

With regard to the comment that CMS would make no additional payment in the future for any new drugs, we do not believe this will be the case. Since publication of the CY 2011 ESRD PPS final rule, CMS has been introduced to novel therapies and drugs that are under development that would require new functional categories. As a result, the drug designation process was designed to address potential new therapies that would necessitate additional payment, at least temporarily in the form of a transitional drug add-on payment adjustment, and perhaps permanently in the form of a change to the base rate.

Comment: A national dialysis organization with the support of other dialysis organizations provided an example of the process they are recommending using with an anti-infective as the new drug in the example. The commenter indicated that the determinations in each step of the process would be made through notice-and-comment rulemaking with CMS providing sufficient data to allow interested stakeholders to fully evaluate the proposals.

Step 1: Determine if the injectable or intravenous drug/biological is substantially the same as a drug/biological that is related to the treatment of ESRD and currently within the ESRD PPS. In the example provided, the anti-infective would likely be used to treat vascular access-related infections. If the anti-infective is substantially the same as drugs currently used to treat infections related to a patient's catheter (for example), then it would be added to the bundle. If, however, the ESRD PPS rate is likely insufficient to cover the cost of providing the drug it should be evaluated through a transition period.

Step 2: Determine the utilization and cost of the injectable and intravenous drug/biological before incorporating it into the bundle. In the example, if the new anti-infective is not substantially the same as an existing drug in the bundle, CMS would establish a 2-3 year transition period during which facilities would be paid separately for the drug at ASP+ 6 percent

under Part B and not as an ESRD service.

Step 3: Determine if the injectable and intravenous drug/biological is a renal dialysis service. Based upon the information collected during the transition period, CMS through notice-and-comment rulemaking would determine whether the item is a renal dialysis service. If so, CMS would value the Part B and beneficiary costs of the item (determined at the time the item is added to the bundle) and add that amount to the base rate without applying the budget neutrality construct.

Another drug manufacturer commented that CMS did not provide enough information about how the cost for new drugs would be incorporated. Several commenters similarly commented that when trying to determine whether an injectable or intravenous drug or biological should be added to the bundle, CMS will need to determine whether it is substantially the same as other drugs or biologicals currently in the bundle. Commenters supported incorporating new drugs or biologicals that are substantially the same as drugs or biologicals currently paid under the ESRD PPS into the bundled payment on a case-by-case basis, foregoing the transition period if it can be shown that the PPS base rate is adequate to cover the cost of the drug or biological. However, commenters stated that if the rate is inadequate to cover the cost of the new drug, the transitional drug add-on payment adjustment should apply to the PPS payment. Commenters noted that it would not be appropriate to add such drugs and biologicals to the bundle without first learning about their utilization patterns or costs and without adjusting the payment rate in a non-budget-neutral manner.

A national dialysis patient advocacy organization explained that if new products are immediately added to the bundle without additional payment it would curtail innovation in treatments for people on dialysis. They believe clinicians should have the ability to evaluate the

appropriate use of a new product and its effect on patient outcomes and that the proposed rule did not allow for this. The commenter explained that Kidney Disease Improving Global Outcomes (KDIGO) and Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines are often updated when evidence of improved therapies on patient outcomes are made available and that this rigorous and evidence-based process is extremely important in guiding widespread treatment decisions in nephrology. The commenter expressed concern that under the proposed rule, reimbursement and contracting arrangements could instead dictate utilization of a product before real world evidence on patient outcomes is ever generated.

Response: We appreciate the commenters' input into the process of determining whether a drug is a renal dialysis service, and if so, whether it fits into one of the current functional categories. The focus of the commenter's suggested three steps seems to be on payment, with the determination of whether a new drug warrants additional payment depending on a determination of whether a new drug is substantially the same as an existing drug. It is unclear to us, however, whether substantially the same means that the new drug has been classified as a generic for an existing drug; that it acts on the same biochemical pathways as a drug currently in the bundle; that there is the same interaction of the drug with its receptors at a molecular level as a drug in the category; or that the new drug does not cost substantially the same as another drug currently in the category. It is unclear what the commenter means when they use the phrase substantially the same to describe a new drug. Nonetheless, we believe the process we proposed is preferable to processes that would use any of the possible substantially the same scenarios described above because we already have dollars in the base rate for drugs in the current functional categories. As we stated previously, we believe that if we adopted the commenter's recommendation, we would encourage over-pricing of all new intravenous and injectable drugs.

The current functional categories include drugs that have demonstrated efficacy as renal dialysis services in the treatment of ESRD. As CMS does not dictate utilization of a drug, the addition of new drugs and biologics to the functional groups is to provide choice to the dialysis suppliers and availability of new products to the beneficiaries. We will monitor changes in utilization of those new drugs by the medical community. Inclusion of a drug in the bundle does not require that nephrologists prescribe it.

If the drug does not fall within one of the functional categories, then a determination will be made as to whether the drug is a renal dialysis service, and a new functional category will be proposed through notice-and-comment rulemaking. A transitional drug add-on payment will be made for a minimum of 2 years. During that time utilization data will be gathered. At the end of that time, the drug will be included within its new functional category and the base rate may or may not be modified to account for the cost of the drug, depending upon what the utilization data show.

With respect to what seem to be commenters' specific concerns that certain high cost new drugs may not be adequately accounted for in the ESRD PPS base rate, we note that we anticipate making further proposals related to the drug designation process to address these unique situations in future rulemaking.

Comment: A national dialysis organization stated that the market basket is an inflationary, not a reimbursement, mechanism. They expressed concern that adjustments to the market basket may have significant time lag between product approval and inclusion in the market basket. They further explained that categories of drug entrants may not match the current price proxies utilized in the ESRD PPS, requiring future revaluation.

Response: The market basket adjusts payments for inflation on a yearly basis. We agree

that there may be a lag between costs for items included in the ESRDB market basket cost weights and costs for newly added or excluded expenses in the ESRD treatment bundle. We note that any CMS PPS payment, updated by a market basket, faces the same potential lag. The data used to construct cost weights for the ESRD providers is based on Medicare Cost Reports which are only available with a lag. Additionally, CMS has found that the cost weights for a market basket do not change significantly from year to year. As we have in the past, we will continue to evaluate the ESRD cost share weights on a regular basis and propose changes to the market basket should data indicate a substantial shift in relative cost weights in providing ESRD bundled services.

Comment: An organization of home dialysis patients commented that the functional categories defined for dialysis medication are too broad and could prevent people on dialysis from receiving needed care and be detrimental to innovation. The commenter stated that in the future there could be a new medication to help with fluid management but patients would be shut out of ever having the option for a new fluid management therapy. An LDO stated that, if implemented, the proposed process could jeopardize patient access to drugs that are clinically superior to existing drugs in the same functional category.

An organization of home dialysis patients is hopeful that there are a number of therapies that will offer choice and better care to people who have an illness. One new area of care is in the form of biologics. In order to incentivize new medications to come to market, the home dialysis patient organization asked that CMS provide additional payment for new drugs that fit into the functional categories in order to incentivize new medications to come to market and to ensure they have the opportunity for better care, choices and treatment.

Response: There seem to be two concerns expressed by the commenters. The first is that

the broad nature of the functional categories will sweep new drugs into the functional categories and beneficiaries will not have access to the drugs because the dialysis organizations will choose not to use the new drugs, whether because of contractual obligations, affiliation with drug manufacturers, or lack of additional dollars in the base rate. The second concern seems to stem from the first in that the organizations will not use the new drugs because they would not be separately paid for using the new drugs. Therefore, ESRD patients will not have access to the new drugs.

To address the first issue, the primary intent of the proposed approach is to provide timely patient access to new drugs for the treatment of ESRD. This includes availability of both new drugs that fit into an existing functional category and drugs for which there is no current functional category. The second issue is a matter of reimbursement. As indicated in the CY 2011 final rule, the current ESRD PPS has dollars built into the base rate for the drugs in the functional categories. After a new drug is approved by the FDA and assigned a HCPCS code, CMS makes a determination as to whether it is a renal dialysis drug. If we determine that the drug is a renal dialysis service drug, then we are not permitted to pay for the drug outside the ESRD PPS bundle.

We appreciate the concerns expressed by the organization of home dialysis patients regarding biologics. The biologics currently included in the ESRD PPS bundled payment are ESAs, which are defined as renal dialysis services in section 1881(b)(14)(B)(ii) of the Act. When a new biologic other than an ESA becomes available, we will treat it as we do any other new drug. Specifically, we will evaluate whether it is a renal dialysis service and if it is, whether it fits into a current functional category.

In response to stakeholder concerns regarding the availability and increased cost of new

drugs, we recognize that newer drugs may be more costly; however, the new drug may replace the functional use of one or more drugs within one or several functional categories. Nonetheless, we understand commenters' concerns about the potential cost of new drugs that fall into existing categories and we will consider these unique situations in future rulemaking.

Comment: A product manufacturer pointed out that under the proposal, new products would qualify as outlier services, and if we fail to allow separate payment at launch, there would be no ASP upon which to base an outlier payment. They recommend that we consider how to avoid jeopardizing beneficiary access by implementing an outlier payment based on wholesale acquisition cost (WAC) or another readily available price.

Response: We agree with the commenter that in the event we do not establish an ASP, WAC could be used. We consider WAC pricing to be a part of the pricing methodologies specified in section 1847A of the Act, and we would use the methodologies available to us under that authority in order to accurately determine a price for the calculation of outlier payments for new injectable and intravenous drugs that fit into one of the existing the functional categories.

ii. Transitional Drug Add-On Payment Adjustment

In the proposed rule (80 FR 37832), we explained that we anticipate that there may be new drugs that do not fall within the existing ESRD PPS functional categories and therefore, are not reflected in the ESRD PPS bundled payment. Where a new injectable or intravenous product is used to treat or manage a condition for which there is not a functional category, we proposed to pay for the new injectable or intravenous product using a transitional drug add-on payment adjustment under the authority of section 1881(b)(14)(D)(iv) of the Act. We proposed that the transitional drug add-on payment adjustment would be based on the ASP pricing methodology and would be paid until we have collected sufficient claims data for rate setting for the new

injectable or intravenous product, but not for less than 2 years. We explained that a 2-year timeframe is necessary for adequate data collection, rate-setting and regulation development. We further explained that 2 years is necessary for rulemaking purposes because it is a year-long process that involves developing policies based on data, proposing those policies, allowing for public comment, finalizing the proposed rule, and allowing for a period of time before the rule becomes effective. We stated that the minimum 2-year period would also allow 1 year for payment of the adjustment to be paid before the beginning of a rulemaking cycle in which we could propose to add the drug to the bundled payment. For these reasons, we believed that 2 years was the minimum amount of time necessary to pay the adjustment and we proposed the regulation text for the transitional drug add-on payment adjustment at § 413.234(c).

In the proposed rule (80 FR 37832), we explained that paying a transitional drug add-on payment adjustment for new injectable and intravenous products would allow us to analyze price and utilization data for both the injectable and, if applicable, any oral or other forms of the drug in order to pay for the drugs under the ESRD PPS. We proposed that when a facility furnishes the new injectable drug they would report the drug to Medicare on the monthly facility bill and would append a CMS payment modifier that would instruct our claims processing systems to include a payment amount that equals the Part B drug payment amount, which is derived using the methodologies specified under section 1847A of the Act, which can include ASP + 6 percent pricing. We further explained that this payment approach is consistent with the policy we finalized in the CY 2013 ESRD PPS final rule (77 FR 67463), which states that we would use the ASP methodology, including any modifications finalized in the Physician Fee Schedule (PFS) final rules, to compute outlier MAP amounts, the drug add-on(formerly paid under the composite rate and no longer paid as part of the ESRD PPS), and any other policy that requires

the use of payment amounts for drugs and biologicals that would be separately paid absent the ESRD PPS. We explained in the proposed rule that we would issue sub-regulatory billing and payment guidance along with the payment modifier in conjunction with our final rule guidance. Then, under the regulations at §413.234(c), following payment of the transitional drug add-on payment adjustment, we would modify the ESRD PPS base rate, if appropriate, to account for the new injectable or intravenous product.

In the proposed rule (80 FR 37833), we noted that outlier payments would not be available for new injectable or intravenous products during the time in which these products are paid for using the new transitional drug add-on payment adjustment. We explained that while a new injectable drug or biological being paid using the transitional drug-add would otherwise be considered an outlier service because the drug or biological would have been considered separately billable prior to the implementation of the ESRD PPS, we do not believe that it would be appropriate to include the payment amount for the new drug or biological in the outlier calculation during this interim transition period. This is because during the interim period we would be making a payment for the specific drug in addition to the base rate, whereas outlier services have been incorporated into the base rate. For example, we have included the MAP amount for EPO in the base rate and it qualifies as an outlier. We noted that when the product is reflected in the base rate after payment of the transitional drug add-on payment adjustment, it would be considered eligible for outlier payments discussed in section II.B.2.c of this rule.

Comment: During the time in which a drug is paid for using the transitional drug add-on payment adjustment (2-3 years), a commenter stated that CMS would need to determine how dialysis facilities report new drug cost data. For example, CMS would need to determine whether it is appropriate to create a specific data element within the dialysis facility cost report to

capture the cost of the eligible new drugs during the transition period and whether such data should be reported without any artificial cost limitations (otherwise imposed in the cost-reporting process) to ensure that, where appropriate, the true drug costs are reflected within the ESRD PPS base rate when the transition period ends. The commenter explained that based on the utilization data collected during the transition period, CMS would consider the prevalence of a new drug as a measure of whether it is essential for the delivery of dialysis (that is, an ESRD-related drug) or whether it should remain separately billable.

For example, if the utilization data show that a new drug is furnished to a *majority* of ESRD patients, then it would be considered ESRD-related, and the ESRD PPS base rate would be adjusted accordingly; conversely, if the data show that *less than a majority* of patients received the drug, then it would remain separately billable following the transition period. For drugs to be incorporated into the ESRD PPS, CMS should clarify how it will analyze the cost data and track cost following the transition period to ensure that the calculation used was accurate or whether revisions are required.

They also recommended that CMS work with stakeholders to develop a similar process so that transitional drug add-on payments are available until the ESRD bundle is appropriately recalibrated to accommodate the new class of products. They also recommended that we adopt a process for determining when a drug is so costly that the ESRD PPS payment would be considered inadequate.

Response: We appreciate the suggestions for revisions to the ESRD cost report and the recommendation for capturing utilization data for new injectable and intravenous drugs used for the treatment of ESRD, and we will review the possibility of operationalizing these suggestions in the future. We recognize the importance of making new therapies available to ESRD patients

and because of this, we will include new drugs that are determined to be renal dialysis services and fit into current functional groups. We plan to track utilization of all new renal dialysis service drugs, including those currently in the functional categories, those newly added to the functional categories, and those drugs that are candidates to be included in newly-created functional categories. We have heard from patients that they want to have access to new therapies and drugs. Through section 1881(b)(14)(A)(i) of the Act, the Congress requires the Secretary to implement the ESRD PPS, under which a single payment is made to a provider of services for renal dialysis services in lieu of any other payment. The renal dialysis services that are included in the ESRD PPS bundle are described in section 1881(b)(14)(B) of the Act and include other items and services furnished to individuals for the treatment of ESRD. The statutory definition of renal dialysis services is not limited to those services furnished to the majority of ESRD patients. Drugs that were separately billable were included in the ESRD PPS base rate, and the in CY 2011 final rule, those drugs were placed into categories. If renal dialysis service drugs fit into those functional categories, then they are included. This gives the patients access to those new drugs that fit into the functional categories. With regard to the recommendation that we adopt a process for determining when a drug is so costly that the ESRD PPS payment would be considered inadequate, we are concerned that establishing such a process for these drugs would lead to overpricing of drugs. We do, however, understand commenters' concerns and will consider addressing this issue in future rulemaking.

Comment: Some dialysis organizations are most concerned that a drug may be added to a functional category even if there is no competition for the new drugs in a given functional category. When there is no competition for a given drug, the commenters believe facilities are vulnerable to increased cost.

Response: We believe the commenter is referring to a new drug in a new functional category with no other drug in the category, leading to pricing vulnerability for the dialysis facilities. If the commenter is referring to what occurred with Epogen, with pricing being high due to a monopoly and lack of market competition, it may be that there will be only one drug in a new functional category for several years. All of the drugs in the current functional categories are populated by drugs that function well for the current ESRD population. The inclusion of the new drugs in these functional categories provides access for the beneficiaries to new renal dialysis services, including the drugs for the treatment of ESRD. When there is a new drug that does not fit into the current functional categories, a minimum of 2 years of utilization data is required before we will assess whether a functional category should be created through notice-and-comment rulemaking, as well as how to add the drug to the ESRD base rate. We believe it is in the best interest of the ESRD beneficiary to make these drugs available to them. We appreciate the commenter sharing their concern with us about competition within the functional categories.

Comment: A commenter expressed support for the use of the ASP pricing methodology for the transitional drug add-on payment adjustment for new drugs and biologicals that do not fall within the existing ESRD PPS functional categories. However, an organization representing small and medium dialysis facilities and an MDO are concerned that the proposed transitional add-on payment is calculated based on ASP, which has been shown not to be truly reflective of the actual cost of the drug. One organization pointed out that often there is a data lag between ASP and the actual cost of the drugs and as a result, the transitional add-on payment may not reflect the actual cost of the drug. A drug manufacturer recommended that the transitional drug

add-on payment adjustment be set at ASP + 6 percent and the period of transition be set at 3 years.

Response: The ASP + 6 percent pricing methodology is a part of the pricing methodologies specified in section 1847A of the Act, which also include some wholesale acquisition cost (WAC) pricing during the first quarter of sales. We agree with the commenters that ASP + 6 percent pricing may not always be the most appropriate way to calculate the transitional drug add-on payment adjustment. Accordingly, we are revising the regulation text at 413.234(c)(1) to refer to the pricing methodologies under section 1847A of the Act, rather than ASP pricing methodology, because these methodologies include ASP, WAC, and Average Wholesale Pricing. Information regarding the pricing methodologies specified in 1847A of the Act can be found in Publication 100-04, Chapter 17 – Drugs and Biologicals, section 20.1– MMA Drug Pricing – Average Sales Price.

After consideration of the public comments, we are finalizing the drug designation process and the corresponding regulation text at 42 CFR 413.234.

iii. Determination of When an Oral-Only Renal Dialysis Service Drug is no Longer Oral-Only

Section 217(c)(1) of PAMA requires us to adopt a process for determining when oral-only drugs are no longer oral-only. In our CY 2011 ESRD PPS final rule (75 FR 49038 through 49039), we described oral-only drugs as those that have no injectable equivalent or other form of administration. In the proposed rule (80 FR 37833), we proposed to define the term oral-only drug as part of our drug designation process in our regulations at 42 CFR 413.234(a). For CY 2016, and in accordance with section 217(c)(1) of PAMA, we proposed that an oral-only drug would no longer be considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the FDA. We proposed to codify this process in our regulations at

42 CFR 413.234(d). In addition, we noted that the FDA posted lists of all drug dosages and forms of administration that are approved for use in the United States. For example, one of these lists can be viewed at http://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/datastandardsmanualmonographs/ucm071666

A link for the drug and biologic approval and investigational new drug activity reports can be found at the following link: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/default.htm .

In the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038), we noted that the only oral-only drugs and biologicals that we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism category. We defined these oral-only drugs as renal dialysis services in our regulations at §413.171 (75 FR 49044), delayed the Medicare Part B payment for these oral-only drugs until CY 2014 at §413.174(f)(6), and continued to pay for them under Medicare Part D.

In the proposed rule (80 FR 37833), we explained that under our proposed drug designation process at §413.234(b)(1), if injectable or intravenous forms of phosphate binders or calcimimetics are approved by the FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category so no additional payment would be available for inclusion of these drugs.

However, we recognized the uniqueness of these drugs and we proposed not to apply this process to injectable or intravenous forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never

included in the base rate to account for these drugs. As we discussed above, we determined in CY 2011 that both classes of drugs (phosphate binders and calcimimetics) were furnished for the treatment of ESRD and are therefore renal dialysis services. In addition, in the proposed rule we explained that we had utilization data for both classes of drugs because the oral versions existed at that time. However, for reasons discussed in the CY 2011 ESRD PPS final rule (75 FR 49043 through 49044), we chose to delay their inclusion in the ESRD PPS bundled payment.

Therefore, in the proposed rule, we proposed that when a non-oral version of a phosphate binder or calcimimetic is approved by the FDA, we would include the oral and any non-oral version of the drug in the ESRD PPS bundled payment. Specifically, we proposed that we would develop a computation for the inclusion of the oral and non-oral forms of the phosphate binder or calcimimetic so that the drug could be appropriately reflected in the ESRD PPS base rate. We explained that we would not take this approach for any subsequent drugs that are approved by the FDA and fall within the bone and mineral metabolism functional category (or any other functional categories) because we did not delay payment for any other drugs or biologicals for which we had 2007 utilization data when the ESRD PPS was implemented in CY 2011 and, therefore, we believe the other functional categories appropriately reflect renal dialysis service drugs and biologicals.

Comment: A drug manufacturer expressed concern that the proposal did not address the computation or timing for adding the oral-only drugs into the bundled payment once an injectable or intravenous version is approved for use. The commenter assumes this process would be done through notice and comment rulemaking and urged CMS to specify this fact in the final rule. They pointed out the new drugs come on to the market throughout the year, which may or may not comport with the annual rulemaking cycle for the ESRD PPS.

Response: We intend to use notice-and-comment rulemaking to include the oral and non-oral forms of calcimimetics and phosphate binders in the ESRD PPS bundled payment after the payment of the transitional drug add-on payment adjustment. We will pay for calcimimetics and phosphate binders when those drugs are no longer oral-only drugs, that is, FDA approved and have an HCPCS code, using a transitional drug add-on payment adjustment calculated based on the payment methodologies in section 1847A of the Act. Once the injectable version is approved and has an HCPCS code we will issue a change request to provide notice that the injectable is available. Therefore, both the injectable and oral form will be paid under the ESRD PPS bundled payment using that adjustment. However, we note, any other new injectable or intravenous drug or biological will be assessed as to whether it fits into one of the functional categories. Injectable and intravenous drugs that fit into a functional category will not go through notice-and-comment rulemaking. Rather, they will be added to the functional categories, and thus the ESRD PPS, using a subregulatory process.

Comment: One of the drug manufacturers recommended that in the case of oral equivalents, that first in class drugs receive the full transitional drug add-on payment adjustment, with stepped down payments for new drugs in the same class entering the market during the transitional payment period for the first in class product.

One commenter stated that regardless of the method CMS uses to add these oral-only drugs to the ESRD PPS base rate, their inclusion should result in an increase in the base rate. They believe that PAMA's requirement to update payment rates using data from the most recent year available applies notwithstanding the budget neutrality adjustment that applied when the ESRD PPS was implemented in 2011.

Response: It is unclear whether the drug manufacturer is referring to the oral form of existing oral-only drugs, or oral equivalents of drugs for which there are other types of administration. Oral equivalents of drugs with another form of administration, as well as oral-only drugs other than calcimimetics and phosphate binders, will be subject to the drug designation process. However, for phosphate binders and calcimimetics -- for which there is a functional category -- but no money is in the base rate -- we will utilize the transitional drug add-on payment adjustment to collect utilization data before adding this drug to the ESRD PPS base rate. Once money has been included in the base rate for an injectable or intravenous calcimimetic and phosphate binder in the bone and mineral metabolism functional category, any future injectable or intravenous drugs in this category will be added directly to the functional category and, thus, the bundled payment.

Comment: With regard to the definition of when an oral-only drug is no longer considered oral-only, two drug manufacturers expressed concern that the proposed regulatory text does not include an FDA reference as the standard for determining whether the FDA has approved another form of administration for a specific drug. They note that CMS provided a hyperlink in the proposed rule, but unfortunately, the link did not work. They recommended that we clarify in 42 CFR 413.234(d) whether we will specifically rely on the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the FDA Orange Book) for determining whether an oral drug has an injectable or non-oral form and is no longer in the oral-only category and should be included in the ESRD PPS payment. They point out that the FDA Orange Book identifies all drug products (including dosage forms, routes of administration, etc.) approved by the FDA. To help define terms used in these resources, they suggested we cite an up-to-date FDA website or resource that includes standards for identifying

all drug dosage forms and routes of administration that are approved for use. If CMS is not using the FDA Orange Book, the commenters indicated that CMS should be specific in how it will determine whether a non-oral form of the oral-only drug exists.

A patient organization advocates that before oral-only drugs are incorporated into the bundle, certain measures must be in place to ensure that drugs are appropriate for patients and that costs for the drugs are accurately calculated and paid for. Two pharmaceutical manufacturers recommended that, to avoid confusion, CMS should clarify in the regulation text that CMS will exclude a drug that meets the definition of an oral-only drug and has no injectable or other form of administration.

Response: We thank the commenters for making us aware of the non-working link and have corrected that link in this final rule. The publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). The "Orange Book Search" was added to the FDA website October 31, 1997. We will utilize the Orange Book to assist us in determining whether an injectable or other form of administration of an oral-only drug has been approved by the FDA. When an oral-only drug already determined to be a renal dialysis service is formulated for injectable or intravenous use it will no longer be considered an oral-only drug. The new injectable or intravenous form of the oral-only drug will be assessed as to whether it fits into one of the functional groups. If it does not fit into the current functional groups, a new functional group will be proposed through notice-and-comment rulemaking. Other than oral drugs included in the ESRD PPS bundle that were composite rate drugs, if there is no injectable or intravenous form of an oral-only drug used for the treatment of ESRD, then it is not

considered a part of the ESRD PPS bundle, and is paid for separately. Regarding the costs for the drugs being accurately calculated and paid for, we appreciate the commenter's concerns and anticipate addressing the possibility of these unique situations in future rulemaking.

Regarding the recommendation that CMS should clarify in the regulation text that CMS will exclude a drug that meets the definition of an oral-only drug and has no injectable or other form of administration, we note that the Congress excluded oral-only drugs from the ESRD PPS payment bundle. Payments for oral-only ESRD drugs are not included under the ESRD PPS until 2024 as required by section 632(b)(1) of ATRA, as amended by section 217(a) of PAMA. Section 204 of ABLE further amended section 632(b)(1) of ATRA to provide that payment for oral-only ESRD drugs cannot be made under the ESRD PPS prior to January 1, 2025.

Comment: A national dialysis organization, LDOs, and a professional association stated that when an injectable or intravenous calcimimetic has been approved by the FDA and becomes available, many factors will need to be assessed, including clinical guidelines and indications, which may vary between injectable or intravenous and oral products; utilization and costs per treatment; and range of dosing. One LDO believes that there is insufficient information available regarding the future injectable or intravenous and oral products upon which to base sound payment policy. They pointed out that the oral calcimimetics are used by one-third of their patients. That sizeable population combined with the significant cost of the drug makes it unlikely that the current outlier policy would be sufficient to address utilization differences in patient population among facilities. They requested that CMS allow the injectable or intravenous equivalent of oral Sensipar to remain outside of the bundle for a transition period. Data collected from this period can guide the formation of reimbursement policy to ensure that beneficiaries have proper access to the therapy, that is, injectable, intravenous, or oral, which is best for them

according to the severity of their secondary hyperparathyroidism.

A national dialysis organization recommends that at the end of a 2-year transition period, CMS would value the cost of the injectable or intravenous calcimimetic under Part B, including beneficiary costs, and add that amount to the base rate, if utilization warrants the costs to be spread across all patients. Relying upon the Part D spending data alone would assume that oral drug spending is the same as it would be for an injectable or intravenous, but very little is known about how the drug will be used in the ESRD population. Some commenters are requesting a 2-year delay in incorporating payment for calcimimetics under the ESRD PPS. In addition, they expressed concern that spending for calcimimetics under Part D does not represent all the utilization and dollars because some ESRD patients have no drug plan or are subject to the Part D "donut hole" due to cost. The organization expects that migration of payment from Part D to Part B will increase utilization among this group. The organization pointed out that including calcimimetics under the ESRD PPS will increase Part B expenditures and that the ESRD PPS cannot absorb the cost of calcimimetics without a substantial increase to the base rate. Another large stakeholder supports a transitional payment for injectable or intravenous versions of phosphate binders and calcimimetics because the bundled payment could be improperly inflated by a higher costing injectable or intravenous version that is only benefitting a subset of patients, but all patients would be subjected to a higher coinsurance. Conversely, there could be superior benefit of the injectable or intravenous version that renders the utilization of the oral versions lower.

A drug manufacturer asked how CMS would determine the cost associated with a new drug if there is no utilization data, what sources of data CMS would use to measure utilization of an oral drug by beneficiaries not enrolled in Part D and whether payment rates could be adjusted

mid-year to provide timely payment for new drugs upon approval or launch. They expressed concern that not having utilization for the 30 percent of beneficiaries without Part D coverage will likely result in an inappropriate payment amount. The manufacturer also expressed concern that payments for new injectable or intravenous versions of oral-only drugs will also be inaccurate if the amount is based solely on Part D data. The manufacturer recommended that CMS conduct analyses to determine the adherence rate for the oral-only products using Part D claims to measure the medication possession ratio (MPR) and, assuming 2100 percent adherence under Part B, estimate the gap that needs to be accounted for in the payment computation. MPR has been shown to be a useful metric in measuring patient adherence.

A professional association agrees with paying ASP+6 percent for injectable or intravenous treatments for bone and mineral disorders until the utilization of the new product is sufficiently mature to be subsumed into the PPS with accurate cost and use data.

Another commenter was also concerned about the timing of the roll-out of the injectable or intravenous phosphate binders and calcimimetics with the annual rulemaking cycle for the ESRD PPS. They are concerned about the ability for dialysis facilities to adopt a new non-oral calcimimetic or phosphate binder if there is no opportunity for payment until the next calendar year.

Response: We thank the commenters for their input regarding the process for including calcimimetics and phosphate binders in the ESRD PPS bundled payment. We agree with the industry that injectable or intravenous phosphate binders and calcimimetics that come on the market in the future could have different clinical indications, utilization patterns, and costs than the oral-only versions and we believe it is appropriate to pay for these drugs using the transitional drug add-on payment adjustment for a minimum of 2 years. Once the injectable or

intravenous phosphate binder or calcimimetic are FDA approved and have a HCPCS code, we will issue a change request (as stated above) to pay for all forms of the phosphate binder or calcimimetic using a transitional drug add-on payment based on the payment methodologies under section 1847A of the Act, which could include ASP + 6 percent, for a period of at least 2 years. This will allow us to collect data reflecting current utilization of both the oral and injectable or intravenous forms of the drugs, as well as payment patterns and beneficiary co-pays before we add these drugs to the ESRD PPS bundle. During this period we will not pay outlier payments for these drugs. At the end of the 2 or more years, the methodology for including the phosphate binders and calcimimetics into the ESRD PPS bundled payment will be adopted through notice-and-comment rulemaking.

Regarding the drug manufacturer's recommendation that CMS conduct analyses to determine the adherence rate for the oral-only products using Part D claims to measure the medication possession ratio (MPR) because MPR has been shown to be a useful metric in measuring patient adherence, we will rely on utilization data from the dialysis facilities, which are required to report all separately billable drugs.

We appreciate the support of the professional association for the use of the ASP pricing methodology for the transitional drug add-on payment adjustment and the minimum 2-year timeframe for payment of the adjustment, which we also agree is necessary to collect utilization data for these drugs.

After consideration of public comments, we are finalizing the definition of oral-only drug at 413.234(a), which provides that an oral-only drug is a drug or biological with no injectable equivalent or other form of administration other than an oral form. We are also finalizing our process at 42 CFR 413.234(d) for determining that an oral only drug is no longer considered

oral-only when a non-oral version of the oral-only drug is approved by the FDA. We will include the oral and any non-oral version of the drug in the ESRD PPS bundled payment when it is no longer considered an oral-only drug under this regulation. For at least 2 years we will pay for the existing oral-only drugs – phosphate binders and calcimimetics – using the transitional drug add-on payment adjustment, which will be calculated based on the payment methodologies under section 1847A of the Act. We will add the oral and non-oral forms of the phosphate binders and calcimimetics to the ESRD PPS bundled payment through notice-and-comment rulemaking. For future oral-only drugs for which a non-oral form of administration comes on the market, we will apply our drug designation process as we would for all other new drugs.

4. Delay of Payment for Oral-Only Renal Dialysis Services

As we discussed in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186) and again in the CY 2015 ESRD PPS final rule (79 FR 66147 through 66148), section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and subclause (iii) of such section states that these services include other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

We interpreted this provision as including not only injectable drugs and biologicals used for the treatment of ESRD (other than ESAs and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biologicals used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biologicals used for the treatment of ESRD do not fall

within clause (iii) of section 1881(b)(14)(B), such drugs or biologicals would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B).

We finalized and promulgated the payment policies for oral-only renal dialysis service drugs or biologicals in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), where we defined renal dialysis services at 42 CFR 413.171 as including other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011 under Title XVIII of the Act, including drugs and biologicals with only an oral form. Although we included oral-only renal dialysis service drugs and biologicals in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the PPS until January 1, 2014. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs and biologicals, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only renal dialysis service drugs and biologicals to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biologicals at 42 CFR 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form is incorporated into the PPS payment rates effective January 1, 2014.

On January 3, 2013, ATRA was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under 42 CFR 413.176(f)(6) relating to oral-only renal dialysis service drugs and biologicals prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS until January 1, 2016. We

implemented this delay by revising the effective date at §413.174(f)(6) for providing payment for oral-only renal dialysis service drugs under the ESRD PPS from January 1, 2014 to January 1, 2016. In addition, we changed the date when oral-only renal dialysis service drugs and biologicals would be eligible for outlier services under the outlier policy described in §413.237(a)(1)(iv) from January 1, 2014 to January 1, 2016.

On April 1, 2014, PAMA was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA, which now precludes the Secretary from implementing the policy under 42 CFR 413.174(f)(6) relating to oral-only renal dialysis service drugs and biologicals prior to January 1, 2024. We implemented this delay in the CY 2015 ESRD PPS final rule (79 FR 66262) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS at §413.174(f)(6) from January 1, 2016 to January 1, 2024. We also changed the date in §413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2016 to January 1, 2024.

In the CY 2016 ESRD PPS proposed rule (80 FR 37834) we stated that on December 19, 2014, section 204 of ABLE was enacted, which delays the inclusion of renal dialysis service oral-only drugs and biologicals under the ESRD PPS until 2025. It amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA by striking "2024" and inserting "2025." We explained that as we did in the CY 2014 ESRD PPS final rule (78 FR 72186) and the CY 2015 ESRD PPS final rule (79 FR 66148) referenced above, we proposed to implement this delay by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2024 to January 1, 2025. In addition, we proposed to change the date in §413.237(a)(1)(iv) regarding outlier

payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025.We stated that we continue to believe that oral-only renal dialysis service drugs and biologicals are an essential part of the ESRD PPS bundle and should be paid for under the ESRD PPS.

We did not receive any comments on implementing the delay by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2024 to January 1, 2025. In addition we did not receive comments on the change to the date in §413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025. Therefore, we are finalizing the language at 42 CFR 413.174(f)(6) and §413.237(a)(1)(iv) as proposed.

5. Reporting Medical Director Fees on ESRD Facility Cost Reports

In the 1980s, following audits by the Office of the Inspector General and the Medicare administrative contractors (MACs) that revealed instances in which independent facilities compensated their medical directors and administrators excessively, CMS set limits for reasonable compensation when reporting medical director fees on ESRD facility cost reports. End-Stage Renal Disease Program; Prospective Reimbursement for Dialysis Services and Approval of Special Purpose Renal Dialysis Facilities, 48 FR 21254, 21261 through 21262 (May 11, 1983); End-Stage Renal Disease Program: Composite Rates and Methodology for Determining the Rates, 51 FR 29404, 29407 (Aug. 15, 1986). In Transmittal 12, issued in July 1989, of the Provider Reimbursement Manual Part I, Chapter 27, titled, “Reimbursement for ESRD and Transplant Services,” CMS adopted a policy for reporting allowable compensation for physician owners and medical directors of ESRD facilities and set a limit at the Reasonable

Compensation Equivalent (RCE) limit of the specialty of internal medicine for a metropolitan area of greater than one million people.

In the Provider Reimbursement Manual Part I, Chapter 27 – Outpatient Maintenance Dialysis Services, 2723 – Responsibility of Intermediaries, we explain that the intermediary reviews facility cost reports to ensure that the compensation paid to medical directors does not exceed the RCE limit. The RCE limit for a board-certified physician of internal medicine has been updated over the interim years. The most recent update to the RCE limit was finalized in the FY 2015 IPPS final rule published on August 22, 2014 (79 FR 50157 through 50162). In that rule, CMS finalized an RCE limit of $197,500 per year beginning in CY 2015 for a board-certified physician of internal medicine.

The requirements for medical directors of ESRD facilities are discussed in the Conditions for Coverage for ESRD facilities, which were updated in 2008 to reflect advances in dialysis technology and standard care practices since the requirements were last revised in their entirety in 1976. Conditions for Coverage for ESRD Facilities, 73 FR 20470 (April 15, 2008). With the update to the Conditions for Coverage, all Medicare-certified ESRD facilities are required to have a medical director who is responsible for the delivery of patient care and outcomes in the facility as codified in 42 CFR part 494, titled Conditions for Coverage for End-Stage Renal Disease Facilities. We discuss the qualifications of an ESRD facility medical director in 42 CFR 494.140(a), titled Standard: Medical director, where we require that a medical director must be a board-certified physician in internal medicine or pediatrics by a professional board and have completed a board-approved training program in nephrology with at least 12 months of experience providing care to patients receiving dialysis, but if such a physician is not available, another physician may direct the facility, subject to the approval of the Secretary.

In the CY 2016 ESRD PPS proposed rule (80 FR 37834), we explained that the RCE limit of $197,500 per year for a board-certified physician of internal medicine may be less than the expense a facility incurs if they employ a board-certified nephrologist as their medical director.In that rule, we stated that we could appreciate that the reasonable compensation limits are generally used when determining payment for providers that are reimbursed on a reasonable cost basis; they typically are not used in prospective payment systems, like the ESRD PPS, that update payment rates using market basket methodologies. We further stated that we believe the application of the RCE limit is no longer relevant now that 100 percent of ESRD facilities are paid under the ESRD PPS beginning in CY 2014.

Therefore, we proposed that beginning in CY 2016 we would eliminate the RCE limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports. We noted that the elimination of the RCE limit does not supersede or alter in any way the reporting guidance furnished in the Provider Reimbursement Manual, Part 2, Chapter 42, sections 4210, 4210.1 and 4210.2. In addition, we stated that we will continue to apply the ESRD facility-specific policy under which the time spent by a physician in an ESRD facility on administrative duties is limited to 25 percent per facility unless documentation is furnished supporting the claim. In addition, if an individual provides services to more than one dialysis facility, the individual's time must be prorated among the different facilities and may not exceed 100 percent.

The comments and our responses are set forth below.

Comment: Several national dialysis organizations expressed support for the CMS proposal to eliminate limits on medical director fees reported on cost reports. The commenters requested that we apply this policy change to the 2015 cost reports.

Response: We thank the commenters for their support of the proposal to eliminate the limit for medical director fees on the ESRD facility cost report. This policy change is effective January 1, 2016 for CY 2016. Since the policy is effective for CY 2016, we are not able to apply this policy to cost reports before the effective date and therefore it will not be applicable to the CY 2015 cost reports.

Comment: MedPAC urged CMS to maintain a limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports. They believe the current RCE limit on the medical director compensation creates pressure on facilities to constrain their compensation costs and make better use of beneficiaries' and taxpayers' resources. In addition, eliminating the RCE limit may decrease some facilities' negotiating leverage with prospective medical directors, which in turn, will lead to increased compensation costs. The commenter explained that as providers' costs increase, all other things being equal, the resulting Medicare margin will decrease. MedPAC suggested that, as an alternative to the current RCE limit or no compensation limit, that we adopt a limit used by other Executive branch agencies such as the Title 38 Physician and Dentist Pay under which pay table 2 includes nephrology as a covered clinical specialty and the pay range for the most senior management level is $140,000 to $250,000.

Response: We do not believe that perpetuating a limit for the medical director fee is appropriate for the reasons that we discuss above, including that ESRD facilities are no longer reimbursed on a cost basis. This policy change will not affect the ESRD PPS annual update or increase Medicare spending. In addition, MACs perform a general reasonableness evaluation of a person's compensation by comparing it with the compensation paid to other individuals in similar circumstance. We believe that the elimination of the limit will more accurately represent facility costs on the cost report that is used for margin analysis or refinements to the payment

system.

Based on the comments that we received, we are finalizing that beginning in CY 2016 we are eliminating the RCE limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports.

C. Clarifications Regarding the ESRD PPS

1. Laboratory Renal Dialysis Services

Section 1881(b)(14)(B)(iv) of the Act requires diagnostic laboratory tests not included under the composite payment rate (that is, laboratory services separately paid prior to January 1, 2011) to be included as part of the ESRD PPS payment bundle. In the CY 2011 ESRD PPS final rule (75 FR 49053), we defined renal dialysis services at 42 CFR 413.171 to include items and services included in the composite payment rate for renal dialysis services as of December 31, 2010 and diagnostic laboratory tests and other items and services not included in the composite rate that are furnished to individuals for the treatment of ESRD. The composite payment rate covered routine items and services furnished to ESRD beneficiaries for outpatient maintenance dialysis, including some laboratory tests. We finalized a policy to include in the definition of laboratory tests under 42 CFR 413.171(4) those laboratory tests that were separately billed by ESRD facilities as of December 31, 2010 and laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients that were separately billed by independent laboratories (75 FR 49055). We determined the average Medicare Allowable Payment (MAP) amount was $8.40, as listed on Table 19 titled, "Average Medicare Allowable Payments for composite rate and separately billable services, 2007, with adjustment for price inflation to 2009" (75 FR 49075). This amount included the laboratory tests that were already included under the composite rate, as well as laboratory tests billed separately by ESRD

facilities (that is, all laboratory services paid on the 72X claim furnished in CY 2007) and laboratory tests that were ordered by Monthly Capitation Payment (MCP) practitioners that were separately billed by independent labs in CY 2007.

Through the comments we received on the CY 2011 ESRD PPS proposed rule, we learned that holding the ESRD facilities responsible for any laboratory test that is furnished in the ESRD facility or ordered by an MCP could have unintended consequences to patients (75 FR 49054). In particular, commenters noted that in many instances the MCP physician is the ESRD patient's primary care physician and often orders laboratory tests that are unrelated to the patient's ESRD. These commenters raised concerns that requiring ESRD facilities to pay for these tests would result in large numbers of tests that are unrelated to ESRD being included in the ESRD bundle. We agreed with commenters that it would be in the best interest of the beneficiaries for an ESRD facility to draw blood for laboratory tests that are not for the treatment of ESRD during the dialysis session.

Commenters also requested that we produce a list of the ESRD-related laboratory tests that are included in the ESRD PPS bundle (75 FR 49054). We received several laboratory service lists from the commenters that they considered to be generally furnished for the treatment of ESRD. While there was agreement for many of the laboratory services, the lists were inconsistent and lacked stakeholder consensus. When Medicare provides a payment for a benefit that is based on a bundle of items and services, CMS establishes claims processing edits that prevent payment in other settings for items and services that are identified as being accounted for in the bundled payment. Therefore, we needed to develop a list of ESRD-related laboratory tests to implement claims processing edits that prevent payment in other settings for items and services that are identified as renal dialysis services to ensure that payment is not made to

independent laboratories for ESRD-related laboratory tests. Under the ESRD PPS we call these edits consolidated billing (CB) requirements.

We performed a clinical review of the lists provided by the industry and the laboratory tests reported in the claims data to determine which laboratory tests are routinely furnished to ESRD beneficiaries for the treatment of ESRD. Our clinical review resulted in Table F in the Addendum of the CY 2011 ESRD PPS final rule as the list of laboratory tests that are subject to the ESRD PPS CB requirements (75 FR 49213). We acknowledged in that rule that the list of laboratory tests displayed in Table F is not an all-inclusive list and we recognized that there are other laboratory tests that may be furnished for the treatment of ESRD (75 FR 49169). We stated in the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 11, section 20.2, that the determination of whether a laboratory test is ESRD-related is a clinical decision for the ESRD patient's ordering practitioner. If a laboratory test is ordered for the treatment of ESRD, then the laboratory test is not paid separately.

Due to the commenters' concerns that ESRD beneficiaries should be able to have blood drawn for non-ESRD-related laboratory tests in the ESRD facility, we created a methodology for allowing ESRD facilities to receive separate payment when a laboratory service is furnished for reasons other than for the treatment of ESRD (75 FR 49054). We created CB requirements using a modifier to allow independent laboratories, hospital-based laboratories, or ESRD facilities (with the appropriate clinical laboratory certification in accordance with the Clinical Laboratory Improvement Amendments), to receive separate payment. This modifier, which is called the AY modifier, serves as an attestation that the item or service is medically necessary for the patient but is not being used for the treatment of ESRD.

In the CY 2016 ESRD PPS proposed rule (80 FR 37835), we explained that following publication of the CY 2011 ESRD PPS final rule, we had received numerous inquiries regarding Table F (75 FR 49213). Stakeholders have communicated to us that having a list of laboratory services that is not all-inclusive is confusing because there is no definitive guidance on which laboratory tests are included in, and excluded from, the ESRD PPS. They further stated that leaving the determination of when a laboratory test is ordered for the treatment of ESRD to the practitioner creates inconsistent billing practices and potential overuse of the AY modifier. Stakeholders stated that practitioners can have different positions on when a laboratory test is being ordered for the treatment of ESRD. For example, some practitioners may believe that laboratory tests ordered commonly for diabetes could be considered as for the treatment of ESRD because in certain situations a patient's ESRD is a macrovascular complication of the diabetes. Commenters believe these varying perspectives among practitioners can translate into inconsistent billing practices.

In the proposed rule (80 FR 37835 through 37836), we also explained that stakeholders have expressed concern about potential overuse of the AY modifier because they are aware that CMS monitors the claims data for trends and behaviors. The industry's position is that if there is a laboratory service that is subject to the CB requirements, it is because CMS has determined that test to be routinely furnished for the treatment of ESRD and if certain tests are frequently reported with the AY modifier, then those laboratories or ESRD facilities could appear to be inappropriately billing Medicare.

In the proposed rule (80 FR 37836) we explained that while we recognize stakeholders' concerns, for CY 2016, we did not make a proposal to change the laboratory services policy and reiterated that any laboratory test furnished to an ESRD beneficiary for the treatment of ESRD is

considered to be a renal dialysis service and is not payable outside of the ESRD PPS. We explained that we continue to believe that it is necessary to use a list of laboratory services that are routinely furnished for the treatment of ESRD for enforcing the CB requirements. In addition, we continue to believe it is convenient for ESRD beneficiaries to have their blood drawn at the time of dialysis for laboratory testing for reasons other than for the treatment of ESRD.

In the proposed rule (80 FR 37836) we stated that we have included appropriate payments into the base rate to account for any laboratory test that a practitioner determines to be used for the treatment of ESRD. We explained that it is important that medical necessity be the reason for how items and services are reported to Medicare. When services are reported appropriately, payments are made appropriately out of the Trust Fund and ESRD beneficiaries are not unfairly inconvenienced by constraints placed upon them because a certain laboratory test is or is not included in the ESRD PPS. Therefore, in order to maintain practitioner flexibility for ordering tests believed to be medically necessary for the treatment of ESRD, and have those tests included and paid under the ESRD PPS, we did not make a proposal to adopt a specific list of laboratory services that are always considered furnished for the treatment of ESRD.

We solicited comment on the current list of laboratory services that is used for the ESRD PPS CB requirements to determine if there is consensus among stakeholders regarding whether the list includes those laboratory tests that are routinely furnished for the treatment of ESRD. Table 9is the list of laboratory tests that is used for the CB requirements. We explained in the proposed rule (80 FR 37836) that we agree with the stakeholders that there can be different interpretations among practitioners as to what is considered to be furnished for the treatment of ESRD and that there can be some views that are more conservative than others. Furthermore it is

the patient's ordering practitioner who makes the clinical determination of whether a laboratory test is for the treatment of ESRD.

We did not receive comments from stakeholders indicating if the list of laboratory services used for CB requirements are or are not routinely furnished for the treatment of ESRD.

In the proposed rule (80 FR 37836), we stated that in the context of the clarification, we proposed to remove the lipid panel from the CB list. As we stated in the CY 2013 ESRD PPS final rule (77 FR 67470), it was our understanding that the lipid panel was routinely used for the treatment of ESRD. We explained that because some forms of dialysis, particularly peritoneal dialysis, are associated with increased cholesterol and triglyceride levels, a lipid profile laboratory test to assess these levels would be considered furnished for the treatment of ESRD. In the CY 2016 proposed rule (80 FR 37836) we indicated that since the CY 2013 final rule was published we have learned from stakeholders that the lipid panel is mostly used to monitor cardiac conditions and is not routinely furnished for the treatment of ESRD.

We explained that we believed that the proposal to remove the lipid panel was consistent with the clarification provided in that rule that laboratory services included in Table 9and subject to ESRD consolidated billing are those that are routinely furnished for the treatment of ESRD but that may occasionally be used to treat non-ESRD-related conditions. In contrast, the lipid profile laboratory test is not routinely used for the treatment of ESRD. We solicited comments on this proposal and received several comments as set forth below.

Comment: Many stakeholders (an LDO, two national dialysis organizations, an organization representing small and medium dialysis facilities, and a nonprofit dialysis organization, and two professional associations)expressed support for the proposed elimination of the lipid panel from the consolidated billing list.

Response: We appreciate the commenters support. We are finalizing the removal of the lipid panel from the ESRD PPS consolidated billing list and we will issue subregulatory guidance to that effect. However, we note that even though lipid panels are being removed from the ESRD PPS consolidated billing list, if an ESRD patient's ordering practitioner orders a lipid panel for the treatment of ESRD then it should not be billed separately.

TABLE 9– LABORATORY SERVICES SUBJECT TO ESRD CONSOLIDATED BILLING

Short Description	CPT/HCPCS
Basic Metabolic Panel (Calcium, ionized)	80047
Basic Metabolic Panel (Calcium, total)	80048
Electrolyte Panel	80051
Comprehensive Metabolic Panel	80053
Lipid Panel[1]	80061
Renal Function Panel	80069
Hepatic Function Panel	80076
Assay of serum albumin	82040
Assay of aluminum	82108
Vitamin d, 25 hydroxy	82306
Assay of calcium	82310
Assay of calcium, Ionized	82330
Assay, blood carbon dioxide	82374
Assay of carnitine	82379
Assay of blood chloride	82435
Assay of creatinine	82565
Assay of urine creatinine	82570
Creatinine clearance test	82575
Vitamin B-12	82607
Vit d 1, 25-dihydroxy	82652
Assay of erythropoietin	82668
Assay of ferritin	82728
Blood folic acid serum	82746
Assay of iron	83540
Iron binding test	83550
Assay of magnesium	83735

Short Description	CPT/HCPCS
Assay of parathormone	83970
Assay alkaline phosphatase	84075
Assay of phosphorus	84100
Assay of serum potassium	84132
Assay of prealbumin	84134
Assay of protein, serum	84155
Assay of protein by other source	84157
Assay of serum sodium	84295
Assay of transferrin	84466
Assay of urea nitrogen	84520
Assay of urine/urea-n	84540
Urea-N clearance test	84545
Hematocrit	85014
Hemoglobin	85018
Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count.	85025
Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)	85027
Automated rbc count	85041
Manual reticulocyte count	85044
Automated reticulocyte count	85045
Reticyte/hgb concentrate	85046
Automated leukocyte count	85048
Hep b core antibody, total	86704
Hep b core antibody, igm	86705
Hep b surface antibody	86706
Blood culture for bacteria	87040
Culture, bacteria, other	87070
Culture bacteri aerobic othr	87071
Culture bacteria anaerobic	87073
Cultr bacteria, except blood	87075
Culture anaerobe ident, each	87076
Culture aerobic identify	87077
Culture screen only	87081
Hepatitis b surface ag, eia	87340
CBC/diff wbc w/o platelet	G0306
CBC without platelet	G0307

[1] Effective January 1, 2016, this laboratory service is no longer subject to the ESRD PPS consolidated billing requirements.

In the proposed rule (80 FR 37836), we explained that although we did not propose to change our policy related to payment for ESRD-related laboratory services under the ESRD PPS, we did clarify that to the extent a laboratory test is performed to monitor the levels or effects of any of the drugs that we have specifically excluded from the ESRD PPS, these tests would be separately billable. In the CY 2011 ESRD PPS final rule, we discuss when certain drugs and biologicals would not be considered for the treatment of ESRD. Specifically, Table 10, which appeared as Table 3 – ESRD Drug Category Excluded from the Final ESRD PPS Base Rate in the CY 2011 ESRD PPS final rule (75 FR 49049) lists the drug categories that were excluded from the ESRD PPS and the rationale for their exclusion. In the proposed rule, we clarified that laboratory services furnished to monitor the medication levels or effects of drugs and biologicals that fall in those categories would not be considered to be furnished for the treatment of ESRD. We solicited comment on this clarification and a summary of those comments are set forth below.

Comment: Several organizations expressed support for the clarification of linking coverage of laboratory testing under the ESRD PPS to the drugs and biologicals considered to be renal dialysis services. They indicated that they support the clarifications that a laboratory test that is performed to monitor the levels or effects of any of the drugs that CMS has specifically excluded from the ESRD PPS will be separately billable and not be considered to be furnished for the treatment of ESRD.

Response: We appreciate the commenters support and will update our subregulatory guidance with this clarification.

Comment: One health plan requested that we also remove Vitamin D/Hydroxy lab service (CPT 82306) as this lab is not routinely or consistently provided to ESRD patients and not necessary for the treatment of ESRD. Stakeholders stated that considering any laboratory test furnished to an ESRD beneficiary for the treatment of ESRD to be a renal dialysis service and therefore not payable outside of the ESRD PPS is imprecise and harms all parties involved – including dialysis facilities, independent laboratories, and patients – by guaranteeing widespread inconsistent billing practices and unpredictable medical review outcomes, and by ignoring the fundamental principles of consolidated billing and the PPS methodology, which depend on predictability to enable efficient cost management. Instead they recommend that CMS adopt an objective standard, such as clearly stating that laboratory tests included in the consolidated billing list constitutes an all-inclusive list of laboratory tests included in the ESRD PPS.

Response: We plan to reassess the laboratory services policies under the ESRD PPS, including whether to establish an all-inclusive list of laboratory tests, in light of the clarification of our policy that links laboratory tests under the ESRD PPS with renal dialysis service drugs. With regard to the specific suggestion that we remove Vitamin D/Hydroxy laboratory service, we will address this suggestion in future guidance once we assess the extent to which the laboratory test is used and whether it is related to renal dialysis service drugs.

TABLE 10- ESRD DRUG CATEGORIES EXCLUDED FROM THE FINAL ESRD PPS BASE RATE

Drug Category	Rationale for Exclusion
Anticoagulant	Drugs labeled for non-renal dialysis conditions and not for vascular access.
Antidiuretic	Used to prevent fluid loss.
Antiepileptic	Used to prevent seizures.
Anti-inflammatory	May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions.
Antipsychotic	Used to treat psychosis.
Antiviral	Used to treat viral conditions such as shingles.
Cancer management	Includes oral, parenteral and infusions. Cancer drugs are covered under a separate benefit category.
Cardiac management	Drugs that manage blood pressure and cardiac conditions.
Cartilage	Used to replace synovial fluid in a joint space.
Coagulants	Drugs that cause blood to clot after anti-coagulant overdose or factor VII deficiency
Cytoprotective agents	Used after chemotherapy treatment
Endocrine/metabolic management	Used for endocrine/metabolic disorders such as thyroid or endocrine deficiency, hypoglycemia, and hyperglycemia
Erectile dysfunction management	Androgens were used prior to the development of ESAs for anemia management and currently are not recommended practice. Also used for hypogonadism and erectile dysfunction.
Gastrointestinal management	Used to treat gastrointestinal conditions such as ulcers and gallbladder disease
Immune system management	Anti-rejection drugs covered under a separate benefit category.
Migraine management	Used to treat migraine headaches and symptoms

Drug Category	Rationale for Exclusion
Musculoskeletal management	Used to treat muscular disorders such as prevent muscle spasms, relax muscles, improve muscle tone as in myasthenia gravis, relax muscles for intubation and induce uterine contractions
Pharmacy handling for oral anti-cancer, anti-emetics and immunosuppressant drugs	Not a function performed by an ESRD facility
Pulmonary system management	Used for respiratory/lung conditions such as opening airways and newborn apnea
Radiopharmaceutical procedures	Includes contrasts and procedure preparation
Unclassified drugs	Should only be used for drugs that do not have a HCPCS code and therefore cannot be identified
Vaccines	Covered under a separate benefit category

2. Renal Dialysis Service Drugs and Biologicals

a. 2014 Part D Call Letter Follow-up

In the proposed rule (80 FR 37837), we explained that last year we received public comments that expressed concern that the 2014 Part D Call Letter provision for prior authorization for drug categories that may be used for ESRD as well as other conditions resulted in Part D plan sponsors inappropriately refusing to cover oral drugs that are not renal dialysis services. Specifically, they noted that beneficiaries had difficulties obtaining necessary medications such as oral antibiotics prescribed for pneumonia and that the 2014 Part D Call Letter provision led to confusion for Part D plan sponsors and delays in beneficiaries obtaining essential medications at the pharmacy.

In response to the comments, we explained that the guidance in the 2014 Part D Call Letter was issued in response to increases in billing under Part D for drugs that may be prescribed for renal dialysis services but may also be prescribed for other conditions. The guidance strongly encouraged Part D sponsors to place beneficiary-level prior authorization edits on all drugs in the seven categories identified in the CY 2011 ESRD PPS final rule as drugs that may be used for dialysis and non-dialysis purposes (75 FR 49051). These include: antiemetics, anti-infectives, anti-pruritics, anxiolytics, drugs used for excess fluid management, drugs used for fluid and electrolyte management including volume expanders, and drugs used for pain management (analgesics). We indicated in the CY 2015 ESRD PPS final rule (79 FR 66151) that we were considering various alternatives for dealing with this issue, as it has always been our intention to eliminate or minimize disruptions or delays in ESRD beneficiaries receiving essential medications and that we planned to issue further guidance to address the issue.

In the Health Plan Management System memo issued on November 14, 2014, we encouraged sponsors to remove the beneficiary-level prior authorization (PA) edits on these drugs. When claims are submitted to Part D for drugs in the seven categories, we expect that they are not being used for the treatment of ESRD and, therefore, may be coverable under Part D. We also expect that Medicare ESRD facilities will continue to provide all of the medications used for the treatment of ESRD, including drugs in the seven categories. We will continue to monitor the utilization of renal dialysis drugs and biologicals under Part B and Part D.

b. Oral or Other Forms of Renal Dialysis Injectable Drugs and Biologicals

The ESRD PPS includes certain drugs and biologicals that were previously paid under Part D. Oral or other forms of injectable drugs and biologicals used for the treatment of ESRD,

for example, vitamin D analogs, levocarnitine, antibiotics or any other oral or other form of a renal dialysis injectable drug or biological are also included in the ESRD PPS and may not be separately paid. These drugs are included in the ESRD PPS payment because the payments made for both the injectable and oral forms were included in the ESRD PPS base rate. As discussed in section II.B.4.of this final rule, implementation of oral-only drugs used in the treatment of ESRD (that is, drugs with no injectable equivalent) under the ESRD PPS payment has been delayed until 2025.

In the CY 2011 ESRD PPS final rule (75 FR 49172), we stated that ESRD facilities are required to record the quantity of oral medications provided for the monthly billing period. In addition, ESRD facilities would submit claims for oral drugs only after having received an invoice of payment. We indicated that we would address recording of drugs on an ESRD claim in future guidance. We included this requirement because renal dialysis drugs and biologicals that were paid separately prior to the ESRD PPS, as many of these oral medications were, are eligible outlier items and services. If an ESRD facility were to report a 90-day supply of a drug on a monthly claim, the claim could receive an outlier payment erroneously.

On June 7, 2013, we issued an update to the Medicare Benefits Policy Manual, Pub. 100-02, Chapter 11 to reflect implementation of the ESRD PPS in Change Request 8261.In section 20.3.C of the updated Medicare Benefits Policy Manual, we stated that for ESRD-related oral or other forms of drugs that are filled at the pharmacy for home use, ESRD facilities should report one line item per prescription, but only for the quantity of the drug expected to be taken during the claim billing period.

Example: A prescription for oral vitamin D was ordered for one pill to be taken 3 times daily for a period of 45 days. The patient began taking the medication on April 15, 2011.

On the April claim, the ESRD facility would report the appropriate National Drug Code (NDC) code for the drug with the quantity 45 (15 days x 3 pills per day). The remaining pills which would be taken in May would appear on the May claim for a quantity of 90 (30 days x 3 pills per day). Prescriptions for a 3 month supply of the drug would never be reported on a single claim. Only the amount expected to be taken during the month would be reported on that month's claim.

In February 2015, we were informed by one of the large dialysis organizations that they, and many other ESRD chain organizations, are out of compliance with the requirement that only the quantity of the drug expected to be taken during the claim billing period should be indicated on the ESRD monthly claim. They indicated that some facilities are incorrectly reporting units that reflect a 60-day or 90-day prescription while other facilities are not reporting the oral drugs prescribed. The reason given for these reporting errors is the lack of prescription processing information. Specifically, while the facilities know when the pharmacy fills the prescription, they do not know when the patient picks up the drug from the pharmacy and begins to take the drug.

Due to this confusion and lack of compliance, we are reiterating our current policy that all renal dialysis service drugs and biologicals prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities and the units reported on the monthly claim must reflect the amount expected to be taken during that month. The facilities should use the best information they have in determining the amount expected to be taken in a given month, including fill information from the pharmacy and the patient's plan of care. Any billing system changes to effectuate this change must be made as soon as possible as this requirement has been in effect since the ESRD PPS began in 2011. We are analyzing ESRD

facility claims data to determine the extent of the reporting error and may take additional actions in the future.

We received the following comment on the clarification which is described below.

Comment: A patient advocacy group requested that CMS change its requirement that the monthly claim submitted by ESRD facilities only report the ESRD-related oral drugs expected to be taken during the month. They believe it is burdensome to ESRD facilities to compute the amount of pills prescribed to a patient within the claim period, especially for smaller facilities, whose limited resources make this type of data manipulation more arduous. They noted that this requirement diverts resources away from patient care.

Response: Unfortunately, we are unable to revise the billing requirements as the commenter suggests. ESRD facilities submit a monthly bill, which needs to include only the items and services utilized during the month. Under the outlier policy, we sum the MAP amounts for the outlier services on the claim to assess whether that amount exceeds the predicted outlier services MAP amount plus the fixed dollar loss amount. If an ESRD facility were to report a 90-day supply of a drug on a monthly claim, the claim could receive an outlier payment erroneously.

c. Reporting of Composite Rate Drugs

As we indicate in the Medicare Claims Processing Manual, Pub. 100-04, Chapter 8, section 50.3, as revised by Change Request 8978, issued December 2, 2014, in an effort to enhance the ESRD claims data for possible future refinements to the ESRD PPS, CMS announced that ESRD facilities should begin reporting composite rate drugs on their monthly claims. Specifically, ESRD facilities should only report the composite rate drugs identified on the consolidated billing drug list and provided below in Table 11.

TABLE 11- COMPOSITE RATE DRUGS AND BIOLOGICALS

Composite Rate Drugs and Biologicals	A4802	INJ PROTAMINE SULFATE
	J0670	INJ MEPIVACAINE HYDROCHLORIDE
	J1200	INJ DIPHENHYDRAMINE HCL
	J1205	INJ CHLOROTHIAZIDE SODIUM
	J1240	INJ DIMENHYDRINATE
	J1940	INJ FUROSEMIDE
	J2001	INJ LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG
	J2150	INJ MANNITOL
	J2720	INJ PROTAMINE SULFATE
	J2795	INJ ROPIVACAINE HYDROCHLORIDE
	J3410	INJ HYDROXYZINE HCL
	J3480	INJ. POTASSIUM CHLORIDE, PER 2 MEQ.
	Q0163	DIPHENHYDRAMINE HYDROCHLORIDE

The ESRD PPS payment policy remains the same for composite rate drugs, therefore, no separate payment is made and these drugs will not be designated as eligible outlier services. This information will provide CMS with the full scope of renal dialysis services which may better target outlier services to the most costly patients. We did not receive any comments on the clarification of reporting composite rate drugs and biologicals.

III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year

A. Background

For more than 30 years, monitoring the quality of care provided by dialysis facilities to patients with end-stage renal disease (ESRD) has been an important component of the Medicare ESRD payment system. The ESRD Quality Incentive Program (QIP) is the most recent step in

fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS. The ESRD QIP is authorized by section 1881(h) of the Social Security Act (the Act), which was added by section 153(c) of the Medicare Improvements for Patients and Providers Act (MIPPA).

Section 1881(h) of the Act requires the Secretary to establish an ESRD QIP by (1) selecting measures; (2) establishing the performance standards that apply to the individual measures; (3) specifying a performance period with respect to a year; (4) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (5) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score (TPS). This final rule discusses each of these elements and our policies for their application to PY 2017, PY 2018, PY 2019, and future years of the ESRD QIP.

We received comments about general policies and principles of the ESRD QIP. The comments and our responses are set forth below.

Comment: Two commenters argued that ESRD QIP standards often prevent improved patient outcomes by being a roadblock to the conduct of clinical trials which, commenters argued, are critically important in the quest for advancement of quality care for patients with ESRD. They added that exemption from certain performance standards and/or quality measures should be available for those patients who are involved in clinical trials, particularly when they involve evidence gathering to promote improved patient outcomes. One commenter specifically recommended that any patients entered into such a trial be exempted from the vascular access measure topic, which assesses the percentage of patients with catheters versus the percentage of patients with fistulas so that their providers can participate in the trial without fear of being

penalized under the ESRD QIP.

Response: We thank commenters for their recommendation and will consider the appropriateness of the ESRD QIP requirements for participation and exceptions thereto for future years of the program.

Comment: A few commenters expressed concerns with the way CMS releases ESRD QIP data. One commenter requested that CMS make all data used in developing proposed rules available at the time the proposed rule is published and another expressed concerns with the format and timing of data releases.

Response: We seek to be as transparent as possible and have released all analyses that we took into consideration in the development of the proposed rule. In addition, we published a public use data file at the same time as the proposed rule for the ESRD QIP that contains the facility-level data used to calculate the performance standards, achievement thresholds, and benchmarks we proposed for the program. These public use files are available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/08_ReportandCert.html. Furthermore, in response to comments received during the notice-and-comment process, we have conducted additional analyses and are describing those results in this final rule and on the CMS Web site, as well as making the details of these additional analyses available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

Comment: Commenters recommended that CMS focus on stabilizing the existing policies and measures in the ESRD QIP before adopting any new measures. They expressed concern that constantly increasing the measure set's size and complexity gives facilities little time to implement new policies and procedures for data collection and reporting while also providing

high quality care on a daily basis. One commenter argued that as the number of measures increases, so too do costs to providers and to CMS. They stated that the QIP should strive to include, to the extent feasible, those measures which address multiple domains of CMS's value-based purchasing programs and are not duplicative.

Response: Although we recognize that adopting more measures in the ESRD QIP increases costs to facilities as well as to CMS, we believe these increased costs are outweighed by the benefits to patients of incentivizing quality care in the domains that the measures cover. We agree that adopting measures that span multiple domains, such as the SRR clinical measure, allows us to address multiple aspects of quality, reduces the total number of measures in the ESRD QIP, and presents less burden for facilities than adopting multiple measures that each address a single domain. Going forward, we will continue to strive to ensure that the ESRD QIP measure set is as parsimonious as possible.

Comment: One commenter requested information regarding the claims that we used to calculate facility performance on the dialysis adequacy clinical measures for the PY 2016 ESRD QIP.

Response: For PY 2016, CY 2014 Medicare outpatient dialysis claims (bill type 72) were used to calculate the dialysis adequacy measures. These claims data were extracted from CMS systems on April 24, 2015 and included all fully adjudicated claims submitted by facilities that were in final action status[2] as of that date.

Comment: One commenter requested clarification on how the ESRD QIP accounts for patients who switch modality mid-month for measures collected using CROWNWeb.

2 A claim is considered to be in final action status when it reflects services billed by the facility for facility costs, has been processed by the Medicare Administrative Contractor, has been resubmitted and corrected if necessary, and has been finalized.

Response: For PY 2016 there was no distinction made between hemodialysis and peritoneal dialysis patients with regard to the serum calcium and serum phosphorus values reported in CROWNWeb, which is consistent with the specifications for the Hypercalcemia clinical measure. All clinical values submitted under either modality were reviewed and the last clinical value submitted for each month was used for the calculation of the Hypercalcemia measure. The Mineral Metabolism reporting measure considers the aggregate modality during a month, as defined by the patient's Medicare claims, to determine patient eligibility for the month. If the aggregate modality is in-center hemodialysis and the patient was not treated at least seven times during the month and then changes modality to peritoneal dialysis to home hemodialysis, the patients would be excluded. However, if the patient switches from in-center hemodialysis to peritoneal dialysis or home hemodialysis and the aggregate modality is either home hemodialysis or peritoneal dialysis, the patient would be included in the measure. Regardless of the modality listed on a patient's claims, any serum phosphorus value reported as either a peritoneal dialysis or home hemodialysis in CROWNWeb would count as an eligible serum phosphorus value, but if a patient switched modalities during the month, it could impact their eligibility for that month. The Pain Assessment and Follow-Up and Screening for Clinical Depression and Follow-Up Reporting Measures, which are also collected using CROWNWeb, do not account for a patient's treatment modality in their scoring calculations.

Comment: One commenter requested that only Medicare-based measure data be used to calculate performance scores impacting Medicare payments.

Response: Although payment reductions under the ESRD QIP are made to a facility's Medicare ESRD reimbursement amounts, in order to properly assess whether Medicare beneficiaries are receiving the same quality of care as other patients, we believe it is appropriate

to collect, where possible, all-patient data.

Comment: One commenter urged CMS to create more alignment among its quality programs. The goals of the ESRD QIP, DFC, and the Conditions for Coverage are all designed to ensure the best possible outcomes for patients but when the programs do not align, the commenter argued, facilities are confused and are not as well equipped to meet the demands of the separate programs.

Response: We agree with the goal of creating more alignment among CMS's quality programs. As stated previously in the CY 2015 final rule with comment period (79 FR 66162), the goals of the ESRD QIP closely align with the goals of the CMS Quality Strategy (the CMSQS), which all CMS quality improvement efforts are structured around, including DFC and the ESRD Conditions for Coverage. The CMSQS is designed to guide the activities of various components throughout the Agency and is aligned with the Department of Health and Human Services' (HHS') National Quality Strategy (the NQS). The six goals of the CMSQS—(1) make care safer by reducing harm caused in the delivery of care; (2) strengthen person and family engagement as partners in their care; (3) promote effective communication and coordination of care; (4) promote effective prevention and treatment of chronic disease; (5) work with communities to promote best practices of healthy living; and (6) make care affordable—are organized around NQS's three broad aims of Better Care; Affordable Care; and Healthy People, Healthy Communities and drive and orient all of CCSQ's quality improvement programs, including the ESRD QIP, insofar as these aims align with the statutory goals of the program.

The strategic vision of the ESRD QIP is to adopt measures that address each of these goals. The following table illustrates the program's efforts to implement this strategic vision:

TABLE 12 – CMSQS Goal and ESRD QIP Measure Alignment

CMSQS Goal	Measure	
Promote effective prevention and treatment of chronic disease	Dialysis Adequacy	
	Vascular Access Type Measure Topic	Fistula
		Catheter for at Least 90 Days
	Mineral Metabolism Reporting	
	Anemia Management Reporting	
	Hypercalcemia	
	Standardized Transfusion Ratio	
	Screening for Depression and Follow Up reporting	
	Pain Assessment and Follow-Up reporting	
Strengthen person and family engagement as partners in their care	ICH CAHPS Reporting (**PY 2017**) and clinical (**PY 2018**)	
Promote effective communication and coordination of care	Standardized Readmissions Ratio	
Make care safer by reducing harm caused in the delivery of care	NHSN Bloodstream Infection in Hemodialysis Outpatients	
	NHSN Healthcare Personnel Influenza Vaccination reporting	
Work with communities to promote best practices of healthy living	None.	
Making care affordable	None.	

As the table above illustrates, the ESRD QIP has not adopted measures for the following quality goals:

- Work with communities to promote the best practices of healthy living.
- Making care affordable.

We will evaluate these remaining goals, particularly the goal of making care affordable, to assess their appropriateness as policy goals for the ESRD QIP. In addition to evaluating the ESRD QIP measure set in terms of how well it addresses legislative mandates, NQS and CMSQS

goals, we are also evaluating how well the measure set addresses policy priorities that stakeholders have brought to our attention. We continue to engage both external and internal stakeholders on a regular basis, to communicate the strategic vision of the program as well as to engage in dialogue useful to the development and implementation of policy that will effectively create improvements in the quality of care provided to ESRD beneficiaries.

Comment: One commenter requested that CMS provide a clear definition of when patients are no longer considered ESRD and are therefore excluded from measure calculations.

Response: For claims-based measures, if a facility submits a Medicare outpatient dialysis facility claim (bill type 72) for treatment provided to a patient, then the patient is considered to be on chronic dialysis. Patients are not included in a claims-based measure calculation for a month if a claim is not submitted for the patient for treatment received that month.

For the SRR and STrR measures, details regarding the determination of a patient's time on dialysis and patient attribution to a facility can be found in the "Report for the Standardized Readmission Ratio" and "Report for the Standardized Transfusion Ratio", respectively (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSRRMeasure.pdf ; https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSTrRMeasure.pdf). Finally, for CROWNWeb measures, if a patient is admitted to the facility during the month, the patient is considered to be eligible for the measure calculation until the patient is discharged. Depending on the measure, a patient may be required to be admitted to the facility for the entire reporting month in order to be included in that patient-month. We encourage commenters to review the measure specifications available on the CMS Web site for more information

(http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html).

Comment: Several commenters recommended that CMS work with the kidney community to establish a patient-centric vision for quality that aims to decrease mortality, decrease hospitalizations, increase patient satisfaction, and improve patient experience with care.

Response: We thank the commenters for their recommendation and support of collaboration between CMS and the ESRD community. We note that the ESRD QIP maintains measures that aim to decrease hospitalizations (the Standardized Readmission Ratio clinical measure) and increase patient satisfaction and experience with care (the ICH CAHPS clinical measure), and Dialysis Facility Compare maintains a Standardized Mortality Ratio measure. As such, we continue to engage both internal and external stakeholders on a regular basis, to communicate the strategic vision of the Program as well as to engage in dialogue useful to the development and implementation of policy that will effectively create improvements in the quality of care provided to ESRD patients.

Comment: One commenter recommended that CMS consider adopting the following major tenets: (1) continued transparency and collaboration in measure development and specifications; (2) parsimony in the QIP and other programs that comparatively assess quality of care performance; (3) avoidance of incentives that may undermine the delivery of individualized patient care to obtain a more favorable QIP score; and (4) recognizing promptly when a measure is topped out, either clinically or statistically, to avoid unintended consequences, including loss of the ability to individualize care, pressure to provide care that may not be in the best interests of an individual patient and/or diverting attention from other measures that may be better targets for quality improvement.

Response: We thank the commenter for its recommendations and we agree with the general principles expressed. We also already consider these tenets in the development and refinement of the ESRD QIP. We seek to collaborate with measure developers on measures and specifications and we continue to seek ways to increase transparency. One example of this is the Measures Manual, currently in development and discussed more fully below, which will compile the technical measure specifications of ESRD QIP and Dialysis Facility Compare measures in a single resource that is easy to use. We are also developing a mechanism that will allow stakeholders to recommend refinements to ESRD QIP measures based on their clinical experience.

We also seek parsimony in the QIP and other programs that comparatively assess quality of care. We continue to assess the negative unintended consequences of measures and policies maintained by the ESRD QIP through efforts such as the Access to Care study in an effort to incentivize the delivery of individualized patient care, and will continue to do so. Finally, in the CY 2015 ESRD PPS final rule with comment period (79 FR 66171 through 66174), we developed a set of statistical criteria for determining when a measure is "topped out" and may therefore be eligible for removal from the ESRD QIP. We look forward to continued collaboration with the ESRD community to achieve each of these goals.

Comment: One commenter emphasized the importance of ensuring that all patients are educated about their treatment options and where to get them, and recommended that CMS require the use of a values-based, patient-centered dialysis decision aid for patients. The commenter explained that such a tool would ensure patients have the opportunity to match their values to the varying treatment options and choose a treatment that is a good fit for their lifestyles and preferences.

Response: We agree that it is important for patients to be educated about their treatment options and where various treatments may be available. Dialysis treatment is a highly individualized process of care; we therefore strongly encourage nephrologists and dialysis facilities to discuss treatment options with their patients on an ongoing basis to account for changes in the patient's health and experience with dialysis treatment.

Comment: One commenter urged CMS to consider adopting a bifurcated quality reporting and value based purchasing program for ESRD similar to those we have implemented for the Hospital VBP and Hospital Inpatient Quality Reporting Programs.

Response: We thank commenters for their recommendation and note that we currently adopt some ESRD QIP measures as reporting measures prior to assessing performance on those measures as clinical measures.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2019 Proposed Rule

The proposed rule, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program" (80 FR 37807 through 37860), (hereinafter referred to as the CY 2016 ESRD PPS proposed rule), was published in the **Federal Register** on July 1, 2015, with a comment period that ended on August 25, 2015. In that proposed rule, for the ESRD PPS, we proposed routine updates to the End-Stage Renal Disease Quality Incentive Program, proposed to adopt new measures the PY 2019 ESRD QIP measure set, and proposed to revise the small facility adjuster (SFA) used in facility scoring for the program. We received approximately 37 public comments on our proposals, including comments from: ESRD facilities,

national renal groups, nephrologists and patient organizations, patients and care partners, manufactures, health care systems, and nurses.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ESRD QIP. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

C. Clarification of ESRD QIP Terminology: "CMS Certification Number (CCN) Open Date"

Some stakeholders have expressed confusion about the use of the term "CMS Certification Number (CCN) Open Date" under the ESRD QIP (for example, see 79 FR 66186). We interpret this term to mean the "Medicare effective date" under 42 CFR 489.13, which governs when the facility can begin to receive Medicare reimbursement for ESRD services under the ESRD PPS. Thus, a facility is eligible, with respect to a particular payment year, to receive scores on individual measures and participate in general in the ESRD QIP based on the facility's CCN Open Date (that is, Medicare effective date).

We received comments on this clarification. The comments and our responses are set forth below.

Comment: Many commenters supported our clarification of the term, "CMS Certification Number (CCN) Open Date," and appreciated this clarification. One commenter added that once a facility is eligible to receive payment under the ESRD PPS, it should also be eligible to participate in the ESRD QIP.

Response: We thank the commenters for their support and are pleased that this clarification will reduce confusion for facilities moving forward. We note that facility eligibility

to receive payment under the ESRD PPS is also keyed to a facility's CCN Open Date; therefore, facilities are eligible to receive payment under the ESRD PPS at the same time as they become eligible to participate in the ESRD QIP.

D. Use of the Hypercalcemia Measure as a Measure Specific to the Conditions Treated with Oral-Only Drugs

Section 217(d) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93), enacted on April 1, 2014, amends section 1881(h)(2) of the Act to require the Secretary to adopt measures in the ESRD QIP (outcomes based, to the extent feasible) that are specific to the conditions treated with oral-only drugs for 2016 and subsequent years. We stated in the CY 2015 ESRD PPS final rule (79 FR 66168-69) that we believed the Hypercalcemia clinical measure, which was adopted beginning with the PY 2016 program meets this new statutory requirement; nevertheless, we also recognized that, consistent with PAMA, we could adopt measures as late as for CY 2016, which would be included in the PY 2018 ESRD QIP. We also stated that we would take into account comments on whether the Hypercalcemia clinical measure can be appropriately characterized as a measure specific to the conditions treated with oral-only drugs.

Although section 1881(h)(2)(E)(i) does not define the term "oral-only drugs," we have previously interpreted that term to mean "drugs for which there is no injectable equivalent or other form of administration" (75 FR 49038). We have also previously identified calcimimetics and phosphate binders as two types of "oral-only drugs" (75 FR 49044).

We are currently aware of three conditions that are treated with calcimimetics and phosphate binders: Secondary Hyperparathyroidism, Tertiary Hyperparathyroidism, and Hypercalcemia. Hypercalcemia is a condition that results when the entry of calcium into the

blood exceeds the excretion of calcium into the urine or deposition in bone; the condition may be caused by a number of other conditions, including hyperparathyroidism. Although multiple treatment options are available for patients with early forms of hypercalcemia, calcimimetics are frequently prescribed for those patients who develop hypercalcemia secondary to tertiary hyperparathyroidism, in order to most easily control the patients' serum calcium levels. Because hypercalcemia is a condition that is frequently treated with calcimimetics, and because calcimimetics are oral-only drugs, we believe that the current Hypercalcemia clinical measure (NQF #1454) meets the requirement that the ESRD QIP measure set include for 2016 and subsequent years measures that are specific to the conditions treated with oral-only drugs.

We acknowledge that the Hypercalcemia clinical measure is not an outcome-based measure, and we have considered the possibility of adopting outcome-based measures that are specific to the conditions treated with oral-only drugs. However, we are currently not aware of any outcome-based measures that would satisfy this requirement. We welcomed comments on whether such outcome-based measures are either ready for implementation now or are being developed, and we intend to consider the feasibility of developing such a measure in the future.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* Many commenters did not support use of the Hypercalcemia clinical measure to satisfy the requirements of PAMA. Some commenters stated that CMS's rationale for using this measure is that calcimimetics are oral-only agents commonly used to treat hypercalcemia. The commenters argued however, that only 1/3 of ESRD patients are prescribed a calcimimetic, and noted that, while it is true that the pharmacologic mechanism of calcimimetics results in lower serum calcium, they are not in fact FDA-approved to treat hypercalcemia in patients with

secondary hyperparathyroidism. The commenters maintained that hypercalcemia in ESRD patients is commonly due to the receipt of Vitamin D analogs, which are not oral-only agents. Commenters also noted that the treatment of hypercalcemia commonly includes reducing or discontinuing vitamin D analogs in addition to decreasing the dialysate calcium concentration. One commenter did not support CMS' position that the Hypercalcemia clinical measure meets the requirements of PAMA because the measure only assesses calcium lab values, which are not the most accurate indicator of care for patients prescribed oral-only drugs. Another commenter argued that the Hypercalcemia clinical measure does not satisfy the requirements of PAMA because hypercalcemia may be treated with drugs other than oral-only drugs, including bisphosphonates, IV fluids and diuretics.

Response: We thank the commenters for their comments. We note that the KDIGO clinical practice guidelines recommend maintenance of CKD 3-5D patient's serum calcium in the normal range. This was recognized by the C-TEP members that developed the Hypercalcemia clinical measure in 2010 and other clinical experts (NQF subcommittee and 2013 C-TEP) who reviewed that measure and agreed with the basic justification for the measure that some treatments used to treat hyperparathyroidism have been shown to cause hypercalcemia. Furthermore, clinical concerns about the use of calcium-containing phosphorus binders have been raised by some in the dialysis community related to risk for hypercalcemia and calcium-related vascular mineralization. Hypercalcemia is seen as a potentially dangerous consequence of such treatments, based on a growing laboratory experimental literature and clinical paradigm that points to vascular calcification as an emerging non-traditional risk factor for vascular disease in this population. This emerging paradigm and concerns about unintended consequences of use of vitamin D sterols to treat hyperparathyroidism are reflected in the

KDIGO guideline that specifically recommends reduction or discontinuation of vitamin D therapy in patients who develop hypercalcemia.

The alternative to use of vitamin D sterols for treatment of hyperparathyroidism is cinacalcet, a calcimimetic agent approved for treatment of secondary hyperparathyroidism. As noted in the package insert for cinacalcet, lower serum calcium and even hypocalcemia have been noted with cinacalcet use, demonstrating the complex interplay between alternative drugs used to treat hyperparathyroidism and hyperphosphatemia, and the role of these drugs in the development and treatment of hypercalcemia and hyperparathyroidism.

In addition, although we agree that hypercalcemia may also be treated with drugs that are not oral-only drugs, including bisphosphonates, IV fluids and diuretics, we do not interpret section 217(d) of PAMA as requiring the Secretary to adopt measures which are specific to the conditions treated *only* with oral-only drugs. Because hypercalcemia can be treated with calcimimetics, an oral-only drug, we continue to believe that the hypercalcemia clinical measure satisfies the requirements of PAMA.

We also note that limitations in available evidence have, thus far, prevented us from developing measures that might address oral-only medications that are more broadly used in the ESRD dialysis population. In 2010, a Technical Expert Panel discussed the possibility of developing measures for phosphorous, but was unable to come to a consensus regarding a phosphorus measure that assesses appropriate levels of phosphorous due to a lack of evidence supporting a clinical threshold. A process measure was developed and originally endorsed by the NQF in 2007, and is the measure on which the current Mineral Metabolism reporting measure is based. However, as explained below, we believe that the Mineral Metabolism measure is limited because it only assesses the reporting of phosphorus values, rather than

assessing performance based on the values themselves. In addition, the Mineral Metabolism reporting measure does not meet the requirements of PAMA because this measure, as adopted for the ESRD QIP, is not NQF-endorsed or adopted by another consensus-based entity with expertise in kidney disease. In 2011, NQF reviewed one measure with an upper limit (hyperphosphatemia) and one measure with a lower limit (hypophosphatemia), but did not endorse either measure. A recent 2013 Technical Expert Panel recommended the development of a reporting measure for PTH. However, the panel concluded that there was insufficient evidence to develop a clinical intermediate outcome measure with a target PTH value. We are unaware of more recent evidence suggesting that a new measure meeting the requirements of PAMA will be available in the near future, but are interested in discussing any such evidence with stakeholders.

As the state of clinical evidence evolves to support additional, more comprehensive measures of mineral bone disease, we look forward to continued consultation with the dialysis community.

Comment: A number of commenters did not support the use of the Hypercalcemia clinical measure to satisfy the requirements of PAMA based on belief that the measure does not provide value to the patient, relate to the provision of quality care, or adequately reflect the complexity of bone and mineral disorders. They also noted that the NQF Renal Steering Committee initially recommended against endorsement for the Hypercalcemia clinical measure during its May, 2015 meeting. Several commenters also encouraged CMS to work with experts in the kidney community to develop a composite measure evaluating phosphorus, calcium, and parathyroid hormone levels because such a measure would be more likely to improve patient outcomes than multiple individual measures. Specifically, they recommended that CMS

convene a TEP to develop a measure, which can be submitted for endorsement by NQF, and which would satisfy the statutory and regulatory requirements. Other commenters recommended the adoption of individual measures on serum phosphorus management, hyperphosphatemia, and medication reconciliation.

Response: Although the Hypercalcemia clinical measure does not assess all of the hormone levels mentioned by the commenters, we believe this measure assesses an important aspect of ESRD patients' care because abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced chronic kidney disease. We also believe that the measure relates to the provision of quality care furnished to patients by facilities because issues related to bone mineral metabolism have serious health consequences for patients with ESRD. As discussed above, we would welcome the opportunity to work with stakeholders to develop a more comprehensive measure that meets the requirements of PAMA.

Comment: One commenter did not support the use of the Hypercalcemia clinical measure to satisfy the requirements of PAMA because they believe that an isolated metric to avoid hypercalcemia could have the unintended consequence of leading to a decrease in utilization of vitamin D analogs and calcium-containing phosphate binders, which might result in worsening the incidence of hyperparathyroidism and hyperphosphatemia in ESRD patients.

Response: We agree that it would be beneficial to adopt a more comprehensive mineral bone disease measure, but as explained above, we are currently unaware of any measure on this topic.

Comment: One commenter recommended CMS convene a Technical Expert Panel on oral-only drugs to spur development of a more appropriate measure on this topic.

Response: We thank the commenter for its recommendation, and we intend to examine opportunities to convene a TEP specific to conditions treated using oral-only drugs.

Comment: One commenter recommended that CMS use the current Mineral Metabolism reporting measure to satisfy the requirements of PAMA because hypercalcemia is an incomplete proxy for monitoring conditions currently treated with oral-only drugs. The commenter further noted that a larger proportion of ESRD patients are treated with oral phosphate binder therapy for hyperphosphatemia than with calcimimetics for hypercalcemia.

Response: We note that the Mineral Metabolism reporting measure assesses facilities reporting phosphorous values, not the values themselves. Furthermore, previous attempts to develop measures for phosphorous in 2010 and 2011 were unsuccessful because consensus was not reached regarding an appropriate level of phosphorous due to lack of clinical evidence. We therefore believe that the Hypercalcemia clinical measure is a superior measure of bone mineral metabolism at this time. In addition, the Mineral Metabolism reporting measure does not meet the requirements of PAMA because this measure, as adopted for the ESRD QIP, is not NQF-endorsed or adopted by another consensus-based entity with expertise in kidney disease.

E. Sub-Regulatory Measure Maintenance in the ESRD QIP

In the CY 2013 ESRD PPS final rule, we finalized our policy to use a sub-regulatory process to make non-substantive updates to measures (77 FR 67477). We currently make available the technical specifications for ESRD QIP measures at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html but are in the process of drafting a CMS ESRD Measures Manual which will include not only the ESRD QIP measure specifications, but also technical information on quality indicators that facilities report for other

CMS ESRD programs. We expect to release the first version of the CMS ESRD Measures Manual in the near future at the following web address: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/index.html. The manual will be released before the beginning of the applicable performance period, preferably at least 6 months in advance. We believe that this update frequency will be sufficient to provide facilities with information needed to incorporate these updates into their ESRD data collection activities. We note that this policy is consistent with our policy for updating the CMS National Hospital Inpatient Quality Measures Specifications Manual, which is posted on the QualityNet website (www.qualitynet.org).

We welcomed recommendations from the public on technical updates to ESRD QIP measures. We will consider the appropriateness of all recommendations, notify those who submit recommendations as to whether we accept the recommendation, and incorporate accepted recommendations in a future release of the CMS ESRD Measure Manual. At present, we intend to use JIRA, a web-based collaboration platform maintained by the Office of the National Coordinator for Health Information Technology, to receive, consider, and respond to recommendations for non-substantive measure changes. Further information about how to use the JIRA tool to make such recommendations will be published in an upcoming CROWN Memo and will be posted to http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/index.html.

The comments and our responses are set forth below.

Comment: Many commenters supported CMS's development of an ESRD Measures Manual as an important step in increasing transparency and understanding of the ESRD measures. They also supported our intended use of the JIRA system to accept feedback and

suggestions from stakeholders and also recommended that CMS include contact information for Agency staff so that dialysis providers have a point-of-contact within the Agency who can answer questions regarding the interpretation of measures. One commenter added that the Manual should not replace traditional notice-and-comment rulemaking with respect to measure details, but should instead serve as a document for aggregating technical specifications and implementation rules for all ESRD quality measures. One commenter recommended that CMS make the measure micro-specifications and other technical information part of the rulemaking process to ensure commenters fully understand measure proposals.

Response: We thank commenters for their support and we agree that the ESRD Measures Manual is an important step in increasing transparency and understanding of the ESRD measures as they are currently specified for use in the ESRD QIP and/or DFC. Although we intend to use JIRA as the sole means by which stakeholders communicate with us regarding the measures (outside of the rulemaking process), we will seek to ensure this process is as transparent as possible. The Manual will gather in one resource all measure specifications, including what we refer to as micro-specifications (additional technical details regarding the complexities of calculating measure scores), that are currently made available through separate resources. The Measures Manual will create an additional vehicle for communication and discussion of measure specifications, but will not replace the traditional notice-and-comment rulemaking process, or our policy to use rulemaking to adopt substantive updates to measures. Rather, the Measures Manual will be used to implement technical updates to measures, many of which can be suggested by stakeholders through JIRA. Consistent with our current policy, we will also provide notice of technical updates through CROWN Memos and other means of communication.

Comment: One commenter specifically requested that CMS make available additional detail about the STrR measure's technical specifications in the ESRD Measures Manual, along with detailed flowcharts or computer codes so that the public can replicate the mathematics used, and asked that these be provided prior to adopting any measures in future years of the QIP.

Response: The upcoming Measures Manual will include all necessary information to calculate measure scores for all clinical measures, including the STrR clinical measure. We encourage stakeholders to review and submit comments on the Measures Manual in order to ensure its responsiveness to stakeholder needs.

F. Revision to the Requirements for the PY 2017 ESRD QIP

1. Modifying the Small Facility Adjuster (SFA) Calculation for All Clinical Measures Beginning with the PY 2017 ESRD QIP

In the CY 2013 ESRD PPS final rule we adopted a scoring adjustment for facilities with relatively small numbers of patients, called the small facility adjuster, which aims to ensure that any error in measure rates due to a small number of cases will not adversely affect facility payment (77 FR 67511). Since we first implemented the methodology to implement the small facility adjuster, we have encountered two issues related to basing the adjustment on the within-facility standard error. First, facility scores for some of the outcome measures adopted in the ESRD QIP, such as the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, do not approximate a normal or "bell-shaped" distribution. In such cases, the within-facility standard error does not necessarily capture the spread of the data as it would if facility scores were normally distributed. Second, facilities and other stakeholders have commented that it is difficult for them to independently calculate pooled within-facility standard errors because doing so requires data for all patient-months across all facilities, which makes the

small facility adjuster unnecessarily opaque. For these reasons, we have developed an equation for determining the small facility adjuster that does not rely upon a within-facility standard error, but nonetheless preserves the intent of the adjuster to include as many facilities in the ESRP QIP as possible while ensuring that the measure scores are reliable.

Therefore, beginning with the PY 2017 ESRD QIP, we proposed to use the following methodology to determine the small facility adjustment:

- For the i^{th} facility, suppose the facility's original measure rate is p_i and the number of patients (or other unit used to establish data minimums for the measure. For example, index discharges for the Standardized Readmission Ratio clinical measure) at the i^{th} facility is n_i.
- Where the number of eligible patients (or other appropriate unit) needed to receive a score on a measure is *L* and the upper threshold for applying the small facility adjuster is *C*, the i^{th} facility will be eligible for the adjustment when $L \leq n_i < C$. Accordingly, *L* and *C* set the upper and lower thresholds of eligible patients (or other appropriate unit) a facility needs to have in order to be considered for a small facility adjustment; consistent with previously finalized policies, facilities with fewer than *L* eligible patients (or other appropriate unit) for a measure will not receive a score on that measure, and facilities with more than *C* eligible patients (or other appropriate unit) for a measure will not receive an adjustment for that measure.
- Assuming $L \leq n_i < C$, let $w_i = \frac{n_i}{C}$, where n_i is the number of patients (or other appropriate unit) at the i^{th} facility and *C* is the upper thresholds of eligible patients (or other appropriate unit) a facility needs to have in order to be considered for a small facility adjustment. This calculation will produce the facility's weighting coefficient for a

given clinical measure, w_i, which provides a metric for assessing the uncertainty due to small facility sizes.

- For measures where higher scores are better (for example, the Vascular Access Type (VAT): Fistula clinical measure and the Dialysis Adequacy clinical measures), a small facility's adjusted performance rates (t_i) will be pegged to the national mean performance rate ($\bar{P}$) as follows:
    - If $p_i < \bar{P}$, then $t_i = w_i * p_i + (1 - w_i) * \bar{P}$,
    - If p_i is greater than or equal to $\bar{P}$, the facility will not receive an adjustment.
- For measures where lower scores are better (for example, VAT: Catheter, NHSN BSI, Hypercalcemia, Standardized Readmission Ratio (SRR), and Standardized Transfusion Ratio (STrR) clinical measures), a small facility's adjusted performance rates (t_i) will be pegged to the national mean performance rate ($\bar{P}$) as follows:
    - If $p_i > \bar{P}$, then $t_i = w_i * p_i + (1 - w_i) * \bar{P}$
    - If p_i is less than or equal to $\bar{P}$, then the facility will not receive an adjustment
- For the standardized ratio measures, such as the SRR and STrR clinical measures, the national mean measure rate (that is, $\bar{P}$) is set to 1.

We note that the equation $t_i = w_i * p_i + (1 - w_i) * \bar{P}$ is designed to "shrink" the facility mean toward the national mean, and that w_i reflects the degree of confidence in the estimation of the facility mean, because it depends on facility size. Some research has shown that this type of "shrinkage estimator" equation gives a small mean squared error (that is, the combination of bias and variance) if the national mean truly reflects the performance of a small facility, which was the intention of the equation.[3]

3 Efron B, Morris C. Empirical Bayes on vector observations: An extension of Stein's method. *Biometrika*, 59(2):335-347. Ahmed SE, Khan SM. Improved estimation of the Poisson parameter. *Statistica*, anno LIII n.2, 268-

To assess the impact of the proposed small facility adjuster, we conducted an impact analysis of this proposed methodology on individual measure scores and facility TPSs, using the final dataset used to calculate PY 2015 ESRD QIP scores. The full results of this analysis can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Small-Facility-Adjustment-Proposal-for-the-ESRD-QIP.pdf. Table 13 summarizes these results, presenting changes in measure scores observed after applying the proposed small facility adjuster, as compared to measure scores calculated with the existing small facility adjuster. For the purposes of this analysis and for all of the measures, *L* was set to 11 and *C* was set to 26.

TABLE 13 – IMPACT OF PROPOSED SMALL FACILITY ADJUSTER ON INDIVIDUAL MEASURE SCORES, USING THE FINAL DATASET FOR THE PY 2015 ESRD QIP

Measure	# facilities received SFA in PY 2015	National mean in the performance period (CY 2013)	# facilities receiving SFA under new method	# facilities with score change due to new SFA method N (% out of scored facilities)	# facilities with higher score under new SFA method	# facilities with lower score under new SFA method
Hgb $\geq$ 12	1,253	0.4%	63	32 out of 5,513 (0.6%)	32	0
Fistula	938	64.1%	391	341 out of 5,547 (6.1%)	66	275
Catheter	826	11.7%	352	301 out of 5,562 (5.4%)	65	236
HD Kt/V	588	91.1%	173	248 out of 5,641 (4.4%)	22	226
Ped HD Kt/V	11	80.1%	1	8 out of 11 (72.7%)	0	8
PD Kt/V	787	76.4%	192	400 out of 1,203 (33.3%)	62	338
TPS				513 out of 5,650 (9.1%)	96	417
Reduction				43 out of 5,650 (0.8%)	23	20

As the results in Table 13 indicate, fewer facilities received an adjustment under the proposed small facility adjuster methodology, because small facilities with performance rates above the

286, 1993. Ahmed SE. Combining Poisson means. *Communications in Statistics: Theory and Methods*, 20, 771-789, 1991.

national mean do not receive an adjustment. However, those facilities that did receive an adjustment generally received a larger adjustment under the proposed methodology. For example, of the 43 facilities that received a different payment reduction under the proposed small facility adjuster, 23 (53 percent) received a lower payment reduction.

We also assessed the impact of the proposed small facility adjuster on the distribution of payment reductions, using the final dataset used to calculate PY 2015 ESRD QIP payment reductions. The full results of this analysis can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Small-Facility-Adjustment-Proposal-for-the-ESRD-QIP.pdf. Table 14 below compares the distribution of payment reductions using the existing small facility adjuster to the distribution of payment reductions using the proposed small facility adjuster. For the purposes of this analysis and for all of the measures, *L* was set to 11 and *C* was set to 26.

TABLE 14 – COMPARISON OF THE DISTRIBUTION OF PAYMENT REDUCTIONS DETERMINED WITH THE EXISTING AND PROPOSED SMALL FACILITY ADJUSTER, USING THE FINAL DATASET FOR THE PY 2015 ESRD QIP

Payment reduction distribution in PY 2015 using the existing SFA			Estimated payment reduction distribution in PY 2015 using the new SFA		
Payment Reduction	Number of Facilities	Percent of Facilities	Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	5,307	93.93%	0.0%	5,296	93.73%
0.5%	242	4.28%	0.5%	255	4.51%
1.0%	41	0.73%	1.0%	45	0.80%
1.5%	23	0.41%	1.5%	26	0.46%
2.0%	378	0.65%	2.0%	28	0.50%

Note: This table excludes 488 facilities that did not receive a score because they did not have enough data to receive a TPS.

These results suggest that a similar number of facilities would receive a payment reduction under the proposed small facility adjuster methodology. A total of 343 (6.1 percent) facilities would receive a payment reduction with the existing small facility adjuster; under the proposed small facility adjuster methodology, a total of 354 (6.3 percent) facilities would have

received a payment reduction. Based on the results of these analyses, we believe that the proposed small facility adjuster does not systematically alter the distribution of measure scores, TPSs, and payment reductions, as compared to the existing small facility adjuster. Coupled with the benefits of removing the within-facility standard error variable from the existing adjuster (discussed above), this leads us to believe that the benefits of the proposed adjuster outweigh the benefits of the existing adjuster. We therefore proposed to modify the methodology for determining the small facility adjustment as explained above.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Several commenters supported the overall objectives of the proposed small facility adjuster modification, but expressed concern with the proposed methodology and its alignment with the intended purpose of the SFA. These commenters were primarily concerned that too few facilities would receive an adjustment under the proposed SFA and recommended that CMS consider an SFA formula that more closely approximates the current SFA's effect on measure scores. One commenter asserted that because small facilities with performance rates above the national mean will not receive an adjustment under the proposed small facility adjuster calculation, they will experience the SFA as a performance reduction, when compared to the current SFA, which goes against the goals of the SFA generally.

Another commenter conducted a detailed analysis of the proposed SFA using data from Dialysis Facility Compare and found that, of the 3,598 facilities in DFC, 480 met the following two criteria: (1) a facility sample size between 11 and 25, and (2) their un-adjusted performance rate was above the national median, for at least one measure. Additionally, this commenter found that 266 facilities met these criteria for at least two measures, meaning they would have

received an adjustment under the current SFA but would no longer receive one under the proposed SFA. This commenter also analyzed the average magnitude that the proposed SFA would have on facilities' scores and found that for the fistula measure, for example, the current SFA adjusts performance up by an average of 2.9 percent for small facilities, whereas the proposed SFA increases performance only by an average of 1.1 percent. The commenter found similar results for other measures, and therefore urged CMS to adopt an SFA formula which more closely approximates the current SFA's impact on measure scores.

One commenter offered an alternative to the proposed Small Facility Adjuster, which was also supported by several other commenters who reviewed the alternative calculation. This alternative Small Facility Adjuster is expressed as follows:

- For the i^{th} facility, suppose the facility's original measure rate is p_i and the number of patients (or other unit used to establish data minimums for the measure; for example, index discharges for the Standardized Readmission Ratio clinical measure) at the i^{th} facility is n_i.
- Where the number of eligible patients (or other appropriate unit) needed to receive a score on a measure is *L* and the upper threshold for applying the small facility adjuster is *C*, the i^{th} facility will be eligible for the adjustment when $L \leq n_i < C$. Accordingly, *L* and *C* set the upper and lower thresholds of eligible patients (or other appropriate unit) a facility needs to have in order to be considered for a small facility adjustment; consistent with previously finalized policies, facilities with fewer than *L* eligible patients (or other appropriate unit) for a measure will not receive a score on that measure, and facilities with more than *C* eligible patients (or other appropriate unit) for a measure will not receive an adjustment for that measure.

- Assuming $L \leq n_i < C$, let $w_i = \frac{n_i}{C}$, where n_i is the number of patients (or other appropriate unit) at the i^{th} facility and C is the upper thresholds of eligible patients (or other appropriate unit) a facility needs to have in order to be considered for a small facility adjustment. This calculation will produce the facility's weighting coefficient for a given clinical measure, w_i, which provides a metric for assessing the uncertainty due to small facility sizes.
- For measures where higher scores are better (for example, the Vascular Access Type (VAT): Fistula clinical measure and the Dialysis Adequacy clinical measures), a small facility's adjusted performance rates (t_i) will be pegged to the benchmark, or 90th percentile of national facility performance on a measure ($\bar{B}$) as follows:
    - If $p_i < B$, then $t_i = w_i * p_i + (1 - w_i) * \bar{B}$,
    - If p_i is greater than or equal to $\bar{B}$, the facility will not receive an adjustment.
- For measures where lower scores are better (for example, VAT: Catheter, NHSN BSI, Hypercalcemia, Standardized Readmission Ratio (SRR), and Standardized Transfusion Ratio (STrR) clinical measures), a small facility's adjusted performance rates (t_i) will be pegged to the benchmark, or 90th percentile of national facility performance on a measure ($\bar{B}$) as follows:
    - If $p_i > \bar{B}$, then $t_i = w_i * p_i + (1 - w_i) * \bar{B}$
    - If p_i is less than or equal to $\bar{B}$, then the facility will not receive an adjustment
- For the standardized ratio measures, such as the SRR and STrR clinical measures, the national mean measure rate (that is, $\bar{B}$) is set to 1.

As with the proposed SFA, the alternative SFA formula suggested by the commenter does not assume a bell-shaped distribution, nor does it require the calculation of a pooled within-

facility standard error. The commenter asserted that only difference between its alternative SFA calculation and the proposed SFA is that the proposed SFA uses the 50th percentile of national facility performance, whereas the commenter's alternative SFA uses the 90th percentile (that is, the benchmark) of national facility performance, to determine which small facilities should receive an adjustment. The commenter argued that using the 90th percentile of facility performance to determine which facilities will receive an adjustment provides some positive adjustment for all small facilities which may have been adversely affected by one or two challenging patients. The adjustment would be larger for worse performers and for smaller facilities and the magnitude of the adjustment under this alternative SFA would be similar to that of the current SFA.

Response: We agree that the alternative SFA suggested by a commenter and the proposed SFA accomplish very similar goals using virtually identical methodologies. Like the proposed SFA, the alternative SFA does not assume a bell-shaped distribution, nor does it require the calculation of pooled within-facility standard errors required in the current SFA. We therefore believe that, like the proposed SFA, facilities should be able to replicate this alternative SFA formula more easily than the current SFA, which requires the calculation of pooled within-facility standard errors. We also agree that the alternative SFA provides some positive adjustment for a greater number of small facilities that may be adversely affected by a small number of outlier patients than the proposed SFA, as well as provides a greater adjustment for smaller facilities and those who appear to be "worse" performers based on their measure scores. We believe this particular aspect of the alternative SFA—that it provides adjustments across the range of facility performance, as opposed to only adjusting the scores of below-average performers—addresses the primary concern raised by commenters that the application of the

proposed SFA did not have the same magnitude of impact on facility scores as the current SFA.

For these reasons, we are finalizing the SFA suggested by a commenter and described above for PY 2017 and future payment years of the ESRD QIP. Specifically, we are adopting the 90th percentile of facility performance as the measure score threshold for facility eligibility for the small facility adjuster instead of the proposed 50th percentile of facility performance. Under this methodology, facilities treating between 11 and 25 patients and scoring below the benchmark (that is, the 90th percentile of national facility performance) for a measure will receive an adjustment to their measure scores using the calculation provided above.

Comment: One commenter requested that CMS conduct a new analysis of the proposed small facility adjuster as applied to the proposed combined dialysis adequacy measure as the analysis provided in the proposed rule is based on the individual dialysis adequacy measures previously used in the QIP.

Response: We have conducted the analysis as requested, but have substituted the alternative small facility adjuster described above, which we are adopting for PY 2017 and future payment years, for the small facility adjuster proposed in the CY 2016 ESRD PPS proposed rule. The results of this analysis are available below using data from CY 2014.

Table 15 demonstrates the impact of the small facility adjuster we are finalizing on the PY 2018 ESRD QIP measure set, which includes all four dialysis adequacy measures, and Table 16 demonstrates the impact of the small facility adjuster on the measure set with the single comprehensive Dialysis Adequacy measure.

Table 15 – Estimated Number of Facilities Receiving a Payment Reduction for PY 2018 based on the Small Facility Adjuster Being Finalized (PY 17 through 19 SFA)

Reduction	Estimated Number of Facilities Receiving a Reduction	% of Facilities Receiving a Reduction
0%	4889	80.98%
0.5%	817	13.53%
1.0%	263	4.36%
1.5%	57	0.94%
2.0%	11	0.18%

Note: This table excludes 296 facilities that did not receive a score because they did not have enough data to receive a TPS.

Table 16 – Estimated Number of Facilities Receiving a Payment Reduction Scale for PY 2019 based on the alternative Small Facility Adjuster (PY 17 through 19 SFA)

Reduction	Estimated Number of Facilities Receiving a Reduction	% of Facilities Receiving a Reduction
0%	4618	76.38%
0.5%	976	16.14%
1.0%	366	6.05%
1.5%	69	1.14%
2.0%	17	0.28%

Note: This table excludes 287 facilities that did not receive a score because they did not have enough data to receive a TPS.

As demonstrated in the analyses above, using the PY 2018 measure set and the small facility adjuster suggested by a commenter on the PY 2018 measure set, approximately 18.1 percent of facilities would receive a reduction. By contrast, under the PY 2019 measure set and using this small facility adjuster, approximately 23.62 percent of facilities would receive a payment reduction. While this analysis reflects a small increase in the number of facilities receiving a reduction between PY 2018 and PY 2019, we believe this increase is likely the result of more facilities being eligible to receive a score on the single comprehensive Dialysis Adequacy clinical measure than on the four individual dialysis adequacy measures, as well as a decrease in the number of facilities qualifying for an adjustment on this measure for PY 2019.

Comment: One commenter expressed concerns that the proposed SFA is less transparent than the current small facility adjuster. The commenter stated that the complicated formula makes it difficult to tell if the adjuster is achieving its desired outcome and may prove difficult for small facilities to replicate without additional resources. The commenter stated that it is difficult to determine whether small facilities are receiving lower scores because of their low patient volume, as opposed to their quality of care. The commenter stated that the SFA formula should be easy to use and its impact on small facilities should be easy to replicate and understand.

Response: We believe that the proposed SFA is more transparent than the current SFA, because facilities are able to calculate the proposed SFA using data available to the facility, which facilities cannot do for the current SFA. However, as explained above, we are finalizing an alternative SFA suggested by a commenter, which we also believe will be easier to replicate than the current SFA.

Comment: One commenter expressed concerns that a smaller percentage adjustment was applied to facilities for PY 2016 than the commenter believed was going to be applied based on the example calculation provided in the CY 2014 ESRD PPS final rule with comment period.

Response: The SFA calculation for PY 2016 was implemented as finalized, and although the actual size of the adjustments was different than the estimated size of the adjustments that we set forth in the CY 2014 ESRD final rule with comment period, the estimates in that final rule were intended to be for illustrative purposes only.

For these reasons, we are finalizing the alternative SFA suggested by a commenter and described above, under which facilities treating between 11 and 25 patients and scoring below the benchmark for a clinical measure (that is, the 90^{th} percentile of national facility performance)

will receive an adjustment to their measure scores using the calculation provided above.

2. Reinstating Qualifying Patient Attestations for the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized our proposal to remove the case minimum attestation for the ICH CAHPS reporting measure due to facility confusion regarding the attestation process (79 FR 66185). We further finalized that we would determine facility eligibility for the ICH CAHPS reporting measure based on available data submitted via CROWNWeb, Medicare claims, and other CMS administrative data sources. Following the publication of that rule we have determined that we do not have reliable data sources for determining some of the patient-level exclusions. For example, we have been unable to locate a reliable data source for determining whether a patient is receiving hospice care or is residing in an institution such as a prison or a jail.

Although some facilities may be experiencing issues related to the attestation process (for example, during the preview period, we have encountered numerous instances where facilities have either attested inappropriately or have failed to attest in a timely fashion), we believe that facilities are generally able to determine whether their patients meet one or more of the exclusion criteria for the measure. For this reason, we believe that having facilities attest that they are ineligible for the measure will result in more accurate measure scores, as compared to using unreliable data sources to determine whether facilities treated the requisite number of eligible patients during the eligibility period, (defined as the calendar year immediately preceding the performance period). Because we have no reason to believe that reliable data sources for some of the patient-level exclusions for the ICH CAHPS clinical measure will become available in the near term, and because the PY 2017 ICH CAHPS reporting measure and the PY 2018 ICH CAHPS clinical measure employ the same exclusion criteria, we proposed to reinstate the

attestation process we previously adopted in the CY 2014 ESRD PPS final rule (78 FR 72220 through 72222) beginning with the PY 2017 program year. However, we are now proposing to have facilities attest on the basis of the eligibility criteria finalized in the CY 2015 ESRD PPS final rule (79 FR 66169 through 66170). Accordingly, facilities seeking to avoid scoring on the ICH CAHPS measure due to ineligibility must attest in CROWNWeb by January 31 of the year immediately following the performance period (for example, January 31, 2017, for the PY 2018 ESRD QIP) that they did not treat enough eligible patients during the eligibility period to receive a score on the ICH CAHPS measure. Facilities that submit attestations regarding the number of eligible patients treated at the facility during the eligibility period by the applicable deadline will not receive a score on the ICH CAHPS clinical measure for that program year. Facilities that do not submit such attestations will be eligible to receive a score on the measure. However, even if a facility is eligible to receive a score on the measure because it has treated at least 30 survey-eligible patients during the eligibility period (defined as the calendar year before the performance period), the facility will still not receive a score on the measure if it cannot collect at least 30 survey completes during the performance period. Facility attestations are limited to the number of eligible patients treated at the facility during the eligibility period, and are not intended to capture the number of completed surveys at a facility during the performance period. The ESRD QIP system will determine how many completed surveys a facility received during the performance period. We are not proposing to change any of the other data minimum requirements for the PY 2017 ICH CAHPS reporting measure, or for the ICH CAHPS clinical measure in PY 2018 and future payment years. To reduce confusion, we will release a CROWN Memo detailing how facilities are expected to attest.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Many commenters supported the proposal to reinstate qualifying patient attestations for the ICH CAHPS measure. One commenter additionally recommended that CMS establish a process for facilities to confirm that the attestation has been received and that CMS delay the measure's conversion to a clinical measure until the appropriate facility exclusion data is available.

Response: We thank commenters for their support. We agree that it would be ideal if facilities could confirm that their attestation has been received, and we will consider the feasibility of implementing such a process in the future.

Comment: One commenter did not support CMS' proposal to reinstate the qualifying patient attestations for the ICH CAHPS measure because the process is challenging for smaller facilities to understand. The commenter recommended that CMS adopt ICH CAHPS patient attestations forms similar to the Home Health Care CAHPS Survey Participant Exemption Request form.

Response: The reinstated attestation for the ICH CAHPS measure is unchanged from that previously adopted in the CY 2014 ESRD PPS final rule with comment period (78 FR 72220 through 72222); we therefore believe that facilities have had sufficient experience with the attestation process and exclusion criteria to justify reinstating the attestation in order to ensure more accurate measure scores for facilities. In order to ease any residual confusion regarding the reinstated ICH CAHPS qualifying patient attestation, we will release a CROWN Memo detailing how facilities are expected to attest and the exclusion criteria for the ICH CAHPS measure prior to the attestation deadline for PY 2017. For future years of the ESRD QIP, we will consider the

feasibility of adopting ICH CAHPS patient exemption request form similar to the Home Health Care CAHPS Survey Participant Exemption Request form.

For the reasons discussed above, we are finalizing our proposal to reinstate the qualifying patient attestations for the ICH CAHPS measure beginning with the PY 2017 ESRD QIP.

G. Requirements for the PY 2018 ESRD QIP

1. Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Finalized for the PY 2018 ESRD QIP

In the CY 2015 ESRD PPS final rule, we stated that we would publish values for the PY 2018 clinical measures, using data from CY 2014 and the first portion of CY 2015, in the CY 2016 ESRD PPS final rule (79 FR 66209). Upon publication of the CY 2016 ESRD PPS proposed rule, we did not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks for the clinical measures, because we did not yet have complete data from CY 2014. Since that time, we have collected the data needed to calculate finalized performance standards for the PY 2018 ESRD QIP. For all of the clinical measures, including the SRR clinical measure, this data comes from the period of January through December 2014. Table 17 lists the finalized numerical values for all of the finalized PY 2018 ESRD QIP clinical measures except the ICH CAHPS clinical measure.

TABLE 17 – ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2018 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement Threshold	Benchmark	Performance Standard
Vascular Access Type			
%Fistula	53.51%	79.60%	65.94%
%Catheter	16.79%	2.59%	8.80%
Kt/V			
Adult Hemodialysis	91.08%	99.35%	96.89%
Adult Peritoneal Dialysis	75.42%	97.06%	89.47%
Pediatric Hemodialysis	84.16%	99.06%	94.44%
Pediatric Peritoneal Dialysis	43.22%	88.39%	72.60%
Hypercalcemia	3.92%	0.00%	1.19%
NHSN Bloodstream Infection SIR	1.812	0	0.861
Standardized Readmission Ratio	0.996	0.555	0.996
Standardized Transfusion Ratio	1.470	0.431	0.923
ICH CAHPS	50th percentile of eligible facilities' performance during CY 2015	15th percentile of eligible facilities' performance during CY 2015	90th percentile of eligible facilities' performance during CY 2015

We believe that the ESRD QIP should not have lower performance standards than in previous years. Accordingly, if the final numerical value for a performance standard, achievement threshold, and/or benchmark is worse than it was for that measure in the PY 2017 ESRD QIP, then we proposed to substitute the PY 2017 performance standard, achievement threshold, and/or benchmark for that measure.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported the estimated performance standard, achievement threshold, and benchmark for the ICH CAHPS clinical measure for the PY 2018 ESRD QIP.

Response: We thank the commenter for its support.

Comment: Several commenters supported CMS's proposal, for PY 2018, to set the Performance Standard, Achievement Threshold and Benchmark at the 50th, 15th, and 90th percentiles respectively, for the Clinical Measures finalized for the PY 2018 ESRD QIP, particularly where those values are higher than the current PY 2017 values.

Response: We thank the commenters for their support. For this reason, we will finalize our proposal to utilize performance standards from the previous year if they are higher than those of the next year. Accordingly, we are substituting the PY 2017 performance standards, achievement thresholds, and benchmarks for the Adult Hemodialysis Adequacy, Pediatric Hemodialysis Adequacy, and SRR clinical measures for the PY 2018 values for these measures.

Comment: One commenter expressed support for CMS's policy to maintain a previous year's benchmark if it is worse than it was for the measure in the previous year, but suggested that if data shows that performance is not as strong for a particular measure, then there may be an issue with the measure itself. The commenter recommended that rather than using prior benchmark data, CMS should consider the root cause of why performance isn't improving for those measures.

Response: We continue to believe that using prior benchmark data helps drive quality improvement for facilities and encourages them to conduct their own quality improvement initiatives. When we encounter measures with data showing that performance is consistently poor or otherwise failing to improve meaningfully over time, we look into the root cause and the reasons performance is not improving. We have done this for the measures currently included in the QIP and, where appropriate, are using prior benchmarks. In addition, we have analyzed the performance gaps between CY 2013 and CY 2014 for measures where we are substituting the PY 2017 performance standards, and have not identified any underlying issues with those

measures. We will continue to monitor measure performance data in future years of the program.

Comment: One commenter requested that CMS reevaluate the PY 2018 performance standards for the NHSN BSI, SRR, and STrR clinical measures because their estimated values are all below 1.0, meaning facility performance falling within the range of expected events may generate lower QIP scores. The commenter expressed concern that this scoring issue could misrepresent performance by facilities on these measures. Another commenter did not support the estimated performance standards for the SRR or STrR clinical measures because they seem unattainable given facilities' experience with the NHSN BSI clinical measure.

Response: We thank the commenters for their comments. We note, however, that the curve for the NHSN BSI clinical measure as seen in the PY 2016 ESRD QIP is skewed due to an additional policy impacting this measure, under which facilities that fail to report a full 12 months of data for the measure automatically receive a score of zero on the measure. We have not implemented a corresponding policy for the SRR or STrR clinical measures; therefore, we have no reason to believe scores on these measures will be impacted in this way. In addition, the performance standards for the PY 2018 ESRD QIP are only used to determine the minimum TPS for a given year of the ESRD QIP. The median performance rates for the SRR, STrR, and NHSN BSI clinical measures were determined to be 0.998, 0.923, and 0.862 for SRR, STrR, respectively, for the PY 2018 ESRD QIP. The minimum TPS was determined to be the same when these values were set to 1.0. Therefore, use of the calculated median rather than 1.0 has no impact on facility-level QIP scores.

We further disagree that the estimated performance standards for the SRR or STrR clinical measures are unattainable. First, we note that the performance standards for these

measures are set at the 50th percentile of facility performance, meaning that 50 percent of facilities achieve or surpass this standard. These measures are standardized ratios of performance, evaluating facilities' actual performance against their expected performance. Therefore, each facility's score on these measures will be reflective of the facility's particular patient mix and other adjustments. In addition, the achievement threshold, benchmark and performance standard for those measures are determined using the same standards as those for all of the other clinical measure, which are intended to incentivize quality improvements while also accounting for individual facilities' past performance on the measure. We therefore believe it is appropriate to maintain uniform performance standard, achievement threshold, and benchmark policies across the ESRD QIP clinical measures.

Comment: One commenter recommended that CMS avoid implementing measures without numerical values for performance standards because it creates a moving target for quality improvement. Specifically, the commenter expressed concern about the proposed performance standard, achievement threshold, and benchmark for the PY 2018 ICH CAHPS clinical measure because performance data is not available to estimate a numerical value for these elements, and recommended that CMS revert the ICH CAHPS measure to a reporting measure. The commenter asserted that numerical performance standards inform facility decision-making in how to address patient concerns and improve patient experience ratings.

Response: We thank commenter for its recommendation and note that, in general, we seek to avoid implementing measures without numerical values for their performance standard, achievement threshold, and benchmark. In the CY 2016 ESRD PPS proposed rule, we used the most recently available data and provided numerical values for all clinical measures except the ICH CAHPS clinical measure (80 FR 37842). For the ICH CAHPS clinical measure, CY 2015 is

the first year for which we will have data. Accordingly, we will propose numerical values for the performance standard, achievement threshold, and benchmark once we have collected the data for CY 2015 and conducted the necessary analyses.

Comment: One commenter recommended that CMS maintain consistency in the ESRD QIP performance period and performance standard methodology, and encouraged CMS to finalize performance periods and standards in a timely manner.

Response: We agree that maintaining consistency in the ESRD QIP performance periods and performance standards is important because it simplifies the administrative burden associated with participating in the ESRD QIP and aids facilities in understanding the requirements of the program. We note that the performance period for the majority of measures in the ESRD QIP aligns with the calendar year, and only deviates in the case of the NHSN HCP Influenza Vaccination reporting measure, for which the performance period generally aligns with the influenza season. Additionally, we appreciate that facilities want to learn as soon as possible what the ESRD QIP measure set and performance standards will be for a given year of the program. Numerical performance standards for the ESRD QIP measure set are calculated using the most recent data available for those measures in advance of the applicable performance period. We understand that this process results in facilities only receiving the finalized numerical performance standards two months before the beginning performance period; however, we believe this process is necessary in order to ensure that we set accurate performance standards for use in scoring facility performance on the ESRD QIP measure set for a given year.

For the reasons discussed above, for PY 2018, we are finalizing that we will use the performance standards in Table 17 above.

2. Modification to Scoring Facility Performance on the Pain Assessment and Follow-Up

Reporting Measure

In the CY 2015 ESRD PPS final rule, we finalized the following calculation for scoring facility performance on the Pain Assessment and Follow-Up reporting measure under the PY 2018 ESRD QIP (79 FR 66211):

$$\left[\frac{\text{Number of patients for whom facility reports one of six conditions during the first six months}}{\text{Number of eligible patients in the first six months}} + \frac{\text{Number of patients for whom facility reports one of six conditions during the second six months}}{\text{Number of eligible patients in the second six months}}\right] \div 2$$

We have since determined that this calculation may unduly penalize facilities that treat no eligible patients in one of the two six-month periods evaluated under this measure; under this calculation, those facilities would have a "0" for the applicable period's data, in effect giving the facility half of its score on the remaining 6-month period as a measure score. In order to avoid such an undue impact on facility scores, we proposed that, beginning with the PY 2018 ESRD QIP, if a facility treats no eligible patients in one of the two 6-month periods, then that facility's score will be based solely on the percentage of eligible patients treated in the other six-month period for whom the facility reports one of six conditions.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Several commenters supported the proposal to modify the Pain Assessment and Follow-Up reporting measure scoring methodology.

Response: We thank the commenters for their support.

Comment: Some commenters requested additional clarification regarding the reasons for the proposed modification to scoring facility performance on the Pain Assessment and Follow-Up reporting measure as well as information about how the modifications will be operationalized.

Response: Under the previously finalized calculation for scoring facility performance on the Pain Assessment and Follow-Up reporting measure, facilities may have been unduly penalized for treating no eligible patients during one of the two 6-month periods that together make-up the performance period. The proposed modification is an alteration to the scoring methodology for the Pain Assessment and Follow-Up reporting measure, and therefore does not impact facilities' requirements under the measure.

For example, if a facility had zero eligible patients in the first 6-month period, then treated eligible patients in the second 6 months, the facility would automatically receive no greater than 5 points for the measure. We did not fully anticipate that such a scenario could arise, and it is one which we wish to avoid. Therefore, under the proposed calculation modification, facilities that only treat eligible patients in one of two the 6-month periods will be scored only on the percentage of eligible patients treated during that 6-month period.

Comment: One commenter requested clarification from CMS regarding the proposed modification to the Pain Assessment and Follow-Up reporting measure because it is unclear how the six-month periods relate to the measure attestations. The commenter further recommended implementing the same proposed modification for the Screening for Clinical Depression and Follow-Up reporting measure.

Response: In order to comply with the requirements of the Pain Assessment & Follow-Up Measure, facilities must report one of six conditions in CROWNWeb once every six months per performance period for every qualifying patient, meaning that facilities will provide two separate rounds of attestations for this measure. Conditions covering the first six months of the performance period must be reported in CROWNWeb before August 1 of the performance period, and conditions covering the second 6 months of the performance period must be reported

in CROWNWeb before February 1 of the year directly following the performance period (79 FR 66203 through 66204).

We did not propose to implement a corresponding modification for the Screening for Clinical Depression and Follow-Up reporting measure because facilities are only required to report one of the six conditions listed in CROWNWeb once per performance period (that is, once per calendar year) under this measure (79 FR 66200). Because reporting for the Screening for Clinical Depression and Follow-Up reporting measure occurs once per performance period, and not twice for the performance period (once every 6 months), there will not be instances where a facility is eligible for scoring based on one part of the performance period but not the other. Therefore, there is no need to change the scoring methodology for the Screening for Clinical Depression and Follow-Up reporting measure.

For the reasons discussed above, we are finalizing as proposed the modified methodology for scoring facility performance on the Pain Assessment and Follow-Up reporting measure beginning with the PY 2018 ESRD QIP.

3. Payment Reductions for the PY 2018 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the ESRD QIP scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2015 ESRD PPS final rule, we finalized our proposal for calculating the minimum TPS for PY 2018 and future payment years (79 FR 66221 through 66222). Under our current policy, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (i) it performs at the performance standard for each clinical measure; and (ii) it receives the number

of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2016 reporting measures (79 FR 66221). We proposed to clarify how we will account for measures in the minimum TPS when we lack the baseline data necessary to calculate a numerical performance standard before the beginning of the performance period (per criterion (i) above), because we inadvertently omitted this detail in the CY 2015 ESRD PPS final rule. Specifically, we propose, for the PY 2018 ESRD QIP, to add the following criterion previously adopted for the PY 2017 program (79 FR 66187): "it received zero points for each clinical measure that does not have a numerical value for the performance standard established through rulemaking before the beginning of the PY 2018 performance period." Under this proposal, for PY 2018, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (i) it performs at the performance standard for each clinical measure; (ii) it received zero points for each clinical measure that does not have a numerical value for the performance standard established through rulemaking before the beginning of the PY 2018 performance period; and (iii) it receives the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2016 reporting measures.

We were unable to calculate a minimum TPS for PY 2018 in the CY 2015 ESRD PPS final rule because we were not yet able to calculate the performance standards for each of the clinical measures. We therefore stated that we would publish the minimum TPS for the PY 2018 ESRD QIP in the CY 2016 ESRD PPS final rule (79 FR 66222).

Based on the estimated performance standards listed above, we estimated that a facility must meet or exceed a minimum TPS of 39 for PY 2018. For all of the clinical measures except the SRR, STrR, and ICH CAHPS clinical measures, these data come from CY 2014. The data

for the SRR and STrR clinical measures come from CY 2013 Medicare claims. For the ICH CAHPS clinical measure, we set the performance standard to zero for the purposes of determining this minimum TPS, because we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the PY 2018 performance period. We proposed that a facility failing to meet the minimum TPS, as established in the CY 2016 ESRD PPS final rule, will receive a payment reduction based on the estimated TPS ranges indicated in Table 18 below.

TABLE 18 – ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2018 BASED ON DATA AVAILABLE AT PUBLICATION OF THE PROPOSED RULE

Total Performance Score	**Reduction**
100 – 39	0.0%
38 – 29	0.5%
28 – 19	1.0%
18 – 9	1.5%
8 – 0	2.0%

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: Several commenters supported CMS' proposal to continue, for PY 2018, the same policy used in PY 2017 for determining payment reductions, including the process for setting the minimum TPS. One commenter urged CMS to maintain consistency in its payment reduction methodology for future years of the ESRD QIP, because this would allow beneficiaries to better compare facility performance over time.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern about the estimated minimum TPS for PY 2018, and requested that CMS provide clarification on how the mTPS was calculated.

Specifically, commenter is concerned that we proposed to lower the minimum TPS for PY 2018 from 60 (the mTPS for PY 2017) to 39. The commenter stated that this proposal was confusing in light of CMS's request for comments on potentially raising the performance threshold to the 25th percentile.

Response: We have recalculated the minimum TPS for PY 2018 for all measures using updated data, including data for the NHSN BSI clinical measure, which we lacked at the time of the proposed rule's publication. Using this data, we have determined that the updated minimum TPS for PY 2018 is 49. Facilities failing to meet this minimum TPS will receive a payment reduction based on the updated TPS ranges indicated in Table 19, below.

TABLE 19 –PAYMENT REDUCTION SCALE FOR PY 2018 BASED ON THE MOST RECENTLY AVAILABLE DATA FROM CY 2014

Total Performance Score	**Reduction**
100 – 49	0.0%
48 – 39	0.5%
38 – 29	1.0%
28 – 19	1.5%
18 – 0	2.0%

We have also provided two sets of tables below detailing how the minimum TPS was calculated for the PY 2018 ESRD QIP. Table 20 provides the measure score calculations used for the updated minimum TPS. Table 21 provides the total performance score calculations used to determine the minimum TPS in the proposed rule.

Table 20 – Minimum TPS Measure Score Calculation for PY 2018 Using Most Recently Available Data

Measure	Median Score for Measure Topics	Measure Weight	Measure Topic Weight Score (=Median Score*Measure Weight)
CLINICAL MEASURES			
Clinical Care Subdomain		**50%**	
Kt/V (4 combined measures)	6	18%	1.08
VAT (2 combined measures)	6	18%	1.08
Hypercalcemia	7	7%	0.49
STRR	5	7%	0.35
Patient and Family Engagement/Care Coordination Subdomain		**30%**	
SRR	4	10%	0.4
ICH CAHPS	0	20%	0
Safety Subdomain		**20%**	
NHSN	5	20%	1
Clinical Subtotal			***4.4***
REPORTING MEASURES			
Mineral Metabolism	9	20%	0.18
Anemia Management	10	20%	0.20
Pain	10	20%	0.20
Depression	10	20%	0.20
NHSN HCP	10	20%	0.20
Reporting Subtotal			***9.8***

Table 21 – Total Performance Score Calculation Used to Determine the PY 2018 Minimum TPS

	Measure Topic Weight Score (From previous table)	Clinical and Reporting Weights	Clinical and Reporting Sub-scores (=Measure Topic Score * Weight)	Final Scores (=Clinical and Reporting Sub-scores *10)
Clinical Subtotal	4.4	90%	3.96	39.6
Reporting Subtotal	9.75	10%	0.975	9.8
TPS (Clinical + Reporting Subtotals)			4.96	49.4
TPS (rounded)				***49***

We note that our minimum TPS policy is independent from the achievement threshold as used in the ESRD QIP scoring policy, and that these policies serve different the purposes in scoring facility performance in the ESRD QIP. The minimum TPS establishes the TPS a facility must achieve in order to avoid receiving a payment reduction for the applicable payment year of the ESRD QIP, and serves as the basis for the PY's payment reduction scale. The achievement threshold, on the other hand, is set at the 15th percentile of national performance and is used to score facility performance on individual clinical measures for a given year of the program. We therefore believe these separate policies provide distinct incentives for quality improvement among dialysis facilities. We are also continuing to look for ways to further incentivize quality improvement, one of which would be to increase the achievement threshold from the 15^{th} to the 25^{th} percentile.

Comment: One commenter urged CMS to monitor the implementation and impact of the QIP scoring model on the standardized ratio measures because they are fundamentally different than the other QIP clinical measures in terms of how they are calculated and the level of control dialysis facilities have on the results. The commenter pointed out that the QIP scoring model

was originally designed for "rates of compliance" measures and is concerned about how these measures will influence QIP results given that the results are reported categorically (i.e. "worse/better than expected" or "as expected.")

Response: We acknowledge that the standardized ratio measures differ from other ESRD QIP clinical measures. However, we lack reason to believe that the current ESRD QIP scoring methodology is insufficient or inappropriate for calculating facility performance on the ESRD QIP measures when the standardized ratio measures are included in a facility's score. In addition, we note that other value-based purchasing programs, such as the Hospital Value-Based Purchasing Program, score standardized ratio measures. We will continue to monitor the implementation and impact of these measures in future years of the ESRD QIP to determine if further modification to the ESRD QIP scoring methodology is necessary.

For the reasons discussed above, we are finalizing the revised minimum TPS policy for PY 2018 as proposed. We are also finalizing the updated mTPS and payment reduction scale for PY 2018 as discussed above.

4. Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. We began a pilot data-validation program in CY 2013 for the ESRD QIP, and procured the services of a data-validation contractor that was tasked with validating a national sample of facilities' records as reported to CROWNWeb. For validation of CY 2014 data, our first priority was to develop a methodology for validating data submitted to CROWNWeb under the pilot data-validation program. That methodology was fully developed and adopted through the rulemaking process. For the PY 2016 ESRD QIP (78 FR 72223 through 72224), we finalized a requirement to sample approximately

10 records from 300 randomly selected facilities; these facilities had 60 days to comply once they received requests for records. We continued this pilot for the PY 2017 ESRD QIP, and proposed to continue doing so for the PY 2018 ESRD QIP. Under this continued validation study, we will sample the same number of records (approximately 10 per facility) from the same number of facilities (that is, 300) during CY 2016. If a facility is randomly selected to participate in the pilot validation study but does not provide us with the requisite medical records within 60 days of receiving a request, then we proposed to deduct 10 points from the facility's TPS. Once we have developed and adopted a methodology for validating the CROWNWeb data, we intend to consider whether payment reductions under the ESRD QIP should be based, in part, on whether a facility has met our standards for data validation.

In the CY 2015 ESRD PPS final rule, we also finalized that there will be a feasibility study for validating data reported to CDC's NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure. Healthcare-Acquired Infections (HAI) are relatively rare, and we finalized that the feasibility study would target records with a higher probability of including a dialysis event, because this would enrich the validation sample while reducing the burden on facilities. For PY 2018, we proposed to use the same methodology that was discussed in the CY 2015 ESRD QIP final rule (79 FR 66187). This methodology resembles the methodology we use in the Hospital Inpatient Quality Reporting Program to validate the central line-associated bloodstream infection measure, the catheter-associated urinary tract infection measure, and the surgical site infection measure (77 FR 53539 through 53553). For the PY 2018 ESRD QIP, we proposed to randomly select nine facilities to participate in the feasibility study for data reported in CY 2016. A CMS contractor will send these facilities quarterly requests for lists of candidate dialysis events (for example, all positive blood cultures drawn from its patients

during the quarter, including any positive blood cultures that were collected from the facility's patients on the day of, or the day following, their admission to a hospital). Facilities will have 60 days to respond to quarterly requests for lists of positive blood cultures and other candidate events. A CMS contractor will then determine when a positive blood culture or other "candidate dialysis event" is appropriate for further validation. With input from CDC, the CMS contractor will utilize a methodology for identifying and requesting the candidate dialysis events other than positive blood cultures. The contractor will analyze the records of patients who had candidate events in order to determine whether the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event Protocol. If the contractor determines that additional medical records are needed from a facility to validate whether the facility accurately reported the dialysis events, then the contractor will send a request for additional information to the facility, and the facility will have 60 days from the date of the letter to respond to the request. Overall, we estimate that, on average, quarterly lists will include two positive blood cultures per facility, but we recognize these estimates may vary considerably from facility to facility. If a facility is randomly selected to participate in the feasibility study but does not provide CMS with the requisite lists of positive blood cultures or the requisite medical records within 60 days of receiving a request, then we proposed to deduct 10 points from the facility's TPS.

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: Several commenters requested that CMS conduct a more robust validation study for NHSN BSI, examining both the completeness of BSI data collection and the accuracy of the data collected. They argued that selecting such a small number of facilities to participate in the study may be inadequate to validate the data reported to the NHSN Dialysis Event Module

and recommended that CMS reconsider the proposed sample size to include more facilities, ideally at least 5 percent of facilities. One commenter offered specific suggestions for increasing the size of the validation study. Specifically, the commenter recommended that CMS evaluate under-reporting, access type errors, application of the NHSN criteria, accessibility of reports of positive blood cultures from inpatient facilities to outpatient dialysis facilities, and the accuracy of manual- vs. electronically-submitted data. The commenter urged CMS to ensure that both small and large dialysis facilities, hospital-based centers and for-profit centers are included. Additionally, the commenter recommended that CMS validate data from facilities that use paper medical records and from facilities that use electronic medical records. Some commenters argued that the targeting of the validation study is too narrowly focused on patients with positive blood cultures and feel that the study should be expanded beyond those patients with positive blood cultures. They also argued that the validation study should look at instances where a facility reports no positive blood cultures, which is likely the result of intentional or accidental under-reporting. One commenter specifically recommended that CMS review the CDC-funded data validation project for dialysis events performed by the Tennessee Health Department and fund state health departments for on-site data validation and examination of vaccination rate reporting.

Response: We thank commenters for their recommendations about ways to improve the NHSN BSI validation study. As noted in the CY 2015 ESRD PPS final rule with comment period (79 FR 66188), we believe it is important to demonstrate the study's feasibility and further develop the study's methodology before expanding the study to include more facilities. For future years of the program, we will consider increasing the size of the validation study to include a greater number of facilities. However, we currently include a wide variety of types of

facilities, both small and large, hospital-based and for-profit, etc. in our study. In addition, the validation study is not currently limited to events collected in the dialysis facility, as one commenter suggested; it also includes positive blood cultures collected or identified at hospitals. We look forward to continuing to refine this study to ensure that we are collecting as much reliable and useful data about bloodstream infections as possible.

Comment: Numerous commenters did not support CMS's proposal to deduct 10 points from a facility's TPS if they are selected to participate in a data validation study and fail to provide CMS with the requested data within the allotted time because 10 points can have such a significant impact on selected facilities' TPSs and because the Conditions for Coverage already require that facilities comply with data validation requests. Several commenters expressed concerns that this 10-point deduction for non-compliance could mislead beneficiaries on the quality of care delivered by the facility and argued that there is no evidence that facilities are noncompliant with requests for this data. Commenters argued that failing to supply CMS with this data does not measure the quality of care provided by the facility. Additionally, commenters stated that facilities should not be penalized without having the opportunity to dispute the noncompliance allegations and to make any needed corrections as appropriate.

Response: We appreciate commenters' concerns about the impact of a 10-point reduction to a facility's TPS based on noncompliance with the data request. We also recognize that the ESRD Conditions for Coverage already require facilities to comply with these requests for medical records, and we are not aware of any evidence suggesting that they are not already doing so. Nevertheless, we continue to believe that assessing penalties on a facility's TPS is the surest way to ensure that facilities provide the medical records needed to complete the studies. This is because facilities are not typically surveyed for compliance with the Conditions for Coverage

every year, so deducting points from a facility's TPS provides a more certain process for penalizing noncompliance with the requirements of the validation studies. As stated in the CY 2015 ESRD PPS final rule with comment period, our policy to deduct points from a facility's TPS is consistent with section 1881(h)(3)(A)(i) of the Act, because it is part of our methodology for assessing the total performance of each provider of services and renal dialysis facility based on the performance standards with respect to the measures selected (79 FR 66189). The main purpose of these studies is to assess whether facilities are reporting accurate data, and we have determined that review of medical records is integral to that determination. We will consider the feasibility of implementing a method for facilities to dispute the noncompliance allegations and to make any needed corrections for future years of the ESRD QIP.

Comment: One commenter requested that CMS publish the results of the ongoing CROWNWeb validation study as well as a timeline for the expected release of such results.

Response: We anticipate releasing the results of this study in the near future, and are aiming for publication by December 2015.

Comment: One commenter expressed concerns with the proposed 60-day compliance requirement for the NHSN BSI measure, and suggested that a 90-day period would be more appropriate.

Response: We disagree that the 60-day timeframe is too short for facilities to respond to requests to validate medical records, because facilities should have these records on hand, and sampled facilities will only be required to submit a small number of medical records for the NHSN Bloodstream Infection study.

Comment: A few commenters raised concerns that the data validation study appears to be an audit of facility data to confirm the accuracy of the data reported and that therefore it is

important to ensure that there are processes in place to address disputes which may arise and to protect facilities so that they have the opportunity to appeal both at the contractor and at higher levels of review if necessary.

Response: As stated previously in the CY 2015 final rule with comment period (79 FR 66188), we agree that one of the purposes of the validation pilot is to identify instances in which facilities are reporting invalid data to CROWNWeb. However, we do not believe it is appropriate to designate the validation study as an "audit" of facility data, because the ultimate objective of the study is to improve the validity of data reported to CROWNWeb, rather than to penalize facilities for reporting invalid data. We further note that we did not propose to penalize facilities for reporting invalid data; if and when we propose to do so in future rulemaking, we will consider implementing an appeal process facilities can use to contest CMS determinations that invalid data was reported to CROWNWeb.

Comment: One commenter encouraged CMS to suspend the validation study and the resulting payment penalties in favor of working directly with facilities that appear to have data submission problems to help them identify workable solutions which can be remedied. In this way, accurate data submission will be encouraged rather than penalizing facilities as much for not submitting data as they would be penalized for not providing quality patient care. Another commenter argued that, given that CMS is conducting a feasibility study of a validation methodology, those facilities chosen should not be penalized with a deduction in their TPS as a result of non-compliance. The commenter recommended that the penalty be delayed until a full validation study is in place.

Response: We thank the commenter for its recommendation. However, before we can undertake a work-intensive and highly individualized remediation effort such as that described

by the commenter, we must develop a more fulsome understanding of the issues impacting facility data reporting. We believe the current data validation studies are a first and critical step toward developing this understanding. In the interim, we urge facilities experiencing issues with data submission to contact the CROWNWeb and/or NHSN Help Desks for support. We also note that the current data validation studies do not penalize facilities for reporting incorrect or invalid data; the 10-point TPS reduction is keyed to non-compliance with only the submission of data needed for the studies themselves. We also disagree that the penalty for non-compliance with the feasibility study of our proposed validation methodology should be delayed until a full validation is in place. Facility compliance is essential to the success of the feasibility study, and we wish to provide a strong incentive for facilities to transmit the requested medical records needed to validate the NHSN data. Most importantly, however, this feasibility study will provide the basis for a more comprehensive validation study that we hope to begin in the near future.

Comment: One commenter expressed concerns that obtaining only positive blood culture data may not lead to comprehensive validation of data reported to NHSN and recommended that IV antimicrobial start and pus, redness or increased swelling at the vascular access site should also be considered.

Response: We will take this recommendation into consideration as we continue to refine the NHSN data validation feasibility study.

Comment: One commenter supported the quarterly collection of NHSN BSI data and stated that such a requirement is not a burdensome task for facilities, especially when the expectation is clearly articulated in advance.

Response: We agree that the quarterly collection of NHSN BSI data is not a burdensome task for facilities.

For these reasons, we are finalizing, as proposed, the continuation of the CROWNWeb pilot data validation and the feasibility study for the validating data reported to CDC's NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure.

H. Requirements for the PY 2019 ESRD QIP

1. Replacement of the Four Measures Currently in the Dialysis Adequacy Clinical Measure Topic Beginning with the PY 2019 Program Year

We consider a quality measure for removal or replacement if: (1) measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made (in other words, the measure is topped-out); (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative or unintended consequences (77 FR 67475). In the CY 2015 ESRD PPS final rule, we adopted statistical criteria for determining whether a clinical measure is topped out, and also adopted a policy under which we could retain an otherwise topped-out measure if we determined that its continued inclusion in the ESRD QIP measure would address the unique needs of a specific subset of the ESRD population (79 FR 66172 through 66174).

Subsequent to the publication of the CY 2015 ESRD PPS final rule, we evaluated the finalized PY 2018 ESRD QIP measures against all of these criteria. We determined that none of these measures met criterion (1), (2), (3), (5), (6), or (7). As part of this evaluation for criterion one, we performed a statistical analysis of the PY 2018 measures to determine whether any measures were "topped out." The full results of this analysis can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Topped-Out-Analysis-of-ESRD-QIP-Clinical-Measures-for-PY-2018.pdf and a summary of our topped-out analysis results appears in Table 22 below.

TABLE 22 – PY 2018 CLINICAL MEASURES USING CROWNWeb AND MEDICARE CLAIMS DATA

Measure	**N**	**75th percentile**	**90th percentile**	**Std. Error**	**Statistically Indistin-guishable**	**Truncated CV**	**TCV < 0.10**
Adult HD Kt/V	5822	97.0	98.3	0.09	No	0.03	Yes
Pediatric HD Kt/V	7	94.4	96.9	13.4	Yes	0.23	No
Adult PD Kt/V	1287	94.4	97.1	0.45	No	0.10	No
Pediatric PD Kt/V	3	88.4	88.4	13.9	Yes	N/A[1]	N/A[1]
VAT: Fistula[2]	5763	73.3	79.7	0.15	No	0.14	No
VAT: Catheter[3]	5744	5.4	2.7	0.10	No	<0.01	Yes
Hypercalcemia[2]	6042	0.33	0.0	0.03	No	<0.01	Yes

[1] Insufficient data
[2] Medicare claims data from CY 2014 were used in these calculations.
[3] CROWNWeb data from CY 2014 was used in this calculation.

As the information presented in Table 22 indicates, none of these clinical measures are currently topped-out in the ESRD QIP. We note that only three facilities had 11 or more qualifying patients for the Pediatric Peritoneal Dialysis Adequacy clinical measure, resulting in insufficient data available to calculate a truncated coefficient of variation. However, because the Pediatric Peritoneal Dialysis Adequacy clinical measure addresses the unique needs of the pediatric population, we are not proposing to remove the measure at this time. Accordingly, we

are not proposing to remove any of these measures from the ESRD QIP.

Beginning with the PY 2019 ESRD QIP, we proposed to replace the four measures in the Kt/V Dialysis Adequacy measure topic—(1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: Minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy— with a single more broadly applicable measure for the topic. The new measure, Delivered Dose of Dialysis above Minimum – Composite Score clinical measure ("Dialysis Adequacy clinical measure") (Measure Applications Partnership #X3717) 4, is a single comprehensive measure of dialysis adequacy assessing the percentage of all patient-months, for both pediatric and adult patients, whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified Kt/V threshold during the performance period. As discussed in more detail below, this measure's specifications allow the measure to capture a greater number of patients, particularly pediatric hemodialysis and peritoneal dialysis patients, than the four individual dialysis adequacy measures, and will result in a larger and broader collection of data from patients whose dialysis adequacy is assessed under the ESRD QIP. The measure assesses the adequacy of dialysis using the same thresholds applied to those patients by the existing dialysis adequacy measures, as described below. For these reasons, we believe the new dialysis adequacy measure meets criterion four above. We therefore proposed to remove the four individual measures within the Kt/V Dialysis Adequacy Measure Topic, as well as the measure topic itself, and to replace those measures with a single Dialysis Adequacy clinical measure beginning with the PY 2019 ESRD QIP. However, if based on public comments, we do

4 Although we correctly identified the name of the proposed measure and the specifications for that measure in the proposed rule, we inadvertently misidentified the MAP ID number as X3717. The correct MAP ID number for the proposed measure is X2051. See https://www.qualityforum.org/map/. The description of the measure can be found under the title "Spreadsheet of MAP 2015 Final Recommendations."

not finalize our proposal to adopt the Dialysis Adequacy clinical measure, then we would not finalize this proposal to remove these measures and the Dialysis Adequacy measure topic.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Several commenters supported CMS's continued efforts to examine dialysis adequacy in the ESRD QIP as well as the proposal to remove the four separate dialysis adequacy clinical measures and replace them with a single comprehensive dialysis adequacy clinical measure because this single measure will capture a greater number of patients and make it less likely for one patient at a smaller facility to skew the facility's results on a measure.

Response: We thank the commenters for their support.

Comment: Once commenter expressed concerns about the fact that CMS removed the dialysis adequacy measure from the PQRS because it is "topped out." The commenter fears that including the measure in one quality reporting program and not in another sends a mixed message. Furthermore, the commenter argued that there should be common goals among all providers, facilities and physicians alike, in order to deliver high quality patient outcomes.

Response: We acknowledge that, in the CY 2016 PFS proposed rule, CMS proposed to remove the Adult Kidney Disease: Hemodialysis Adequacy: Solute measure due to this measure representing a clinical concept that does not add clinical value to PQRS, and because eligible professionals consistently meet performance on this measure with performance rates close to 100 percent, suggesting that there is no gap in care (80 FR 41861). However, quality measures may be topped-out in one program and not in another because the goals, patient populations, and clinical concerns addressed in these programs are often quite different. While the PQRS Adult Kidney Disease measure is similar to the ESRD QIP measure, the PQRS measure is specified at

the eligible professional level, assessing the care that each eligible professional is providing to his or her patients. In contrast, the ESRD QIP measure is specified for use at the facility level and therefore reflects the ESRD QIP's focus on ensuring that facilities, as a whole, provide quality care to all patients. In addition, the PQRS measure assesses only the care provided to adult hemodialysis patients, whereas the ESRD QIP measure assesses the care provided to adult and pediatric patients on either hemodialysis or peritoneal dialysis.

2. Measures for the PY 2019 ESRD QIP

We received a number of comments regarding the ESRD QIP measure set generally and the direction of future measure development and adoption for the program.

Comment: One commenter urged CMS to adopt more clinical risk-adjusted measures that capture the effective management of dialysis patients, such as the Standardized Hospitalization Ratio (SHR) or the Standardized Mortality Ratio (SMR). The commenter added that the agency previously considered, but did not adopt, the SHR measure for the PY 2014 ESRD QIP and believes that these measures should be considered for future payment years.

Response: We are continuing to develop additional appropriate clinical risk-adjusted measures to include in the ESRD QIP's measure set, and invite the ESRD community to work with us to identify such measures for future payment years.

Comment: Several commenters criticized the ESRD QIP's current measure set for several reasons: first, they believe that the measures focus predominantly on in-center hemodialysis patients without examining the unique circumstances of home hemodialysis patients; second, they would like CMS to implement more pediatric ESRD quality measures in the ESRD QIP; third, commenters would like CMS to adopt more evidence-based measures that promote the delivery of high-quality care and improved patient outcomes; and finally, commenters would like

CMS to consider more patient-reported outcomes.

Some of the specific measures commenters would like to see are: (1) measures that account for the unique circumstances of patients on home hemodialysis; (2) a reporting measure assessing whether the patient "has a voice" during dialysis treatment, under which a patient would be asked about their experience on dialysis immediately following each treatment (commenters stated that these conversations might help facilities to better understand the patient's concerns about his or her particular treatment and any possible need for adjustments based on patient preference); (3) a measure establishing a minimal standard for anemia management because current evidence regarding the reduction of ESA use does not evaluate whether this decline is consistent with good patient care, particularly for home hemodialysis patients who are only seen in the dialysis facility setting once per month; (4) a measure of the percent of patients at a clinic who are using a home dialysis option; (5) a Patient Informed Consent for Anemia Treatment clinical measure that includes quality of life data; (6) a measure examining the percentage of incident patients, those who are initially starting hemodialysis or peritoneal dialysis for the first time with AVF, arteriovenous graft, and PD catheters; (7) a measure examining the percentage of prevalent patients, those patients already on dialysis and who have working vascular or PD access excluding central venous catheters; (8) a measure on Cramping and Washed-Out feeling; (9) a measure on Healthy Days at home; (10) a measure on Advanced Directives in patients with ESRD. One commenter noted that the two recommended catheter measures listed above (#6 and 7) are important because catheter use continues to be very high among prevalent ESRD patients, despite the improved clinical outcomes associated with arteriovenous access, and argued that these recommended measures could decrease catheter use among ESRD patients.

Response: We thank the commenters for their recommendations, and will take these measure topics into consideration as we continue to develop the ESRD QIP measure set for future years of the program. We note that because the home hemodialysis, peritoneal dialysis and pediatric dialysis patient populations remain relatively small, establishing facility-level measures specific to these populations present substantial challenges. Specifically, there is a lack of clinical evidence available to set performance standards because there are relatively few home hemodialysis, peritoneal dialysis and pediatric dialysis patients, compared to in-center hemodialysis patients. In addition, small patient populations within individual facilities may result in measure reliability issues, which will need to be addressed before the measure can be operationalized in the ESRD QIP.

Comment: One commenter requested that CMS develop a validated experience instrument for assessing the home dialysis population because home hemodialysis patients constitute 10 percent of the ESRD population and are currently excluded from the ICH CAHPS clinical measure, the only patient experience measure in the ESRD QIP.

Response: We appreciate the commenter's interest in ensuring that home dialysis patients are appropriately included in the ESRD QIP. While we are aware of interest in an experience of care survey, such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, for home dialysis patients, we do not have immediate plans to extend the types of patients covered by our experience of care surveys in this area, due to resource constraints and questions regarding the feasibility of expanding the current survey to include home hemodialysis patients. As we continue with the initial implementation and public reporting for the In-Center Hemodialysis CAHPS Survey, we will consider ways to capture these patients in the ESRD QIP, including developing measures that would assess their quality of care.

Comment: One commenter supported the adoption of measures on bloodstream infection levels in ESRD patients, and recommended that CMS be mindful of the fact that the pediatric patient population may be disproportionately at risk for bloodstream infections.

Response: We will continue to take the unique needs and characteristics of the pediatric patient population into consideration in future measure development efforts.

Comment: One commenter suggested that CMS convene a Technical Expert Panel to develop a measure capturing patient education. The commenter further recommended that a good first step would be to compile education-related responses to the CAHPS survey (specifically questions 26, 27 and 30).

Response: We thank the commenter for the suggestion to develop a measure on patient education. We are considering a variety of measure development activities for the coming years, and will take this suggestion into consideration.

Comment: One commenter supported CMS's decision not to include hospitalizations and mortality in the ESRD QIP's measure set because of a belief that such measures are inappropriate in a pay-for-performance program while the impact of socio-demographic status on their rates is still being fully debated. Additionally, the commenter added that if these measures are adopted in future years of the QIP, facilities should be compared to peers serving similar socio-demographic populations.

Response: We appreciate the commenter’s support and will consider the recommendation in the event that the SMR and SHR measures are considered for adoption in future years of the QIP.

Comment: One commenter expressed concern about the number of measures included in the QIP that are not NQF-endorsed.

Response: We agree that in general it is best for the ESRD QIP to adopt measures that are NQF-endorsed. Where it is feasible and practicable to adopt an NQF-endorsed measure, we do so. However, in instances where a measure has not been NQF-endorsed for a topic that we feel is of importance for the clinical care and outcomes of patients with ESRD, or where we feel a non-endorsed measure is superior to an NQF-endorsed measure on the same topic, we believe it is appropriate to adopt a non-endorsed measure. In proposing to adopt non-endorsed measures, we give due consideration to NQF-endorsed measures, as well as those adopted by other consensus organizations.

a. PY 2018 Measures Continuing for PY 2019 and Future Payment Years

We previously finalized 16 measures in the CY 2015 ESRD PPS final rule for the PY 2018 ESRD QIP, and these measures are summarized in Table 23 below. In accordance with our policy to continue using measures unless we propose to remove or replace them, (77 FR 67477), we stated in the proposed rule that we would continue to use 12 of these measures in the PY 2019 ESRD QIP. We also proposed to remove four clinical measures—(1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: Minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy—and replace them with a single, comprehensive clinical measure covering the patient populations previously captured by these four individual clinical measures.

TABLE 23 – PY 2018 ESRD QIP MEASURES BEING CONTINUED IN PY 2019

NQF #	Measure Title and Description
0257	Vascular Access Type: AV Fistula, a clinical measure Percentage of patient-months on hemodialysis during the last hemodialysis treatment of the month using an autogenous AV fistula with two needles.
0256	Vascular Access Type: Catheter $\geq$ 90 days, a clinical measure Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A[1]	National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients, a clinical measure Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.
1454	Hypercalcemia, a clinical measure Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
2496	Standardized Readmission Ratio, a clinical measure Standardized hospital readmissions ratio of the number of observed unplanned readmissions to the number of expected unplanned readmissions.
N/A	Standardized Transfusion Ratio, a clinical measure Risk-adjusted standardized transfusion ratio for all adult Medicare patients.
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Facility administers, using a third-party CMS-approved vendor, the ICH CAHPS survey in accordance with survey specifications and submits survey results to CMS.
N/A[2]	Mineral Metabolism Reporting, a reporting measure Number of months for which facility reports serum phosphorus or serum plasma for each Medicare patient.
N/A	Anemia Management Reporting, a reporting measure Number of months for which facility reports ESA dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient.
N/A[3]	Pain Assessment and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period.
N/A[4]	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient once before February 1 of the year following the performance period.
N/A[5]	NHSN Healthcare Personnel Influenza Vaccination, a reporting measure Facility submits Healthcare Personnel Influenza Vaccination Summary Report to CDC's NHSN system, according to the specifications of the Healthcare Personnel Safety Component Protocol, by May 15 of the performance period.

[1] We note that this measure is based upon a current NQF-endorsed bloodstream infection measure (NQF#1460).
[2] We note that this measure is based upon a current NQF-endorsed serum phosphorus measure (NQF #0255).
[3] We note that this measure is based upon a current NQF-endorsed pain assessment and follow-up measure (NQF #0420).
[4] We note that this measure is based upon a current NQF-endorsed clinical depression screening and follow-up measure (NQF #0418).
[5] We note that this measure is based upon an NQF-endorsed HCP influenza vaccination measure (NQF #0431).

We received comments on PY 2018 Measures Continuing for PY 2019 and future years. The comments and our responses are set forth below.

Comment: A number of commenters expressed views on measures which were

previously adopted in the ESRD QIP. Some commenters were supportive of previously adopted measures, and some recommended changing measure specifications for some measures. Other commenters requested that CMS consider removing previously added measures from the ESRD QIP, specifically, the NHSN BSI clinical measure, the SRR clinical measure, the STrR clinical measure, the ICH CAHPS clinical measure, the NHSN HCP Influenza Vaccination reporting measure, the Screening for Clinical Depression and Follow-Up reporting measure, and the Pain Assessment and Follow-Up reporting measure, because a number of these measures are under review at NQF, are inappropriate for facilities due to concerns about measure reliability or validity, or are too burdensome for facilities.

Response: We thank the commenters for their suggestions. At this time, we are not removing or modifying any of the measures suggested by commenters. We did not propose to remove any measures from the ESRD QIP in the CY 2016 ESRD PPS proposed rule. Further, there is no evidence that continued use of the measures as specified raises patient safety concerns that would require immediate removal of the measures based on the process finalized in the CY 2013 ESRD PPS final rule with comment period (77 FR 67475). However, we will take these suggestions into consideration in future years using the measure removal criteria we finalized in the CY 2013 ESRD PPS final rule with comment period (77 FR 67475) and further clarified in the CY 2015 ESRD PPS final rule with comment period (79 FR 66171 through 66174). We continue to believe there is value in collecting and reporting these measures at this time.

Comment: Numerous commenters requested that CMS modify the SRR clinical measure's exclusion criteria to reflect the measure as recently modified and endorsed at NQF under the All-Cause Admissions and Readmissions Measures project. Specifically, commenters requested that CMS incorporate an exclusion for patients who are readmitted to a hospital within

the first one-to-three days following their hospital discharge.

Response: The SRR clinical measure was submitted for review as part of the NQF's All-Cause Admissions and Readmissions Measures project, during which the Steering Committee, NQF members, and the public discussed the appropriateness of including patients who are readmitted to a hospital within three days of discharge in the measure. In the CY 2015 ESRD PPS final rule with comment period, we expressed our initial belief that these patients should be included in the SRR measure because this three-day readmission timeframe represents an opportunity for quality improvement (79 FR 66177). However, following detailed discussions at NQF, we now believe that excluding readmissions within the first three days of discharge is critical in order to avoid holding facilities accountable for events largely beyond their control. These readmissions are likely to occur during the period when the dialysis facility may not have had an opportunity to see the patient for treatment, and, at present, facilities do not systematically receive data about their patients from the hospital when they are readmitted, thus limiting the facilities' ability to engage in quality improvement for this specific subpopulation at this time. As stated in the CY 2014 ESRD PPS final rule with comment period, we believe it is important to have in place a process which allows the ESRD QIP to incorporate non-substantive updates to a measure, in order to ensure that measures adopted for the ESRD QIP remain up-to-date and clinically relevant (77 FR 67476-67477). We believe that excluding readmissions within the first three days of discharge constitutes a non-substantive technical update to the measure; for these reasons, beginning with PY 2017, we are making this technical update to the SRR clinical measure and are adopting this exclusion. We will exclude readmissions within the first 1-3 days of an initial discharge from the SRR clinical measure. The SRR clinical measure specifications, as well as the SRR measure methodology report, are both available at:

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html and https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSRRMeasure.pdf , respectively.

b. Dialysis Adequacy Clinical Measure Beginning with the PY 2019 ESRD QIP

Section 1881(h)(2)(A)(i) of the Act states that the ESRD QIP measure set must include measures on "dialysis adequacy." Kt/V is a widely accepted measure of dialysis adequacy in the ESRD community. It is a measure of small solute (urea) removal from the body, is relatively simple to measure and report, and is associated with survival among dialysis patients. While the current dialysis adequacy measures have allowed us to capture a greater proportion of the ESRD population than previously accounted for under the URR Hemodialysis Adequacy clinical measure, the specifications for these measures still result in the exclusion of some patients from the measures. For example, the Pediatric Hemodialysis Adequacy clinical measure's specifications have limited the number of pediatric patients included in the ESRD QIP because very few facilities (10 facilities, based on CY 2013 data) were eligible to receive a score on the measure. We are therefore proposing to adopt a single comprehensive Dialysis Adequacy clinical measure under the authority of section 1881(h)(2)(A)(i) of the Act.

The Measure Applications Partnership conditionally supported the proposed Dialysis Adequacy clinical measure in its *2015 Pre-Rulemaking Report*, noting that this measure meets critical program objectives to include more outcome measures and measures applicable to the

pediatric population in the set.[5]

The Dialysis Adequacy clinical measure assesses the percentage of all patient-months for both adult and pediatric patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the performance period. A primary difference between the single comprehensive Dialysis Adequacy clinical measure and the four previously finalized dialysis adequacy clinical measures is how facility eligibility for the measure is determined. Under the four previously finalized dialysis adequacy clinical measures, facility eligibility was determined based on the number of qualifying patients treated for each individual measure (for example, the number of qualifying adult hemodialysis patients for the Hemodialysis Adequacy: Minimum Delivered Hemodialysis Dose clinical measure). As a result, a facility had to treat at least 11 qualifying patients for each of these measures in order to receive a score on that measure. By contrast, a facility's eligibility to receive a score on the proposed Dialysis Adequacy clinical measure, which includes both adults and children, and both hemodialysis and peritoneal dialysis modalities, is determined based on the total number of qualifying patients treated at a facility. As a result, a facility that would not be eligible to receive a score on one or more of our current dialysis adequacy clinical measures because it did not meet the case minimum for one or more of those measures would be eligible to receive a score on the proposed dialysis adequacy measure if it had at least 11 total qualifying patients, defined as adults and pediatric patients receiving either hemodialysis or peritoneal dialysis. Therefore, we anticipate that adopting the single comprehensive Dialysis Adequacy clinical measure will allow us to evaluate the care provided to a greater proportion of ESRD patients, particularly pediatric ESRD patients.

5 https://www.qualityforum.org/map/. This report can be found at the preceding Web site under the title "Spreadsheet of MAP 2015 Final Recommendations."

We proposed that patients' dialysis adequacy would be assessed based on the following Kt/V thresholds previously assessed under the individual dialysis adequacy clinical measures:

- For hemodialysis patients, all ages: spKt/V $\geq$ 1.2 (calculated from the last measurement of the month)
- For pediatric (age < 18 years) peritoneal dialysis patients: Kt/V urea $\geq$ 1.8 (dialytic + residual, measured within the past six months)
- For adult (age $\geq$ 18 years) peritoneal dialysis patients: Kt/V urea $\geq$ 1.7 (dialytic + residual, measured within the past four months)

These thresholds reflect the best evidence-based minimum threshold for adequate dialysis for the described patient groups and are consistent with dialysis adequacy measures previously implemented in the QIP. Patient eligibility for inclusion in the measure would be determined on a patient-month level, based on the patient's age, treatment modality type, whether a patient has been on dialysis for 90 days or more, and the number of hemodialysis treatments the patient receives per week. All eligible patient-months at a facility would be counted toward the denominator. Eligible patient months where the patient met the specific dialysis adequacy threshold would be counted toward the numerator. Technical specifications for the Dialysis Adequacy clinical measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

We sought comments on our proposal to adopt this measure beginning with the PY 2019 ESRD QIP. The comments and our responses are set forth below.

Comment: A number of commenters supported the comprehensive Dialysis Adequacy clinical measure because adopting the single measure in place of the four individual measures would reduce the dilution of measure scores in the ESRD QIP and simplify the ESRD QIP

measure set.

Response: We thank the commenters for their support.

Comment: One commenter expressed concerns with removing the current indicators for dialysis adequacy because of the possibility this will lead to inaccurate reporting. The commenter argued that removing the Pre/post dialysis urea nitrogen, Pre/post dialysis weight, and duration of treatment will enable the facility to report adequacy based on inaccurate blood draws, access recirculation, etc., thereby increasing the likelihood of better outcomes for the facility. Because Kt/V is a calculated outcome, the commenter urged CMS to consider having the CROWNWeb database calculate the actual Kt/V using the already available information, which could potentially eliminate the tweaking of data currently being submitted.

Response: The proposed Dialysis Adequacy clinical measure uses the same data submission requirements previously used for the four individual dialysis adequacy clinical measures, and is therefore not subject to the concerns raised. Furthermore, facilities have never been required to report pre/post dialysis urea nitrogen, pre/post dialysis weight or duration of treatment in the QIP.

Comment: One commenter urged CMS to consider patients who transfer from one modality to another to be new patients in that modality for adequacy scoring. The commenter explained that when a patient transitions from hemodialysis to peritoneal dialysis, the peritoneal dialysis scoring methodology assumes there is a peritoneal dialysis Kt/V reading within the last 4 months, without recognition that the patient has recently transitioned to this modality. The commenter argued that, as a result of this scoring methodology, dialysis facilities are forced to attempt to immediately conduct a peritoneal dialysis adequacy test, without a sufficient stabilization period in the new treatment modality.

Response: Under the single comprehensive Dialysis Adequacy clinical measure, if a patient changes from hemodialysis to peritoneal dialysis during a month, the patient would be included in both the HD and PD Kt/V measure calculations. The 2006 KDOQI Clinical Practice Guidelines for peritoneal dialysis adequacy (Guideline 2.1.2) state ''the total solute clearance (residual kidney and peritoneal, in terms of Kt/V) should be measured within the first month after initiating dialysis therapy and at least once every 4 months thereafter.'' While this measure is consistent with the guideline, we acknowledge that a patient may be included in the peritoneal dialysis Kt/V measure calculation in the same month their modality changed to peritoneal dialysis, and that peritoneal dialysis clearance is typically not measured right away or even in the same month as the peritoneal dialysis catheter insertion, as the peritoneal membrane is in a state of flux and its membrane transport characteristics are unstable for a few weeks. We therefore use the data reported in conjunction with Medicare dialysis facility claims value code D5: Result of last Kt/V reading and occurrence code 51: Date of last Kt/V reading, to determine whether the patient was on peritoneal dialysis or hemodialysis, and whether they switched modalities during the reporting month. The claims reporting instructions indicate that for peritoneal dialysis patients this should be within the last 4 months of the claim date of service. All monthly claims with valid peritoneal dialysis Kt/V values will be used in the calculation.

Comment: One commenter expressed concern that benchmarking all facilities treating any pediatric patients against those treating larger volumes of pediatric patients under the comprehensive Kt/V Dialysis Adequacy clinical measure may skew the results for ESRD facilities treating smaller numbers of pediatric ESRD patients because these facilities are less familiar with how to best manage dialysis treatments for pediatric patients.

Response: Performance on the Dialysis Adequacy clinical measure is based on the total number of qualifying patients—adult and pediatric, and hemodialysis and peritoneal dialysis modalities—treated at the facility, and the number of those patients meeting the applicable Kt/V threshold. Therefore, under this measure, facilities are assessed on the clinical care provided to all qualifying patients, and performance across facilities is based on the same holistic view of clinical care. As a result, facilities' management of a specific subgroup will not be compared directly to that of other facilities. We believe this measure therefore properly incentivizes facilities to properly manage the care of all patients, including pediatric patients, seen at the facility.

Comment: One commenter noted that when this measure was reviewed by the Measure Applications Partnership, it was characterized by CMS as a composite measure; however, the proposed measure as described appears to be a pooled measure with a different set of evaluation criteria.

Response: We acknowledge that there might have been some confusion surrounding our use of the term "composite" in the title of the proposed measure, especially because we are now aware that the NQF uses a specific set of criterion to determine whether a measure is a composite for endorsement purposes. However, the measure specifications presented in the CY 2016 ESRD PPS proposed rule are identical to those submitted for review by the Measure Applications Partnership, and the calculation methodology uses a pooled approach. We have developed the following table comparing the specifications of the Delivered Dose of Dialysis above Minimum – Composite Score measure submitted to the Measure Applications Partnership and the Dialysis Adequacy clinical measure, which we have renamed in full as Delivered Dose of Dialysis above Minimum.

Table 24 – Comparison of Delivered Dose of Dialysis above Minimum – Composite Score Measure and Proposed Dialysis Adequacy Clinical Measure Specifications

Specification Component	Delivered Dose of Dialysis above Minimum – Composite Score[6]	Proposed Dialysis Adequacy Clinical Measure[7]
Numerator	Number of patient months in the denominator whose delivered dose of dialysis met the specified thresholds. The thresholds are as follows: • Hemodialysis (all ages): Kt/V >= 1.2 • Peritoneal dialysis (pediatric): Kt/V >= 1.8 (within past 6 months) • Peritoneal dialysis (adult): Kt/V >= 1.7 (within past 4 months)	Number of patient months in the denominator whose delivered dose of dialysis met the specified thresholds. The ranges are as follows: • Hemodialysis (all ages): Kt/V >= 1.2 (calculated from the last measurement of the month) • Peritoneal dialysis (pediatric): Kt/V >= 1.8 (dialytic + residual, measured within the past 6 months) • Peritoneal dialysis (adult): Kt/V >= 1.7 (dialytic + residual, measures within the past 4 months)
Denominator	To be included in the denominator for a particular month, patients need to meet the following requirements that month: • Peritoneal dialysis patients: All peritoneal dialysis patients who have been on dialysis for at least 90 days. • Hemodialysis patients: Pediatric (<18 years old) in-center HD patients who have been on dialysis for 90 days or more and dialyzing thrice weekly, adult >= 18 years old) patients who have been on dialysis for 90 days or more and dialyzing thrice weekly.	• All adult hemodialysis patients who received dialysis greater than two and less than four times a week (adults, ≥ 18 years) and all pediatric in-center hemodialysis patients who received dialysis greater than 2 and less than five times a week (pediatric, < 18 years), and did not indicate frequent dialysis • All patients (both HD and PD) who are assigned to the facility for the entire month, and have had ESRD for 90 days or more

Comment: One commenter expressed concern about the proposed Dialysis Adequacy measure because smaller facilities that would not have had 11 patients in any given dialysis

6 Specifications for the Delivered Dose of Dialysis above Minimum – Composite Score measure reviewed by the Measure Applications Partnership are available at https://www.qualityforum.org/map/ under the document titled "Spreadsheet of MAP 2015 Final Recommendations."

7 Specifications for the Dialysis Adequacy clinical measure proposed in the CY 2016 ESRD PPS proposed rule are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Proposed-PY-2019-measure-specs_6-24-15.pdf.

adequacy category under the four individual measures may now be included in the combined measure. Additionally, the commenter recommended that CMS convene a TEP to discuss additional ways in which CMS can include more patients and facilities in the QIP generally.

Response: We proposed to adopt this measure, in part, because we wanted to be able to assess dialysis adequacy in a greater percentage of ESRD patients. We will take the recommendation to convene a TEP in order to explore additional ways to include more ESRD patients in the ESRD QIP into consideration.

Comment: A few commenters requested that CMS retain the seven-treatment per month exclusion from the previous dialysis adequacy measures because facilities rarely collect Kt/V for transient patients. One commenter further requested that CMS allow facilities to submit Kt/V collected from an outside source for these patients. Another commenter recommended that CMS define the minimum number of treatment days under the care of a facility for peritoneal dialysis patients when calculating the current peritoneal dialysis adequacy clinical measures, and recommended a threshold of approximately 14 peritoneal dialysis treatment days.

Response: The measure specifications for the proposed Dialysis Adequacy clinical measure exclude from the denominator "all patients who were not assigned to the facility for the entire month," which will have effect of excluding all peritoneal dialysis patients who are treated less than seven times per month and all peritoneal dialysis patients who are not assigned to the facility for the entire month.

Comment: One commenter requested that CMS provide additional information regarding the benchmarks and achievement thresholds for the comprehensive Dialysis Adequacy clinical measure, citing concerns that these values may be difficult to determine because the Kt/V thresholds for the measures within the comprehensive Dialysis Adequacy clinical measure vary

across patient age and treatment modality.

Response: Facility performance on the measure will be evaluated in much the same way as facility performance on the dialysis adequacy measure topic that was part of the QIP for three payment years. Kt/V values for a particular patient month will be compared to the threshold for the given modality and patient age, and assigned to numerators and denominators as appropriate. Much like the previously finalized Dialysis Adequacy Measure Topic, numerators and denominators for the four sub-groupings of age and modality will be aggregated together and weighted according to the number of patient months represented.

Comment: Some commenters requested that CMS modify the comprehensive Dialysis Adequacy clinical measure's hemodialysis threshold to account for the higher Kt/V values for nocturnal dialysis patients.

Response: The previously implemented dialysis adequacy measures did not distinguish between types of hemodialysis patients, other than to identify frequency of treatment on a weekly basis, nor was this recommended by Technical Expert Panels convened for the purpose of developing the proposed comprehensive dialysis adequacy measure. As always, we continue an ongoing measure maintenance cycle where these and other recommendations may be considered within the context of available data and existing clinical evidence.

Comment: Several commenters did not support the proposed comprehensive Dialysis Adequacy clinical measure because the measure pools the scores from the four dialysis populations, despite the vast differences between these groups, which make it difficult to accurately assess a facility's quality under the proposed measure. Some of these commenters expressed concerns that the pooled approach may obscure differences in quality of care for pediatric patients, peritoneal dialysis patients, and home hemodialysis patients. Commenters

also stated that the effect of one or two outliers may distort the overall quality of care provided at facilities with a small number of patients.

Response: The Dialysis Adequacy Clinical Measure is does not clinically co-mingle peritoneal dialysis and hemodialysis modalities. Peritoneal dialysis patients are assessed based on clinical standards appropriate for these patients, while hemodialysis patients are assessed based on clinical standards appropriate for them. We understand that patient groups that comprise a smaller percentage of a facility's total population will have less impact on the facility's performance score for the Dialysis Adequacy clinical measure; however, failure to incorporate pediatric, peritoneal, and home dialysis patients into the four individual dialysis adequacy measures due to reporting requirements significantly limits the ability to evaluate facility performance for those subgroups. We also note that individual-level data remains available upon request for all QIP measures following calculation of measure scores for a given payment year of the ESRD QIP, should facilities wish to investigate their internal performance while reviewing their Preview Performance Score Report for that year. More granular detail is also available via the annually published Dialysis Facility Reports and the Dialysis Facility Compare tool. Clinically, the proposed measure assesses each patient on clinically appropriate standards, and the measure addresses whether each patient has received adequate dialysis based on that individual's needs. As a result, the performance rate is a description of the rate at which a facility is adequately meeting the dialysis needs of its patients, regardless of their age and modality. We therefore believe that any potential for the proposed measure to "mask" facility performance for smaller segments of its population is outweighed by the benefit of including these patients in the measure population.

Comment: Commenters expressed concerns about the Dialysis Adequacy clinical

measure because of the concerns raised during the NQF Renal Standing Committee. Specifically, the commenters do not support the measure because the NQF recommended against endorsement.

Response: While the NQF Renal Standing Committee has not yet issued its final report, we understand that the Committee's current recommendation is against endorsement for this measure, because the Committee determined that measure failed the NQF's Importance to Measure and Report criterion. Specifically, the NQF Renal Standing Committee expressed concerns about the strength of evidence supporting the pediatric hemodialysis and peritoneal dialysis Kt/V thresholds established under this measure. However, we continue to believe that including pediatric patients in assessments of dialysis adequacy is critical, because these patients constitute a unique subpopulation of ESRD patients and are often excluded from other ESRD QIP quality measures. Very few facilities treating pediatric patients qualify to receive a score under the current Pediatric Hemodialysis Adequacy and Pediatric Peritoneal Dialysis Adequacy clinical measures, and adopting the single, comprehensive Dialysis Adequacy clinical measure will allow us to capture the quality of care provided to a greater proportion of pediatric patients nationally.

Comment: One commenter did not support adoption of the comprehensive Dialysis Adequacy clinical measure because it includes pediatric patients receiving dialysis three and four times a week when the evidence for the measure is based on patients receiving treatments three times a week.

Response: The 2010 TEP that recommended this measure originally specified the measure to include pediatric patients on dialysis 3 or 4 times per week, based in part on analyses showing that 4 times per week hemodialysis was observed in approximately 5.6 percent of

pediatric patient weeks, and nearly 90 percent of pediatric patient weeks reflected either 3 or 4 times per week hemodialysis (based on 2007 Medicare claims data). Given that this was a significant proportion of patients, the TEP concluded that these patients should all be included in this measure. While the Delivered Dose of Dialysis above Minimum measure under review by the NQF Renal Standing Committee has revised its measure specifications to capture only pediatric hemodialysis patients dialyzing three times per week, we believe it is important to capture as many pediatric patients as possible in the ESRD QIP. There are currently very few measures that focus on the care provided to pediatric ESRD patients, and excluding pediatric hemodialysis patients dialyzing four times per week from the Dialysis Adequacy clinical measure would exclude those patients from all dialysis adequacy assessment. In addition, we believe that collecting data on the quality of care provided to pediatric hemodialysis patients can influence the standard of care provided by all facilities that treat pediatric patients. For these reasons, we are including pediatric hemodialysis patients who dialyze three or four times per week in the Dialysis Adequacy clinical measure.

Comment: Several commenters recommended that CMS adopt modifications for the upper Kt/V threshold recommended by the NQF Renal Standing Committee; specifically, removing the upper Kt/V threshold exclusion due to insufficient evidence supporting the selected values. One commenter argued that the evidence-based threshold should be the only value in the specifications, and the handling of anomalous data should be addressed by measure implementation and operationalization guidance so that patients with spurious Kt/V values are excluded from the measure calculations.

Response: The proposed Dialysis Adequacy clinical measure does not include upper thresholds for patients' Kt/V (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-

Assessment-Instruments/ESRDQIP/Downloads/Proposed-PY-2019-measure-specs_6-24-15.pdf), and the Dialysis Adequacy measure under review by the NQF Renal Standing Committee was also revised to remove these upper thresholds.

Comment: One commenter requested that CMS provide additional details about the technical specifications for the comprehensive Dialysis Adequacy clinical measure in the ESRD Measures Manual.

Response: We intend to incorporate the Dialysis Adequacy clinical measure into the CMS ESRD Measures Manual before the beginning of the measure's performance period in CY 2017. The Measures Manual, will provide detailed measure specifications for all measures used in the ESRD QIP and other CMS ESRD programs, such as Dialysis Facility Compare, and will be updated in the future as new measures are implemented, such as the comprehensive Dialysis Adequacy clinical measure

Comment: One commenter recommended that CMS include residual renal function in dose calculations for hemodialysis patients only if the urine collection used to measure it was performed within the last 90 days.

Response: The current dialysis adequacy measures do not currently include residual renal function as part of the NQF endorsed specifications, and the proposed measure retains this form. In addition, the Technical Expert Panels convened for the purpose of developing these measures have not recommended the inclusion of residual renal function to date. As always, we maintain an ongoing measure maintenance cycle where these and other recommendations may be considered within the context of available data and existing clinical evidence.

Comment: One commenter expressed concern about the impact of peritoneal dialysis patients' noncompliance with treatment protocols on facility performance. Specifically, the

commenter recommended that facilities should either receive credit for their efforts to get peritoneal dialysis patients to visit the facility in a given month, or that noncompliant peritoneal dialysis patients should be excluded from the facilities' measure scores.

Response: Our quality measures do not currently assess patient compliance directly, as currently available data sources are unable to capture the information. Moreover, while we recognize that some patients may follow a course of treatment less assiduously than others, we believe it remains the facility's responsibility to continue reaching out to these patients for the purpose improving their quality of care.

For these reasons, we are finalizing the single comprehensive Dialysis Adequacy clinical measure as proposed, beginning in PY 2019.

c. Reporting Measures Proposed, Beginning with the PY 2019 ESRD QIP

i. Proposed Ultrafiltration Rate Reporting Measure

The ultrafiltration rate measures the rapidity with which fluid (ml) is removed at dialysis per unit (kg) body weight in unit (hour) time. A patient's ultrafiltration rate is under the control of the dialysis facility and is monitored throughout a patient's hemodialysis session. Studies suggest that higher ultrafiltration rates are associated with higher mortality and higher odds of an "unstable" dialysis session,[8] and that rapid rates of fluid removal during dialysis can precipitate events such as intradialytic hypotension, subclinical yet significantly decreased organ perfusion, and in some cases myocardial damage and heart failure.

Section 1881(h)(2)(A)(iv) gives the Secretary authority to adopt other measures for the

8 Flythe SE, Kimmel SE, Brunelli SM. Rapid fluid removal during dialysis is associated with cardiovascular morbidity and mortality. Kidney International (2011) Jan; 79(2):250-7. Flythe JE, Curhan GC, Brunelli SM. Disentangling the ultrafiltration rate—mortality association: The respective roles of session length and weight gain. Clin J Am Soc Nephrol. 2013 Jul;8(7):1151-61. Movilli, E et al. "Association between high ultrafiltration rates and mortality in uraemic patients on regular hemodialysis. A 5-year prospective observational multicenter study." Nephrology Dialysis Transplantation 22.12(2007): 3547-3552.

ESRD QIP that cover a wide variety of topics. Section 1881(h)(2)(B)(ii) of the Act states that "In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of Act [in this case NQF], the Secretary may specify a measure that is not so endorsed so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." We have given due consideration to endorsed measures, as well as those adopted by a consensus organization. Because no NQF-endorsed measures or measures adopted by a consensus organization on ultrafiltration rates currently exist, we proposed to adopt the Ultrafiltration Rate reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

We proposed to adopt a measure that is based on Measure Applications Partnership #XAHMH, "Ultrafiltration Rate Greater than 13 ml/kg/hr" ("Ultrafiltration Rate measure"). This measure assesses the percentage of patient-months for patients with an ultrafiltration rate greater than 13 ml/kg/hr. The Measure Applications Partnership expressed conditional support for the Ultrafiltration Rate measure, noting it would "consider the measure for inclusion in the program once it has been reviewed for endorsement." The measure upon which our proposed measure is based is currently under review for endorsement by NQF; however, we believe the measure is ready for adoption because it has been fully tested for reliability and addresses a critical aspect of patients' clinical care not currently addressed by the ESRD QIP measure set.

For PY 2019 and future payment years, we proposed that facilities must report an ultrafiltration rate for each qualifying patient at least once per month in CROWNWeb. Qualifying patients for this proposed measure are defined as patients 18 years of age or older, on hemodialysis, and who are assigned to the same facility for at least the full calendar month (for

example, if a patient is admitted to a facility during the middle of a month, the facility will not be required to report for that patient for that month). We further proposed that facilities will be granted a one month period following the calendar month to enter this data. For example, we would require a facility to report ultrafiltration rates for January 2017 on or before February 28, 2017. Facilities would be scored on whether they successfully report the required data within the timeframe provided, not on the values reported. Technical specifications for the Ultrafiltration Rate reporting measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: While several commenters supported the proposal to adopt the Ultrafiltration Rate reporting measure or the concept of an ultrafiltration rate measure in the ESRD QIP, many commenters did not support the specific measure proposed. Some commenters stated that ultrafiltration rates are highly variable even within individual patients, and it is unclear whether the proposed measure can influence quality of care without impacting the clinical judgment of ESRD providers. Many commenters also stated that the proposed measure is subject to "gaming" concerns because it relies on a single data point per month, as opposed to other ultrafiltration rate measures, such as NQF #2701, Avoidance of Utilization of High Ultrafiltration rate ($\geq$13 ml/kg/hr), which uses an average across all dialysis treatments provided over the course of a week to determine a patient's average ultrafiltration rate. These commenters further argued that the proposed Ultrafiltration Rate reporting measure's lack of any exclusion criteria or data collection regarding patients with longer time on dialysis also hampers the proposed measure's ability to evaluate the quality of care provided to ESRD patients.

Response: We appreciate the many comments we received on the Ultrafiltration Rate reporting measure. As a result of the significant concerns expressed about the measure, we have decided not to finalize the measure at this time. We will consider alternate approaches to collecting patient ultrafiltration rate data in the future.

For these reasons, we are not finalizing the proposed Ultrafiltration Rate reporting measure for the ESRD QIP.

ii. Proposed Full-Season Influenza Vaccination Reporting Measure

According to the Centers for Disease Control and Prevention (CDC), seasonal influenza, which occurs between October and March/April of the following year, is associated with approximately 20,000 deaths[9] and 226,000 hospitalizations annually.[10] While overall rates of influenza infection are highest among children, rates of serious illness and mortality are highest among adults aged 65 years or older, children aged two or younger, and immunocompromised patients such as patients with ESRD. Observational data have found associations between influenza vaccination and reduced mortality and hospitalization in this patient population. Specifically, multiple studies have found that vaccinated patients have significantly lower odds of all-cause mortality and modestly lower odds of all-cause hospitalization compared to unvaccinated patients.[11] However, influenza vaccination rates in the ESRD population have historically been lower than the Healthy People 2020 goal of 70 percent of both pediatric and

9 Centers for Disease Control and Prevention (CDC). Estimates of Deaths Associated with Seasonal Influenza – United States, 1976-2007. *MMWR* (2010) 59:33. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5933a1.htm.

10 Centers for Disease Control and Prevention (CDC). Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*2010a;59(RR-8):1-62.

11 Bond TC, Spaulding AC, Krisher J, et al. Mortality of dialysis patients according to influenza and pneumococcal vaccination status. Am J Kidney Dis. 2012;60:959-65; Gilbertson DT, Unruh M, McBean AM, et al. Influenza vaccine delivery and effectiveness in end-stage renal disease. Kidney Int. 2003;63:738-43.

adult populations in the United States,[12] with recent reports from the U.S. Renal Data System and Dialysis Facility Reports showing vaccination rates of 67 percent and 68 percent, respectively, among ESRD patients for the 2011-2012 season.[13] Based on these findings, we believe that encouraging closer evaluation of patients' influenza vaccination status in the dialysis facility will increase the number of patients with ESRD who receive an influenza vaccination and increase influenza vaccination rates in this population, which will in turn improve patient health and well-being.

We proposed to use a measure that is based on "ESRD Vaccination – Full-Season Influenza Vaccination" (Measure Applications Partnership #XDEFM). This measure assesses the percentage of ESRD patients $\geq$ 6 months of age on October 1 and on chronic dialysis $\geq$ 30 days in a facility at any point between October 1 and March 31 who either: (1) received an influenza vaccination; (2) were offered but declined the vaccination; or (3) were determined to have a medical contraindication. The Measure Applications Partnership conditionally supported the use of the ESRD Vaccination – Full-Season Influenza Vaccination measure in the ESRD QIP in its January 2014 Pre-Rulemaking Report because "influenza vaccination is very important for dialysis patients." Nevertheless, the Measure Applications Partnership declined to give the measure full support because it was not sure that the measure was more suitable to drive improvement than NQF #0226: "Influenza Immunization in the ESRD Population (Facility Level)". We have reviewed the measure specifications for NQF #0226 and determined that it is not appropriate to use as the basis for a reporting measure because the denominator statement of

12 http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives (Healthy People 2020 IID-12.11 and IID-12.12).

13 US Renal Data System, USRDS 2014 Annual Data Report: An overview of the epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.

NQF #0226 excludes all patients for whom data during the flu season is incomplete, potentially excluding patients who died from influenza, but might not have died if they had received an influenza vaccination. We therefore believe it is more appropriate to adopt a reporting measure based on the ESRD Vaccination – Full-Season Influenza Vaccination measure (Measure Applications Partnership #XDEFM) because this measure includes patients who died from influenza, but might not have died if they had received an influenza vaccination, and we believe it is important to include such patients in an influenza immunization clinical measure for the ESRD QIP, should we propose to adopt such a measure in the future.

For these reasons, we proposed to adopt a reporting measure based on "ESRD Vaccination – Full-Season Influenza Vaccination" ("Full-Season Influenza Vaccination reporting measure") so that we can collect data that we can use in the future to calculate both achievement and improvement scores, should we propose to adopt a clinical version of this measure in future rulemaking.

Section 1881(h)(2)(B)(ii) of the Act states that "In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act [in this case NQF], 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." Because we have given due consideration to endorsed measures, as well as those adopted by a consensus organization, and determined it is not practical or feasible to adopt those measures in the ESRD QIP, we proposed to adopt the Full-Season Influenza Vaccination reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

For PY 2019 and future payment years, we proposed that facilities must report one of the

following conditions in CROWNWeb once per performance period, for each qualifying patient (defined below):

1. If the patient received an influenza vaccination:
    a. Influenza Vaccination Date
    b. Where Influenza Vaccination Received: (1) Documented at facility; (2) Documented outside facility; or (3) Patient self-reported outside facility
2. If the patient did not receive an influenza vaccination:
    a. Reason:
        i. Already vaccinated this flu season
        ii. Medical Reason: Allergic or adverse reaction
        iii. Other medical reason
        iv. Declined
        v. Other reason

We note that while facilities are expected to retain patient influenza immunization documentation for their own records, facilities are not required to supply this documentation to CMS under the Full-Season Influenza Vaccination reporting measure.

For this measure, a qualifying patient would be defined as a patient aged six months or older as of October 1 who has been on chronic dialysis for 30 or more days in a facility at any point between October 1 and March 31. This measure would include in-center hemodialysis, peritoneal dialysis, and home dialysis patients. This proposed measure would capture the same data described in "ESRD Vaccination – Full-Season Influenza Vaccination", but we would require that facilities report the data on or before May 15 following the performance period for that year. We believe this reporting deadline will ensure that facilities have sufficient time to

collect and enter data for all qualifying patients following the influenza season, and aligns this reporting effort with that of the NHSN Healthcare Personnel Influenza Vaccination reporting measure finalized in the CY 2015 ESRD PPS final rule for PY 2018 (79 FR 66206 through 66208). Second, we proposed to score facilities based on whether they successfully report the data, and not based on the measure results. Technical specifications for the Full-Season Influenza Vaccination reporting measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: While several commenters supported the proposal to adopt the Full-Season Influenza Vaccination reporting measure or the concept of a patient-level influenza vaccination measure in the ESRD QIP, many commenters did not support the specific measure proposed. A number of these commenters recommended that CMS adopt a reporting measure that aligns more closely with NQF #0226: Influenza Immunization in the ESRD Population, arguing that the NQF-endorsed measure would better encourage timely vaccination of patients with ESRD and avoid penalizing facilities for patients who die but for whom time remained to meet the measure specifications. Some commenters also expressed concern about the conditions provided for reporting in CROWNWeb because their apparent overlap may result in inaccurate reporting, and other commenters recommended alternative conditions to capture instances such as hospitalized patients. Many commenters also stated that the proposed measure's timeline does not properly account for the reality that the influenza vaccination often becomes available before October 1, and may therefore result in unintended negative consequences for facilities that vaccinate patients before the performance period begins. Other commenters strongly recommended CMS

use the NHSN system instead of CROWNWeb to collect patient influenza immunization data because facilities already use NHSN for other data reporting and adding the proposed measure to NHSN would provide reporting consistency, as well as allow a larger proportion of the ESRD community to access data reported for the measure while simplifying the requirements for ESRD facilities.

Response: We appreciate the many comments we received on the Full-Season Influenza Vaccination reporting measure. As a result of the significant concerns expressed about the measure, we have decided not to finalize the measure at this time. We will consider alternative methods of collecting these important patient care data in the future.

For these reasons, we are not finalizing the proposed Full-Season Influenza Vaccination reporting measure for the ESRD QIP.

3. Performance Period for the PY 2019 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish the performance period with respect to a payment year, and that the performance period occur prior to the beginning of such year. We proposed to establish CY 2017 as the performance period for the PY 2019 ESRD QIP for all but the influenza vaccination measures because it is consistent with the performance period we have historically used for these measures and accounts for seasonal variations that might affect a facility's measure score. We proposed that the performance period for both the NHSN Healthcare Personnel Influenza Vaccination reporting measure and the proposed Full-Season Influenza Vaccination reporting measure will be from October 1, 2016 through March 31, 2017, because this period spans the length of the 2016-2017 influenza season.

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: Several commenters supported the proposed performance period for the PY 2019 ESRD QIP.

Response: We thank the commenters for their support.

Comment: Two commenters recommended that the performance period for both Influenza Vaccination measures be changed to encompass the earliest possible date that the influenza vaccine may be available in a given calendar year. They argued that operationally, facilities begin to vaccinate patients as soon as the vaccine is available, which could be as early as August. This would be consistent with the CDC's NHSN Flu Vaccine Protocol which encompasses "the time from when the vaccine became available through March 31 of the following year."

Response: We thank the commenters for their comments, and note that, as discussed above, we are not finalizing the Full-Season Influenza Vaccination reporting measure at this time. We note, however, that the performance period for the NHSN Healthcare Personnel Influenza Vaccination reporting measure does not restrict facilities to reporting only vaccinations received after October 1; instead, it establishes the period for which the facility must report HCP vaccination status. As a result, we encourage facilities to report vaccination statuses for all HCPs working at the facility and were vaccinated both before and after October 1.

Comment: One commenter expressed concerns that small providers who manually submit data are unduly burdened by the requirements of the ESRD QIP and expressed that with varied performance periods among quality measures, these requirements become very time consuming and burdensome.

Response: For all but one measure in the ESRD QIP, we have used the calendar year as the performance period. The remaining measure, the NHSN HCP Influenza Vaccination

reporting measure, uses a performance period of October 1 of the preceding year through March 31 of the following year to reflect the length and timing of the applicable influenza season. We believe this differing performance period is necessary to ensure the timely administration and monitoring of influenza vaccinations, and is not unduly burdensome on facilities.

For these reasons, we are finalizing the PY 2019 performance periods as proposed.

4. Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2019 ESRD QIP

Section 1881(h)(4)(A) of the Act provides that "the Secretary shall establish performance standards with respect to measures selected . . . for a performance period with respect to a year." Section 1881(h)(4)(B) of the Act further provides that the "performance standards . . . shall include levels of achievement and improvement, as determined appropriate by the Secretary." We use the performance standards to establish the minimum score a facility must achieve to avoid a Medicare payment reduction. We use achievement thresholds and benchmarks to calculate scores on the clinical measures.

a. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2019 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we proposed for PY 2019 to set the performance standards, achievement thresholds, and benchmarks for the clinical measures at the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2015, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2019 program prior to the beginning of the performance period. We continue to believe these standards will provide an

incentive for facilities to continuously improve their performance, while not reducing incentives to facilities that score at or above the national performance rate for the clinical measures.

We sought comments on these proposals. The comments and our responses are set forth below.

Comments: Many commenters supported the proposed performance standards, achievement thresholds, and benchmarks for the PY 2019 ESRD QIP being set at the 50th, 15th and 90th percentiles respectively.

Response: We thank the commenters for their support.

For these reasons, we are finalizing the PY 2019 performance standards, achievement thresholds, and benchmarks as proposed.

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Proposed for the PY 2019 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures, because we do not yet have data from CY 2015 or the first portion of CY 2016. We will publish values for the clinical measures, using data from CY 2015 and the first portion of CY 2016, in the CY 2017 ESRD PPS final rule.

c. Performance Standards for the PY 2019 Reporting Measures

In the CY 2014 ESRD PPS Final Rule, we finalized performance standards for the Anemia Management and Mineral Metabolism reporting measures (78 FR 72213). In the CY 2015 ESRD PPS Final Rule, we finalized our proposal to modify the measure specifications for the Mineral Metabolism reporting measure to allow facilities to report either serum phosphorus data or plasma phosphorus data for the Mineral Metabolism reporting measure (79 FR 66191). We did not propose any changes to these policies for the PY 2019 ESRD QIP.

In the CY 2015 ESRD PPS Final Rule, we finalized performance standards for the Screening for Clinical Depression and Follow-Up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures (79 FR 66209). We did not propose any changes to these policies.

For the Ultrafiltration Rate reporting measure, we proposed to set the performance standard as successfully reporting an ultrafiltration rate for each qualifying patient in CROWNWeb on a monthly basis, for each month of the reporting period.

For the Full-Season Influenza Vaccination reporting measure, we proposed to set the performance standard as successfully reporting one of the above-listed vaccination statuses for each qualifying patient in CROWNWeb on or before May 15th of the performance period.

We sought comments on these proposals. We did not receive comments on these proposals, and are therefore finalizing them as proposed for all measures except the Ultrafiltration Rate reporting measure and the Full-Season Influenza Vaccination reporting measure, which we are not finalizing.

5. Scoring the PY 2019 ESRD QIP

a. Scoring Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). Under this methodology, facilities receive points along an achievement range based on their performance during the performance period for each measure, which we define as a scale between the achievement threshold and the benchmark. In determining a facility's achievement score for each clinical measure under the PY 2019 ESRD QIP, we proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. The facility's achievement score would be calculated

by comparing its performance on the measure during CY 2017 (the proposed performance period) to the achievement threshold and benchmark (the 15th and 90th percentiles of national performance on the measure in CY 2015).

b. Scoring Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). In determining a facility's improvement score for each measure under the PY 2019 ESRD QIP, we proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. Under this methodology, facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We proposed to define the improvement threshold as the facility's performance on the measure during CY 2016. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2017 (the proposed performance period) to the improvement threshold and benchmark.

We sought comment on these proposals. The comments and our responses are set forth below.

Comment: One commenter supported the proposal for scoring the PY 2019 ESRD QIP measures.

Response: We thank the commenter for its support.

Comment: Some commenters expressed concerns about the ESRD QIP scoring methodology. One commenter argued that the scoring methodology is too complex, such that facilities are not afforded the opportunity to make immediate adjustments to care when minimum scores are not met. Another commenter noted that small and medium-sized facilities with

limited resources find the increasingly complicated formulas difficult to understand, and occasionally have to contract with outside firms to understand how proposed changes will affect them, predict how they will perform, and their results.

Response: The ESRD QIP scoring methodology is designed to make facility measure scores and TPSs as fair as possible, given the wide range of facility sizes and populations across the country, and we believe that attempting to further simplify the methodology may result in unfair scoring for facilities. In an effort to help facilities better understand the ESRD QIP's scoring methodology, we provide multiple resources that further elucidate the methodology, including calculation examples in preamble text, National Provider Calls, and the Preview Performance Score Report. We encourage facilities experiencing difficulty in understanding the ESRD QIP's scoring methodology to contact the program for assistance.

We also understand that the current scoring methodology does not allow facilities to calculate their current performance scores in real time for use in their quality improvement efforts. We are looking into opportunities to allow facilities this level of interaction with their ESRD QIP data, but are currently unable to do so due to claims processing timelines and system limitations.

Comment: Commenter expressed concern that that the current ESRD QIP scoring methodology is unfair to smaller facilities because when a small facility and a large facility provide the same quality of care to patients, the lower census facility will lose a higher proportion of points in the calculation. Commenter argued that, as a result of this calculation and weighting issue, it is inappropriate to compare small facilities' performance to large facilities' performance.

Response: We acknowledge that the current scoring methodology may result in a small number of outlier patients unduly impacting the facility's score. In order to alleviate the potential negative impact of a small number of patients on small facilities' scores, we have adopted the Small Facility Adjuster, which provides a positive adjustment to eligible small facilities' measure scores. We believe this adjustment is sufficient to counteract the negative effects of a small patient census on facility scores, but will continue to assess the appropriateness of additional measures to ensure accuracy in measure scoring for small facilities.

For these reasons, we are finalizing the achievement and improvement scoring methodologies for clinical measures in the PY 2019 ESRD QIP as proposed.

c. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through 66210). Under this methodology, facilities will receive an achievement score and an improvement score for each of the three composite measures and three global ratings in the ICH CAHPS survey instrument. A facility's ICH CAHPS score will be based on the higher of the facility's achievement or improvement score for each of the composite measures and global ratings, and the resulting scores on each of the composite measures and global ratings will be averaged together to yield an overall score on the ICH CAHPS clinical measure. For PY 2019, the facility's achievement score would be calculated by comparing where its performance on each of the three composite measures and three global ratings during CY 2017 falls relative to the achievement threshold and benchmark for that measure and rating based on CY 2015 data. The facility's improvement score would be calculated by comparing its performance on each of

the three composite measures and three global ratings during CY 2017 to its performance rates on these items during CY 2016.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported the proposed methodology for scoring the ICH CAHPS clinical measure.

Response: We thank the commenter for its support.

Comment: One commenter expressed concerns about the length of time it is taking for the ICH CAHPS measure to become a clinical performance measure in the QIP.

Response: The ICH CAHPS was first incorporated into the ESRD QIP measure set as a reporting measure for PY 2014; performance on this reporting measure has been included in facility Total Performance Scores for the past three years of the program, and will continue through PY 2017. With each year, we have continued to develop the baseline data and facility experience necessary to implement a clinical measure on ICH CAHPS performance. We agree that the ICH CAHPS clinical measure finalized for PY 2018 will have a greater impact on clinical practice by holding facilities accountable for their actual performance. As discussed in the CY 2015 ESRD PPS final rule with comment period (79 FR 66198), we believe this gradual ramp-up of the ICH CAHPS measure was necessary to ensure facilities are sufficiently versed in the survey administration process to be reliably evaluated on the measure beginning with performance in CY 2016.

Comment: One commenter urged CMS to consider breaking out questions 10 and 12 from the ICH CAHPS survey into separate measures for scoring and reporting. ("Did the dialysis center staff listen carefully to you?" and "Did the dialysis center staff show respect for what you

had to say?").

Response: The current ICH CAHPS survey is divided into two categories, global ratings and composite measures. Questions 10 and 12 are currently part of the Quality of Dialysis Center Care and Operations Composite measure, which integrates answers from a total of 17 individual survey items, all related to the care provided by the dialysis center and to dialysis center operations. We believe this composite measure, which examines the complete ICH CAHPS survey, appropriately addresses a broad range of concerns, and is therefore more reflective of the full care experience of patients at a facility, than a measure would be if it looked at one single question from the survey. However, we encourage individual facilities to monitor responses to individual items as part of their efforts to identify opportunities for quality improvement.

Comment: One commenter requested that CMS further clarify how the scores from each of the two survey administrations will be used in scoring the ICH CAHPS clinical measure.

Response: Under the ICH CAHPS clinical measure, eligible facilities will perform two survey administrations per year, one in the spring and one in the fall. At the conclusion of each of these survey administrations, composite scores and global ratings will be calculated for each survey. The results will then be averaged across the two surveys for the year, and the resulting averages will be used in the calculation of both achievement and improvement scores.

For these reasons, we are finalizing the scoring methodology for the ICH CAHPS clinical measure as proposed for the PY 2019 program.

d. Calculating Facility Performance on Reporting Measures

In the CY 2013 ESRD PPS final rule, we finalized policies for scoring performance on the Anemia Management and Mineral Metabolism reporting measures in the ESRD QIP (77 FR 67506). We did not propose any changes to these policies for the PY 2019 ESRD QIP.

In the CY 2015 ESRD PPS final rule, we finalized policies for scoring performance on the Clinical Depression Screening and Follow-Up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures (79 FR 66210 through 66211). We did not propose any changes to these policies.

With respect to the Ultrafiltration Rate reporting measure, we proposed to score facilities with a CCN Open Date before July 1, 2017 using the same formula previously finalized for the Mineral Metabolism and Anemia Management reporting measures (77 FR 67506):

$$\left[\frac{(\#\text{ months successfully reporting data})}{(\#\text{ eligible months})} \times 12\right] - 2$$

As with the Anemia Management and Mineral Metabolism reporting measures, we would round the result of this formula (with half rounded up) to generate a measure score from 0-10.

With respect to the Full-Season Influenza Immunization reporting measure, we proposed to score facilities with a CCN Open Date before January 1, 2017 based on the proportion of eligible patients for which the facility successfully submits one of the vaccination status indicators listed above by the May 15, 2017 deadline using the following formula:

$$\left[\frac{\left(\begin{array}{c}\text{No. patients for whom facility reports vacc.}\\ \text{status during the performance period}\end{array}\right)}{\left(\begin{array}{c}\text{No. of eligible patients during the performance}\\ \text{period}\end{array}\right)}\right]$$

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: One commenter expressed concern about how CMS would account for patients who are no longer in the facility when the vaccination reporting is due for the Full-

Season Influenza Vaccination reporting measure.

Response: We thank the commenter for its comment. However, we are not finalizing the Full-Season Influenza Vaccination reporting measure at this time.

For these reasons, we are finalizing the scoring methodologies for all reporting measures except the Ultrafiltration Rate reporting measure and the Full-Season Influenza Vaccination reporting measure, which we are not finalizing.

6. Weighting the Clinical Measure Domain and Total Performance Score

i. Weighting the Clinical Measure Domain for PY 2019

In the CY 2015 ESRD PPS final rule, we finalized policies regarding the criteria we would use to assign weights to measures in a facility's Clinical Measure Domain score (79 FR 66214 through 66216). Specifically, we stated that in deciding how to weight measures and measure topics within the Clinical Measure Domain, we would take into consideration: (1) the number of measures and measure topics in a proposed subdomain; (2) how much experience facilities have had with the measures; and (3) how well the measures align with CMS' highest priorities for quality improvement for patients with ESRD.

In the same rule, we finalized the Dialysis Adequacy measure topic and Vascular Access Type measure topic's weights for PY 2018 at 18 percent of a facility's Clinical Measure Domain score because facilities have substantially more experience with the Dialysis Adequacy measure topic as compared to the other measures in the Clinical Care subdomain (79 FR 66214). Beginning in PY 2019, we proposed to remove the Dialysis Adequacy measure topic and replace it with the Dialysis Adequacy clinical measure. Because this proposed measure is a composite of the measures previously included in the Dialysis Adequacy measure topic, with the same Kt/V thresholds currently used for those measures, we believe that facilities are already familiar with

the concepts underlying this proposed measure and that the measure should be weighted at 18 percent of a facility's Clinical Measure Domain score. We are not proposing any further changes to the weighting for the remaining clinical measures and measure topics within the Clinical Measure Domain because the previously finalized weights are aligned with the criteria used to establish measure and measure topic weights. For these reasons, we proposed to use the following weighting system in Table 25 below for calculating a facility's Clinical Measure Domain score beginning in PY 2019.

TABLE 25: PROPOSED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2019 ESRD QIP

Measures/Measure Topics by Subdomain	**Measure Weight in the Clinical Measure Domain Score**
Safety Subdomain	**20%**
NHSN Bloodstream Infection measure	20%
Patient and Family Engagement/Care Coordination Subdomain	**30%**
ICH CAHPS measure	20%
SRR measure	10%
Clinical Care Subdomain	**50%**
STrR measure	7%
Dialysis Adequacy measure	18%
Vascular Access Type measure topic	18%
Hypercalcemia measure	7%

We sought comments on this proposal for weighting a facility's Clinical Measure Domain score. The comments and our responses are set forth below.

Comment: Two commenters supported the proposed measure weights within the clinical measure domain, as well as the proposal to weight the clinical measure domain at 90 percent of a facility's TPS.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS adopt three additional criteria for

determining appropriate weights for clinical measures within the clinical measure domain: (1) strength of evidence; (2) opportunity for improvement; and (3) clinical significance. The commenter also urged CMS to consult with the dialysis community when determining measure weights for the ESRD QIP.

Response: We agree with the commenter that these criteria encompass important considerations for evaluating measures. As stated in the CY 2015 ESRD PPS final rule with comment period (79 FR 66216), we take these criteria into account when making decisions about whether to adopt a measure in the ESRD QIP, because it would be inappropriate to adopt a measure that did not meet these criteria. Based on this understanding, we developed the three criterion discussed above for determining subdomain weighting within the Clinical Measure Domain (80 FR 37849). We believe these criteria account for the programmatic and operational concerns associated with scoring facilities on ESRD QIP while also reflecting our focus on improving the quality of care provided to ESRD patients. This analysis also implicitly includes a review of the strength of the clinical evidence supporting the measure, the opportunity for improvement among facilities, and the clinical significance of the measure because these issues are inextricably linked with an assessment of the measure's appropriateness and importance of measurement within the ESRD QIP. Because the additional criteria recommended by the commenter are used as a threshold for adopting ESRD QIP measures and are sub-components of the three previously finalized measure weighting criteria, we do not believe it would be appropriate to also factor these criteria into decisions about how much weight to give measures in a facility's Clinical Domain Score.

In addition, we currently give the industry an opportunity to provide input into the ESRD QIP measure and domain weights by proposing a weighting scheme each year and responding to

comments received.

Comment: One commenter expressed concerns with the proposed changes to the measure domain weights because ICH CAHPS clinical measure scores will be paired with a readmission penalty. The commenter stated that ICH CAHPS scores should stand alone in their own Patient Experience domain in order to avoid denigrating the importance of the patient feedback survey.

Response: As discussed in the CY 2015 ESRD PPS final rule with comment period, we combined the NQS goals of Care Coordination and Patient- and Caregiver-Centered Experience of care into one subdomain because we believe the two goals complement one another (79 FR 66214). "Care Coordination" refers to the NQS goal of promoting effective communication and coordination of care, while "Patient- and Caregiver- Centered Experience of Care" refers to the NQS goal of ensuring that each patient and family is engaged as a partner in care. In order to engage patients and families as partners, we believe that effective communication and coordination of care must coexist, and that patient and family engagement cannot occur independently of effective communication and care coordination. We therefore believe it is appropriate to combine measures of care coordination with those of patient and family engagement for the purposes of calculating a facility's clinical measure domain score.

In addition, we note that the SRR clinical measure receives substantially less weight than the ICH CAHPS clinical measure in the Patient and Family Engagement/Care Coordination subdomain. The SRR clinical measure is weighted at 10 percent of a facility's clinical measure domain score, whereas the ICH CAHPS clinical measure is weighted at 20 percent of a facility's clinical measure domain score, making the ICH CAHPS clinical measure's weight one of the largest components of a facility's clinical measure domain score. We therefore believe that including both of these measures in a single subdomain does not denigrate the importance of the

ICH CAHPS survey. We will continue to assess the appropriateness of this subdomain combination as the ICH CAHPS and SRR clinical measures are implemented in the ESRD QIP.

Comment: Two commenters did not support the proposed weighting of the clinical measure domain, arguing that the Vascular Access Type measures and Dialysis Adequacy measure should be weighted higher than the NHSN BSI clinical measure due to issues associated with implementing and scoring the NHSN BSI clinical measure. Additionally, they argued that because Vascular Access Type is the measure that is most actionable for facilities, it should be weighted greater than other measures.

Response: We thank the commenters for their recommendation regarding the weighting of the NHSN BSI clinical measure versus the Vascular Access Type measure topic and Dialysis Adequacy measure. However, we believe the technical issues associated with implementation of the NHSN BSI clinical measure noted by the commenters are now resolved and should not impact future payment years.

We do not believe that increasing the weight of the Vascular Access Type measure topic and Dialysis Adequacy clinical measure is appropriate at this time. As stated in the CY 2015 ESRD PPS final rule with comment period (79 FR 66215 through 66216), improving patient safety and reducing bloodstream infections in patients with ESRD is one of our highest priorities, and facilities have a good deal of experience with the NHSN BSI clinical measure. As a result, the NHSN BSI clinical measure is weighted at 20 percent of a facility's TPS, the highest allocation provided to measures within the clinical measure domain. However, we also note that the Vascular Access Type measure topic and Dialysis Adequacy clinical measure are also highly weighted within the Clinical Measure Domain at 18 percent of the Clinical Measure Domain each, to reflect the fact that facilities have substantially more experience with this measure and

measure topic than the other measures in the Clinical Care subdomain. We therefore believe that the weight assigned to these measures within the Clinical Measure Domain is appropriate for the PY 2019 ESRD QIP. We will continue to assess the appropriateness of this weighting allocation for future years of the Program.

Comment: Two commenters urged CMS to place more emphasis on safety in dialysis facilities by increasing the weight of the Safety Subdomain. One commenter requested that CMS assign greater weight to the Safety Subdomain because patient safety is more aligned with facility quality initiatives and can be more readily controlled by facility staff.

Response: We agree that improving patient safety is of the utmost importance in the ESRD community; however, this is only one of the criteria established for determining the weight of subdomains within the Clinical Measure Domain. The Safety Subdomain contains only one measure, the NHSN BSI clinical measure, and the NHSN BSI clinical measure is weighted at 20 percent of the Clinical Measure Domain score, which is the highest weighting allocation for a single measure under the Clinical Measure Domain. Reallocating weight from the Patient and Family Engagement/Care Coordination and Clinical Care subdomains to further increase the Safety subdomain's prominence in the Clinical Measure Domain is inappropriate because doing so would diminish the remaining measures' importance in facility score, and would not accurately reflect our measure weighting prioritization criteria. We therefore believe the Safety subdomain's current weight is appropriate at this time. We will continue to assess the appropriateness of this weighting allocation for future years of the program.

Comment: One commenter did not support weighting the ICH CAHPS clinical measure at 20 percent of the Clinical Measure Domain because of the burden it imposes on small facilities; the difficulty in implementing changes based on survey results before the next

semiannual survey is performed; and the survey fatigue it causes patients, which may in turn impact patient responses.

Response: While we understand that the ICH CAHPS survey may be burdensome for facilities, we believe that measuring patient experience can lead to quality improvement, which may in turn lead to better outcomes. In addition, the ICH CAHPS survey supports the National Quality Forum's strategy priorities of Effective Communication and Care Coordination and Person and Family-Centered Care, as well as the Institute of Medicine's six specific aims for improvement. Furthermore, we note that the case minimum for the ICH CAHPS clinical measure is 30 qualifying patients in the year preceding the performance period. This case minimum is much higher than the 11 qualifying patient minimum used for the majority of the ESRD QIP clinical measures. We believe these thresholds help to decrease the burden on small facilities by exempting from the measure those facilities that do not regularly treat enough qualifying patients, and further avoids unduly impacting small facilities' scores by also exempting otherwise eligible small facilities who do not receive enough completed surveys during the performance period.

Comment: One commenter supported the proposal for weighting the Clinical Measure Domain and the Total Performance Score.

Response: We thank the commenter for its support.

Comment: One commenter expressed concern that the Clinical Measure Domain weighting policy places smaller facilities at a disadvantage in scoring. The commenter noted that when a larger facility and a small facility provide comparable care to patients for a given measure but the small facility is not eligible to receive a score on that measure because it has too few patients, the reallocated measure weight may cause the small facility to lose points from its

TPS. The commenter requested that CMS calculate facilities' TPS based on the facilities' performance on the ESRD QIP measures, regardless of facility size and avoid adjusting measure weighting when the facility is not eligible for some measure due to low facility volume.

Response: We thank the commenter for sharing its concerns. However, we believe scoring facilities on measures for which they treat a very small number of patients (i.e., fewer than 11 qualifying patients) may raise greater concerns than reallocating measure weights, because the effect of a single outlier on facility measure scores increases as the patient census decreases. Therefore, while some small facilities may benefit from receiving a score based on performance for their small patient population, others may receive far lower measure scores that are not reflective of the quality of care provided to all patients at the facility. We therefore believe it is most appropriate to continue reallocating measure weights across the measures for which a facility is eligible to receive a score if a facility is not eligible to receive a score on one or more measures.

For these reasons, we are finalizing the weighting for the Clinical Measure Domain as proposed for the PY 2019 ESRD QIP.

ii. Weighting the Total Performance Score

We continue to believe that while the reporting measures are valuable, the clinical measures evaluate actual patient care and therefore justify a higher combined weight (78 FR 72217). We did not propose to change our policy, finalized in the CY 2015 ESRD PPS final rule (79 FR 66219), under which clinical measures will be weighted as finalized for the Clinical Domain score, and the Clinical Domain score will comprise 90 percent of a facility's TPS, with the reporting measures weighted equally to form the remaining 10 percent of a facility's TPS. We also did not propose any changes to the policy that facilities must be eligible to receive a

score on at least one reporting measure and at least one clinical measure to be eligible to receive a TPS, or the policy that a facility's TPS will be rounded to the nearest integer, with half of an integer being rounded up.

The comments and our responses are set forth below.

Comment: One commenter did not support weighting the Clinical Measure Domain at 90 percent of a facility's TPS and having reporting measures comprise the remaining 10 percent because it does not adequately incentivize reporting for the increasing number of reporting measures in the ESRD QIP. The commenter recommended that CMS weight the clinical and reporting measures at 80 percent and 20 percent of a facility's TPS, respectively.

Response: We thank the commenter for its suggestion, and agree that reporting is an important component of quality improvement efforts. We also acknowledge that weighting the reporting measures to comprise 10 percent of a facility's TPS results in each individual reporting measure carrying less weight in the facility's overall score; however, we disagree that this allocation does not adequately incentivize the reporting measures. We continue to believe that clinical measures should carry substantially more weight than reporting measures in a facility's TPS because clinical measures score providers and facilities based upon actual outcomes, providing a direct assessment of the quality of care a facility provides, relative to either the facility's past performance or standards of care nationwide. Reporting measures, on the other hand, create an incentive for facilities to monitor significant indicators of health and illness, help facilities become familiar with CMS data systems, and allow the ESRD QIP to collect the robust clinical data needed to establish performance standards for clinical measures. We do not believe that facilities are failing to report data for the ESRD QIP reporting measures based on the fact that their reporting measure scores will have less of an impact on their TPSs than their Clinical

Measure Domain scores. For example, for the Anemia Management and Mineral Metabolism reporting measures, the median of national facility performance is 10 points, meaning that the vast majority of facilities are reporting all required data under these measures. We therefore believe the current weighting scheme is appropriate. We will continue to evaluate the appropriateness of this weighting for future years of the ESRD QIP.

For these reasons, we are finalizing the total performance score weighting for the PY 2019 ESRD QIP.

7. Minimum Data for Scoring Measures for the PY 2019 ESRD QIP

Our policy is to score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period. With the exception of the Standardized Readmission Ratio, Standardized Transfusion Ratio, and ICH CAHPS clinical measures, a facility must treat at least 11 qualifying cases during the performance period in order to be scored on a clinical or reporting measure. A facility must have at least 11 index discharges to be eligible to receive a score on the SRR clinical measure and 10 patient-years at risk to be eligible to receive a score on the STrR clinical measure. In order to receive a score on the ICH CAHPS clinical measure, a facility must have treated at least 30 survey-eligible patients during the eligibility period and receive 30 completed surveys during the performance period. We did not propose to change these minimum data policies for the measures that we proposed to continue including in the PY 2019 ESRD QIP measure set.

For the proposed Dialysis Adequacy clinical measure, we proposed that facilities with at least 11 qualifying patients will receive a score on the measure. We believe that maintaining a case minimum of 11 for this measure adequately addresses both the privacy and reliability concerns previously discussed in the CY 2013 ESRD PPS final rule (77 FR 67510 through

67512), and aligns with the case minimum policy for the previously finalized clinical process measures.

For the proposed Ultrafiltration Rate and Full-Season Influenza reporting measures, we also proposed that facilities with at least 11 qualifying patients will receive a score on the measure. We believe that setting the case minimum at 11 for these reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly burden or penalize small facilities. We further believe that setting the case minimum at 11 is appropriate because this aligns with case minimum policy for the vast majority of the reporting measures in the ESRD QIP.

Under our current policy, we begin counting the number of months for which a facility is open on the first day of the month after the facility's CCN Open Date. Only facilities with a CCN Open Date before July 1, 2017 would be eligible to be scored on the Anemia Management, Mineral Metabolism, Pain Assessment and Follow-Up, Clinical Depression Screening and Follow-Up reporting measures, and only facilities with a CCN Open Date before January 1, 2017 would be eligible to be scored on the NHSN Bloodstream Infection clinical measure, ICH CAHPS clinical measure, and NHSN Healthcare Personnel (HCP) Influenza Vaccination reporting measure. Consistent with our policy regarding the NHSN HCP Influenza Vaccination reporting measure, we proposed that facilities with a CCN Open Date after January 1, 2017 would not be eligible to receive a score on the Full-Season Influenza Vaccination reporting measure because these facilities might have difficulty reporting the data by the proposed reporting deadline of May 15, 2017. We further proposed that, consistent with our CCN Open Date policy for other reporting measures, facilities with a CCN Open Date after July 1, 2017, would not be eligible to receive a score on the Ultrafiltration Rate reporting measure because of

the difficulties these facilities may face in meeting the requirements of this measure due to the short period of time left in the performance period. Table 26 displays the proposed patient minimum requirements for each of the measures, as well as the proposed CCN Open Dates after which a facility would not be eligible to receive a score on a reporting measure.

TABLE 26 – PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2019 ESRD QIP

Measure	**Minimum Data Requirements**	**CCN Open Date**	**Small Facility Adjuster**
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11 – 25 qualifying patients
Vascular Access Type: Catheter (Clinical)	11 qualifying patients	N/A	11 – 25 qualifying patients
Vascular Access Type: Fistula (Clinical)	11 qualifying patients	N/A	11 – 25 qualifying patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11 – 25 qualifying patients
NHSN Bloodstream Infection (Clinical)	11 qualifying patients	Before January 1, 2017	11 – 25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11 – 41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10 – 21 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before January 1, 2017	N/A
Anemia Management	11 qualifying	Before July 1, 2017	N/A

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
(Reporting)	patients		
Mineral Metabolism (Reporting)	11 qualifying patients	Before July 1, 2017	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before July 1, 2017	N/A
Pain Assessment and Follow-Up (Reporting)	11 qualifying patients	Before July 1, 2017	N/A
NHSN HCP Influenza Vaccination (Reporting)	N/A	Before January 1, 2017	N/A
Ultrafiltration Rate (Reporting)	11 qualifying patients	Before July 1, 2017	N/A
Full-Season Influenza Vaccination (Reporting)	11 qualifying patients	Before January 1, 2017	N/A

The comments and our responses are set forth below.

Comment: One commenter requested that CMS revert to the minimum data proposal for the Anemia Management and Mineral Metabolism reporting measure as finalized in the PY 2016 ESRD PPS final rule.

Response: In the CY 2015 ESRD PPS final rule with comment period, we finalized our policy to set the case minimum for the Anemia Management and Mineral Metabolism reporting measures at 11 qualifying patients for PY 2017 and future payment years (79 FR 66185). We continue to believe that this case minimum strikes the appropriate balance between the need to maximize data collection and the need to not unduly penalize small facilities that are unable, for legitimate reasons, to meet the reporting requirements previously established for these measures (78 FR 72197 through 72199 and 72220 through 72221).

Comment: One commenter acknowledged that the small number of pediatric ESRD patients often results in facilities not being scored on the pediatric dialysis adequacy measures, but noted that CMS' minimum sample size for the measures is based on CMS' policies related to

compliance with the HIPAA Privacy Regulations, not quality performance policies. Another commenter opposed the minimum data requirements for the proposed Dialysis Adequacy Measure because, if the individual measures are combined, facilities previously excluded for having too few patients, may now be included in the measure, potentially causing privacy concerns.

Response: Given the ESRD QIP's potential to encourage quality improvement, our goal is to ensure the full participation of as many facilities as possible in the program. While patient privacy concerns are one of a number of considerations we take into account when establishing case minimums for measures, we believe that ensuring measure and measure score reliability is vital for quality improvement. As a general principle, reliability improves with increasing case size; that is, the reliability of a measure or score describes numerically to what extent that measure or score assesses the actual differences in performance among facilities as opposed to the random variation within facilities (77 FR 67510). Our current policy is that a facility must treat at least 11 qualifying patients during the performance period in order to be scored on a clinical measure (77 FR 67510 through 67511). This case minimum of 11 patients ensures that the Dialysis Adequacy clinical measure scores meet our standards for measure reliability. We do not believe a case minimum of 11 for the Dialysis Adequacy clinical measure raises privacy concerns, because we do not intend to publish age- or modality-specific performance rates at this time. As a result, patients treated at a facility should not be individually identifiable within the facility's Dialysis Adequacy clinical measure score reflecting the care provided to all eligible patients at the facility.

Comment: One commenter recommended that CMS grant facilities that receive a CCN during the performance period a grace period of 90 days following receipt of their CCN before

being scored based on data reported to CROWNWeb because the CROWNWeb registration process is difficult for new users and may therefore hinder new facilities' ability to submit data by the deadlines established for the ESRD QIP. In the alternative, the commenter recommended granting new facilities an additional 90 days to submit their first three months' data in CROWNWeb in order to ensure the submitted data is correct.

Response: We appreciate the commenter's concerns about the difficulties new facilities face when meeting the requirements of the ESRD QIP. It is because of these concerns that facilities with CCN open dates after July 1 of the performance period are excluded from the reporting measures and are therefore not eligible to receive a TPS for that program year. However, we disagree that new facilities should be given an additional "grace period" of 90 days for data submission to CROWNWeb. First, we note that facilities can gain access to CROWNWeb in order to submit patient data in advance of receiving their CCN, and we encourage new facilities to contact their ESRD Network regarding this process while awaiting receipt of their CCN. In addition, the CROWNWeb system is not configured to allow ad hoc extensions or suspensions of clinical months for individual facilities. We also believe that financial incentives provide the strongest incentive to improve the quality of care provided to patients with ESRD. For these reasons, we do not believe providing new facilities with an extension of time to begin submitting data to CROWNWeb is appropriate at this time.

Comment: One commenter recommended that CMS determine facility eligibility for a given measure based on patient census for both clinical and reporting measures on a monthly basis rather than for the entire performance period.

Response: We believe that determining facility eligibility on a monthly basis rather than using the current methodology would have two negative impacts on the ESRD QIP and, by

extension, the ESRD population. First, determining eligibility on a monthly basis would likely reduce the number of facilities eligible to receive a score on a measure by excluding facilities that would receive scores under the current methodology. For example, monthly eligibility determinations would systematically exclude months in which facilities do not treat enough eligible patients, instead of basing eligibility for the measure on the total number of eligible patients treated throughout the performance period. Monthly eligibility determinations would also effectively exclude all patients treated at a facility during a month in which the facility is not eligible to receive a score from the ESRD QIP, which runs contrary to the ESRD QIP's goal of ensuring quality of care for all ESRD patients. Second, determining facility eligibility on a monthly basis would require extensive and complicated modifications to the current measure scoring methodologies in order to ensure measure and measure score reliability. For example, some clinical measures require multiple months of claims in order to score facility performance on the measure; it is unclear how the commenter's recommended methodology would account for months during that range in which the facility did not treat enough qualifying cases. In addition, for instances where a facility would only be eligible for a number of months during the performance period, as opposed to the entire performance period, the resulting measure score may inaccurately reflect the quality of care provided at the facility. For these reasons, we believe that determining facility eligibility using the entire performance period is the most appropriate policy for the ESRD QIP.

Comment: One commenter recommended that CMS implement a patient-month threshold for facility eligibility for the NHSN BSI clinical measure.

Response: Currently, eligibility for the NHSN BSI clinical measure is determined based on the number of qualifying patients treated during the performance period. We continue to

believe this threshold is appropriate for the NHSN BSI clinical measure because it aligns this measure with the remaining clinical measures in the ESRD QIP, and ensures that the measure captures a larger proportion of dialysis patients than it may otherwise capture.

Comment: One commenter supports the proposed minimum data for scoring measures.

Response: We thank the commenter for its support.

Comment: Two commenters recommended that CMS increase the minimum number of cases from 11 to 26 to avoid anomalous results and to align with the policies used by commercial and managed care value-based purchasing programs. One of the commenters noted that these plans rely upon a minimum of 26 cases and recommended that the ESRD QIP align its minimum data requirements with these plans.

Response: We recognize that measures using a case minimum of 11 could potentially be less reliable than measures using a case minimum of 26. However, we continue to believe that it is essential to score facilities with between 11 and 25 qualifying cases on the applicable ESRD QIP measures, because increasing the minimum number of cases to 26 would result in the exclusion of hundreds of facilities from the ESRD QIP. Based on data from CY 2013, applying a 26-patient case minimum to all the PY 2017 clinical measures would result in the exclusion of 562 facilities from the ESRD QIP, or 9.2 percent of facilities nationwide (79 FR 66185). Given the inherent tradeoff between a modest decline in measure reliability and including these facilities in the ESRD QIP, we believe that on balance it is more important to include these facilities. We also note that the ESRD QIP maintains the SFA in order to ensure that any error in measure rates due to a small number of cases will not adversely affect facility payment.

Comment: One commenter supported CMS's decision to exclude facilities with a CCN Open Date after January 1, 2017 for the Full-Season Influenza Vaccination reporting measure.

Response: We thank the commenter for its support. We note that, based on comments received, we have decided not to finalize the Full-Season Influenza Vaccination reporting measure at this time.

Comment: One commenter supported CMS' proposal to exclude facilities with a CCN Open Date after July 1, 2017 from scoring for the Ultrafiltration Rate reporting measure.

Response: We thank the commenter for its support. We note that, based on comments received, we have decided not to finalize the Ultrafiltration Rate reporting measure at this time.

For these reasons, we are finalizing the minimum data policies for PY 2019 as proposed, with the exception of the Ultrafiltration Rate and Full-Season Influenza Vaccination reporting measure minimum data policies, which we are not finalizing at this time.

8. Payment Reductions for the PY 2019 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. We proposed that, for the PY 2019 ESRD QIP, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if:

- It performed at the performance standard for each clinical measure; and
- It received the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2017 reporting measures.

We did not propose a policy regarding the inclusion of measures for which we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the performance period in the PY 2019 minimum TPS. We did not propose

such a policy because no measures in the proposed PY 2019 measure set meet this criterion. However, we stated that should we choose to adopt a clinical measure in future rulemaking without the baseline data required to calculate a performance standard before the beginning of the performance period, we will propose a criterion accounting for that measure in the minimum TPS for the applicable payment year at that time.

The PY 2017 program is the most recent year for which we will have calculated final measure scores before the beginning of the proposed performance period for PY 2019 (that is, CY 2017). Because we have not yet calculated final measure scores, we are unable to determine the 50th percentile of facility performance on the PY 2017 reporting measures. We will publish that value in the CY 2017 ESRD PPS final rule once we have calculated final measure scores for the PY 2017 program.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2014 ESRD PPS final rule (78 FR 72223 through 72224), we finalized a payment reduction scale for PY 2016 and future payment years: for every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction on its ESRD PPS payments for PY 2016 and future payment years, with a maximum reduction of 2.0 percent. We did not propose any changes to this policy for the PY 2019 ESRD QIP.

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate a proposed minimum TPS at this time. We will publish the minimum TPS, based on data from CY 2015 and the first part of CY 2016, in the CY 2017 ESRD PPS final rule.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Two commenters supported the proposed payment reductions for the PY 2019 ESRD QIP.

Response: We thank the commenters for their support.

For these reasons, we are finalizing the payment reduction policies for the PY 2019 ESRD QIP as proposed.

I. Future Achievement Threshold Policy under Consideration

Under our current methodology, we set performance standards, achievement thresholds, and benchmarks for the clinical measures at the 50th, 15th, and 90th percentiles, respectively, of national performance on the measure during the baseline period (77 FR 67500 through 67502). As we continue to refine the ESRD QIP's policies, we are evaluating different methods of ensuring that facilities strive for continuous improvement in their delivery of care to patients with ESRD. For future rulemaking, we are considering increasing the achievement threshold from the 15th percentile to the 25th percentile of national performance during the baseline period. We believe this increase in the achievement threshold will add additional incentives for facilities to improve performance, thereby improving patient outcomes and quality of care. We have analyzed the impact of this policy change on facility payment reductions using the same data used to calculate the PY 2018 minimum TPS. The full results of this analysis can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Achievement-Threshold-Analysis-using-PY-2015-Results.pdf.

We invited comment on this policy that we are considering for adoption in the ESRD QIP in the future. The comments and our responses are set forth below.

Comment: Many commenters expressed significant concerns with the future achievement threshold policy under consideration. Specifically, commenters are concerned that the increasing use of measures outside the dialysis facility's control, combined with a higher achievement threshold, will result in too many facilities being penalized. Additionally, one commenter described a need, within the ESRD community, to redistribute money currently retained by CMS through the PPS bundle and ESRD QIP payment reductions within the ESRD community to ensure that the quality of patient care improves continuously. One commenter also pointed out that there has been consistent improvement in the numerical values associated with the achievement threshold, suggesting that lower performers have plenty of motivation for improvement, argued that the current achievement threshold policy is already driving improvement among dialysis facilities across all measures, and requested that CMS publish the data used in consideration of inviting comment on this potential future policy proposal. One commenter also expressed concerns that with the new standardized ratio measures being included in the QIP, there may be unexpected effects in QIP scoring. Because decisions to admit patients and transfuse them are generally not made by the dialysis facility, the commenter argued, facilities have little ability to drive improvement or to control how their quality efforts affect patient outcomes. The commenter therefore argued that CMS should wait to see how the current QIP scoring affects those facilities before adding additional uncertainty for them by increasing the achievement threshold.

Response: We thank the commenters for sharing their concerns regarding a potential future policy proposal under consideration that would increase the achievement threshold from

the 15th percentile to the 25th percentile of national performance during the baseline period. We will take these comments into consideration as we further consider whether to propose to adopt a higher achievement threshold in the future.

J. Monitoring Access to Dialysis Facilities

In the CY 2015 ESRD PPS final rule, we finalized our commitment to conduct a study to determine the impact of adopting the Standardized Readmission Ratio (SRR) and Standardized Transfusion Ratio clinical measures on access to care, and stated that we would make further details about the study and its methodology available to the public for review (79 FR 66189). We stated that we intended to publish the methodology for this study in the second half of the year, and encouraged all interested parties to review this methodology and submit any comments using the process outlined on the web page.

We received comments on this issue. The comments and our responses are set forth below.

Comment: Many commenters supported CMS's intent to conduct a study on the impact of adopting the SRR and STrR clinical measures on patient access to care. One commenter recommended that CMS also evaluate the combined effects of socioeconomic status and patient demographics to determine if these attributes influence facility performance on those two measures. Several commenters recommended that CMS exclude these measures from the ESRD QIP until the access to care study results have been thoroughly reviewed and analyzed, or at the very least that CMS delay implementation of the measures until the results of the study are available.

Response: We thank the commenters for their support of the upcoming access to care study, and will take their recommendations regarding the structure and content of the study into

account as we continue to develop the study methodology. We note, however, that the purpose of this study is to assess the impact of the SRR and STrR clinical measures on access to care for dialysis patients. If these measures are removed from the ESRD QIP or suspended during the access to care study, it would be very difficult for the study to accurately assess their impact on admission practices. Therefore, we believe it is inappropriate to remove or suspend the SRR and STrR clinical measures while the access to care study is ongoing.

Comment: Several commenters supported CMS's efforts to evaluate the impact of the SRR and STrR measures on access to care. Commenters recommended that CMS evaluate the effectiveness of the SRR and STrR measures in measuring the actual care provided in dialysis facilities and commended CMS for allowing stakeholders to comment on the study methodology.

Response: We thank the commenters for their support.

We thank commenters for providing input regarding the Access to Care Study methodology, which we intend to publish prior to the end of CY 2015.

IV. Advancing Health Information Exchange

HHS has a number of initiatives designed to improve health and health care quality through the adoption of health information technology and nationwide health information exchange. As discussed in the August 2013 Statement "Principles and Strategies for Accelerating Health Information Exchange" (available at http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf), HHS believes that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to electronic health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health information technology (health IT) that facilitates the secure, efficient

and effective sharing and use of electronic health-related information when and where it is needed is an important tool for settings across the continuum of care, including ESRD facilities.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap" (Roadmap)(available at https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf). The Roadmap describes a shared strategy for achieving nationwide interoperability to enable a learning health system by 2024. In the near term, the Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use priority data domains to improve health care quality and outcomes by the end of 2017. The Roadmap also identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align federal, state, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for interoperability; (3) clarify and align federal and state privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability and address those that impede interoperability, in coordination with stakeholders.

In addition, ONC has released the draft version of the 2016 Interoperability Standards Advisory (available at https://www.healthit.gov/standards-advisory/2016), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these

"best available standards" into account as they implement interoperable health information exchange across the continuum of care.

We encourage stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures, and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce standards through relevant policies and programs.

V. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Requirements in Regulation Text

In sections II.B.1.d.ii, II.B.1.d.iii, II.B.3, and II.B.4 of this final rule, we made changes to regulatory text for the ESRD PPS in CY 2016. However, the changes that are being made do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, this final rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP

a. Wage Estimates

In previous rulemaking, we used the mean hourly wage of a registered nurse as the basis of the wage estimates for all collection of information calculations in the ESRD QIP (for example, 77 FR 67521). However, we believe that reporting data for the ESRD QIP measures can be accomplished by other administrative staff within the dialysis facility. The Bureau of Labor Statistics (the Bureau) is "the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy."[14] Acting as an independent agency, the Bureau provides objective information not only for the government, but also for the public. The Bureau's National Occupational Employment and Wage Estimate describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data.[15] Therefore, we believe it is reasonable assume these individuals would be tasked with submitting measure data to CROWNWeb rather than a Registered Nurse, whose duties are centered on providing and coordinating care for

14 http://www.bls.gov/bls/infohome.htm.
15 http://www.bls/gov/ooh/healthcare/medical-records-and-health-information-technicians.htm

patients.[16] The mean hourly wage of a Medical Records and Health Information Technician is $18.68 per hour.[17] Under OMB Circular 76-A, in calculating direct labor, agencies should not only include salaries and wages, but also "other entitlements" such as fringe benefits.[18] This Circular provides that the civilian position full fringe benefit cost factor is 36.25 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $25.45 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP.

We did not receive comments on this proposal, and are therefore finalizing the change in wage estimates as proposed.

b. Changes in Time Required to Submit Data Based on Proposed Reporting Requirements

In previous rulemaking, we estimated that data entry associated with the ESRD QIP took approximately 5 minutes per data element to complete (for example, 77 FR 67521). However, a large number of facilities now submit data using the batch submission process, which allows facilities to submit data extracted from their internal Electronic Health Records (EHRs) directly to CROWNWeb. Because the batch submission process can be automated with very little human intervention, we believe the overall time required to submit measure data using CROWNWeb is substantially less than previously estimated. We are therefore revising our estimate to be 2.5 minutes per data element submitted, a change of – 2.5 minutes, which takes into account the small percentage of data that is manually reported, as well as the human interventions required to modify batch submission files such that they meet CROWNWeb's internal data validation requirements.

We received comments on this section. The comments and our responses are set forth

16 http://www.bls.gov/ooh/healthcare/registered-nurses.htm.
17 http://www,bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.
18 http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.

below.

Comment: One commenter expressed concern about an under-estimate in the proposed estimated time to complete QIP data submission because they feel it does not properly account for the needs of smaller facilities without data extraction tools. The commenter explained that while larger facilities are able to utilize data extraction tools that minimize the time needed to submit data, smaller facilities without these capabilities must enter this data manually on a monthly basis. The commenter asserted that it takes an estimated 20-30 minutes per patient per month to enter this data for manual entry facilities.

Response: We thank the commenter for sharing their concerns regarding the proposed estimated time to complete QIP data submission. We understand that the amount of time required to enter data for a patient varies among facilities based on a number of factors, including the facility's size, staffing, and access to different technical support tools, and took these concerns into account when estimating the average time needed to complete data entry across all facilities. We also understand that, because this is an estimated time per element across all facilities, some facilities will require more time to complete the required data submission, and others will require less time. However, we believe an estimate of 2.5 minutes per element is appropriate for assessing the impact of ESRD QIP data submission requirements on facilities because it represents an average of the time required across all facilities, and therefore allows us to better assess burden on a national level.

For these reasons, we are finalizing the change in estimated time required to submit data for the ESRD QIP as proposed.

c. Data Validation Requirements for the PY 2018 ESRD QIP

Section III.F.4 in this final rule outlines our data validation proposals for PY 2018.

Specifically, we proposed to randomly sample records from 300 facilities as part of our continuing pilot data-validation program. Each sampled facility will be required to produce approximately 10 records, and the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities x 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the CROWNWeb data validation would be $19,088 (750 hours x $25.45/hour) total or $64 ($19,088 / 300 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request currently available for review and comment, OMB control number 0938-NEW.

Under the proposed continuation of the feasibility study for validating data reported to the NHSN Dialysis Event Module, we proposed to randomly select nine facilities to provide CMS with a quarterly list of all positive blood cultures drawn from their patients during the quarter, including any positive blood cultures collected on the day of, or the day following, a facility patient's admission to a hospital. A CMS contractor will review the lists to determine if dialysis events for the patients in question were accurately reported to the NHSN Dialysis Event Module. If we determine that additional medical records are needed to validate dialysis events, facilities will be required to provide those records within 60 days of a request for this information. We estimate fewer than ten respondents in a 12-month period; therefore, in

accordance with the implementing regulations of the PRA at 44 U.S.C. 3502(3)(A)(i), the burden associated with the aforementioned requirements is exempt.

d. Proposed Ultrafiltration Rate Reporting Measure

We proposed to include, beginning with the PY 2019 ESRD QIP, a reporting measure requiring facilities to report in CROWNWeb an ultrafiltration rate at least once per month for each qualifying patient. However, as discussed in section III.H.2.c.i above, and based on comments received, we decided not to finalize the Ultrafiltration Rate reporting measure at this time. Therefore, facilities will not be subject to additional collection of information requirements for this measure.

e. Proposed Full-Season Influenza Vaccination Reporting Measure

In the CY 2016 ESRD PPS proposed rule, we proposed to include, beginning with the PY 2019 ESRD QIP, a measure requiring facilities to report patient influenza vaccination status annually using the CROWNWeb system. However, as discussed in section III.H.2.c.ii above, based on comments received, we decided not to finalize the Full-Season Influenza Vaccination reporting measure at this time. Therefore, facilities will not be subject to additional collection of information requirements for this measure.

VI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of

the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as economically significant); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is not economically significant within the meaning of section 3(f)(1) of the Executive Order, since it does not meet the $100 million threshold. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact. We solicited comments on the regulatory impact analysis provided.

2. Statement of Need

This rule finalizes a number of routine updates for renal dialysis services and implements several policy changes to the ESRD PPS in CY 2016. The routine updates include: wage index values, wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Other policy changes include implementation of section 1881(b)(14)(F)(i)(I), as amended by section 217 (b)(2) of PAMA, which requires a 1.25 percent decrease to the payment update as discussed in section II.B.2. of this rule, the delay in payment for oral-only drugs under the ESRD PPS until January 1, 2025 as required by section 204 of ABLE, the implementation of a geographic facility adjustment paid to rural facilities, and the updated payment multipliers based upon the regression analysis discussed in section II.B.1.c. of this final rule. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2016.

This rule finalizes requirements for the ESRD QIP, including the adoption of a measure set for the PY 2019 program, as directed by section 1881(h) of the Act. Failure to finalize requirements for the PY 2019 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2018. In addition, finalizing requirements for the PY 2019 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

3. Overall Impact

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $10 million in payments to ESRD facilities in CY 2016, which includes the amount associated with updates to outlier threshold amounts, updates to the wage index, changes in the CBSA delineations, changes in the labor-related share, update to the payment rate and changes involved with the refinement.

For PY 2018, we anticipate that the new burdens associated with the collection of information requirements will be approximately $19 thousand, totaling an overall impact of approximately $11.8 million as a result of the PY 2018 ESRD QIP.[19] For PY 2019, we estimate that the payment reductions will result in a total impact of approximately $15.5 million across all facilities.

B. Detailed Economic Analysis

1. CY 2016 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2015 to estimated payments in CY 2016. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2015 and CY 2016 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used the June 2015 update of CY 2014 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS**.** We updated the 2014 claims to 2015 and 2016 using various updates. The updates to the ESRD PPS base rate are described in section II.B.2.d.of this final rule. Table 27 shows the impact of the estimated CY 2016 ESRD payments compared to estimated payments to ESRD facilities in CY 2015.

19 We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The previously finalized aggregate impact of $11.8 million reflects the PY 2018 estimated payment reductions and the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure.

TABLE 27: IMPACT OF FINAL CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2016 FINAL RULE

Impact of Final Changes in Payments to ESRD Facilities for CY 2016 ESRD Final Rule
[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility Type	Number of Facilities A	Number of Treatments (in millions) B	Effect of 2016 Changes in Outlier Policy C	Effect of 2016 Changes in Wage Indexes, CBSA designations and Labor Share D	Effect of 2016 Changes in payment rate update E	Effect of 2016 Final Refinement Changes to Payment Rate F	Effect of Total 2016 Final Changes (Refinement and Routine Updates to the Payment Rate) G
All Facilities	6,374	44.5	0.0%	0.0%	0.15%	0.0%	0.2%
Type							
Freestanding	5,919	41.9	0.0%	0.0%	0.15%	0.0%	0.2%
Hospital based	455	2.7	0.0%	0.1%	0.16%	-0.1%	0.2%
Ownership Type							
Large dialysis organization	4,446	31.5	0.0%	-0.1%	0.15%	0.1%	0.2%
Regional chain	957	6.8	0.0%	0.2%	0.15%	-0.3%	0.1%
Independent	594	4.0	0.0%	0.1%	0.15%	-0.1%	0.2%
Hospital based[1]	377	2.2	0.0%	0.0%	0.16%	0.3%	0.4%
Geographic Location							
Rural	1,259	6.6	0.0%	-1.2%	0.15%	0.9%	-0.1%
Urban	5,115	37.9	0.0%	0.2%	0.15%	-0.1%	0.2%
Census Region							
East North Central	1,049	6.5	0.0%	-0.2%	0.15%	0.2%	0.1%
East South Central	523	3.3	0.0%	-1.2%	0.15%	0.7%	-0.2%
Middle Atlantic	687	5.4	0.0%	0.8%	0.15%	-0.3%	0.7%
Mountain	365	2.2	0.0%	-0.3%	0.15%	-0.1%	-0.2%
New England	182	1.4	0.0%	0.9%	0.15%	-0.6%	0.5%
Pacific[2]	778	6.2	0.0%	1.7%	0.15%	-0.8%	1.1%
Puerto Rico and Virgin Islands	47	0.3	0.0%	-3.9%	0.15%	-0.2%	-3.8%
South Atlantic	1,414	10.3	0.0%	-0.5%	0.15%	0.3%	0.1%
West North Central	466	2.3	0.0%	-0.8%	0.15%	0.2%	-0.4%
West South Central	863	6.5	0.0%	-0.8%	0.15%	0.2%	-0.3%
Facility Size							
Less than 4,000 treatments[3]	1,416	3.4	0.0%	-0.3%	0.15%	0.4%	0.3%
4,000 to 9,999 treatments	2,346	12.2	0.0%	-0.4%	0.15%	0.0%	-0.1%
10,000 or more treatments	2,596	29.0	0.0%	0.2%	0.15%	-0.1%	0.3%
Unknown	16	0.0	0.0%	-0.3%	0.14%	0.0%	-0.1%
Percentage of Pediatric Patients							

Less than 2%	6,264	44.1	0.0%	0.0%	0.15%	0.0%	0.2%
Between 2% and19%	42	0.4	0.0%	0.1%	0.15%	0.3%	0.6%
Between 20% and 49%	13	0.0	0.0%	-0.1%	0.15%	0.6%	0.7%
More than 50%	55	0.1	-0.1%	-0.2%	0.15%	0.6%	0.5%

1. Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

2. Includes ESRD facilities located in the states in the Pacific region, including those located in Guam, American Samoa, and the Northern Mariana Islands.

3. Of the 1,416 ESRD facilities with less than 4,000 treatments, only 387 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low-volume facilities is a 6.9 percent increase in payments.

Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B.2.c.of this final rule is shown in column C. For CY 2016, the impact on all ESRD facilities as a result of the changes to the outlier payment policy will be a 0.0 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience no effect in their estimated CY 2016 payments as a result of the final outlier policy changes.

Column D shows the effect of the final CY 2016 wage indices, and the final year of the transitions for the implementation of both the new CBSA delineations and the labor-related share. Facilities located in the census region of Puerto Rico and the Virgin Islands would receive a 3.9 percent decrease in estimated payments in CY 2016. Since most of the facilities in this category are located in Puerto Rico, the decrease is primarily due to the change in the labor-related share. The other categories of types of facilities in the impact table show changes in estimated payments ranging from a 1.2 percent decrease to a 1.7 percent increase due to these final updates.

Column E shows the effect of the ESRD PPS payment rate update of 0.15 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2016 of 1.8 percent,

the 1.25 percent reduction as required by the section 1881(b)(14)(F)(i)(I) of the Act, and the MFP adjustment of 0.4 percent.

Column F shows the effect of the ESRD PPS refinement as discussed in section II.B.1. While the overall estimated impact of the refinement is 0.0 percent, the impact by categories ranges from a 0.8 percent decrease to a 0.9 percent increase.

Column G reflects the overall impact (that is, the effects of the final outlier policy changes, the final wage index, the effect of the change in CBSA delineations, the effect of the change in the labor-related share, the effect of the payment rate update, and the effect of the refinement). We expect that overall ESRD facilities will experience a 0.2 percent increase in estimated payments in 2016. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive a 3.8 percent decrease in their estimated payments in CY 2016. This larger decrease is primarily due to the negative impact of the change in the labor-related share. The other categories of types of facilities in the impact table show impacts ranging from a decrease of 0.4 percent to an increase of 1.1 percent in their 2016 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers, (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2016, we estimate that the final ESRD PPS will have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2016 will be approximately $9.6 billion. This estimate takes into account a

projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.4 percent in CY 2016.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 0.2 percent overall increase in the final ESRD PPS payment amounts in CY 2016, we estimate that there will be an increase in beneficiary co-insurance payments of 0.2 percent in CY 2016, which translates to approximately $0 million due to rounding.

e. Alternatives Considered

In section II.B.1.c.1. of this final rule, we finalized the updated payment multipliers for five age groups resulting from our regression analysis. In section II.B.2.d., we discuss and finalize a refinement budget-neutrality adjustment to account for the overall effects of the refinement. We are finalizing a 4 percent reduction (that is, a factor of .960319) to the ESRD PPS base rate to account for the additional dollars paid to facilities through the payment adjustments. We indicated that a significant portion of additional impact of the adjusters on the base rate arises from changes in the age adjustments. To mitigate some of the reduction, we considered reducing the number of age categories to three and providing a payment adjustment for only those patients in the youngest (18-44) and oldest (80+) age groups. We did not adopt this approach because while it would reduce the impact of the age adjustments on the base rate, it would also significantly reduce the explanatory power of the system and reduce payments to facilities with patients who are between the ages of 44 through 79, that is, approximately 75 percent of patients.

Also, in section II.B.1.d. of this final rule, we finalized the eligibility criteria for the low-

volume payment adjustment by excluding facilities of common ownership that are located within 5 road miles off one another. We considered a geographic proximity criterion of 10 road miles; however, this approach negatively impacted rural facilities which are important to ensure access to essential renal dialysis services.

2. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2019 ESRD QIP

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS. The methodology that we are using to determine a facility's TPS for PY 2019 is described in section III.H.8 of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2019 ESRD QIP would affect the facility's reimbursement rates in CY 2019.

We estimate that, of the total number of dialysis facilities (including those not receiving a TPS), approximately 23 percent or 1,405 of the facilities would likely receive a payment reduction in PY 2019. Facilities that do not receive a TPS are not eligible for a payment reduction.

In conducting our impact assessment, we have assumed that there will be an initial count of 6,264 dialysis facilities paid under the ESRD PPS. Table 28 shows the overall estimated distribution of payment reductions resulting from the PY 2019 ESRD QIP.

TABLE 28: ESTIMATED DISTRIBUTION OF PY 2019 ESRD QIP PAYMENT REDUCTIONS

Percentage Reduction	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
0	4629	76.72	4629	76.72
0.5	961	15.93	5590	92.64
1	362	6.00	5952	98.64
1.5	65	1.08	6017	99.72
2	17	0.28	6034	100.00

Note: This table excludes 230 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a Total Performance Score

To estimate whether or not a facility would receive a payment reduction in PY 2019, we scored each facility on achievement and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 29.

TABLE 29: DATA USED TO ESTIMATE PY 2019 ESRD QIP PAYMENT REDUCTIONS

Measure	**Period of Time Used to Calculate Achievement Thresholds, Performance Standards, Benchmarks, and Improvement Thresholds**	**Performance Period**
Vascular Access Type		
% Fistula	Jan 2013 – Dec 2013	Jan 2014 – Dec 2014
% Catheter	Jan 2013 – Dec 2013	Jan 2014 – Dec 2014
Dialysis Adequacy	Jan 2013 – Dec 2013	Jan 2014 – Dec 2014
Hypercalcemia	Jan 2013 – Dec 2013	Jan 2014 – Dec 2014
SRR	Jan 2013– Dec 2013	Jan 2014 – Dec 2014
STrR	Jan 2013– Dec 2013	Jan 2014 – Dec 2014
NHSN BSI	Jan 2014 – Dec 2014	Jan 2014 – Dec 2014

Clinical measure topic areas with less than 11 cases for a facility were not included in that facility's Total Performance Score. Each facility's Total Performance Score was compared to the estimated minimum Total Performance Score and the payment reduction table found in

section III.H.8 of this final rule. Facility reporting measure scores were estimated using available data from CY 2014. Facilities were required to have a score on at least one clinical and one reporting measure in order to receive a Total Performance Score.

To estimate the total payment reductions in PY 2019 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the one year period between January 2014 and December 2014 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: (Total ESRD payment in January 2014 through December 2014 times the estimated payment reduction percentage). For PY 2014, the total payment reduction for the 1,405 facilities estimated to receive a reduction is approximately $15.5 million ($15,470,309). As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $15.5 million in PY 2019, as a result of the CY 2016 ESRD PPS final rule with comment period.

Table 30 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2019. The table estimates the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the time periods used for these calculations will differ from those we are proposing to use for the PY 2019 ESRD QIP, the actual impact of the PY 2019 ESRD QIP may vary significantly from the values provided here.

TABLE 30: IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2019

	Number of Facilities	*Number of Treatments 2014 (in millions)*	*Number of Facilities with QIP Score*	*Number of Facilities Expected to Receive a Payment Reduction*	*Payment Reduction (percent change in total ESRD payments)*
All Facilities	6,264	40.0	6,023	1,313	-0.15%
Facility Type:					
Freestanding	5,812	37.7	5,625	1,215	-0.15%
Hospital-based	452	2.3	398	98	-0.23%
Ownership Type:					
Large Dialysis	4,380	28.5	4,271	870	-0.13%
Regional Chain	926	6.0	891	196	-0.15%
Independent	584	3.6	536	165	-0.26%
Hospital-based (non-chain)	374	1.9	325	82	-0.24%
Facility Size:					
Large Entities	5,306	34.5	5,162	1,066	-0.13%
Small Entities[1]	958	5.5	861	247	-0.25%
Rural Status:					
1) Yes	1,332	6.5	1,257	194	-0.10%
2) No	4,932	33.5	4,766	1,119	-0.16%
Census Region:					
Northeast	861	6.2	832	199	-0.17%
Midwest	1,490	7.9	1,392	336	-0.17%
South	2,744	18.1	2,658	602	-0.15%
West	1,112	7.5	1,088	150	-0.09%
US Territories[2]	57	0.4	53	26	-0.44%
Census Division:					
East North Central	1,036	5.8	966	272	-0.20%
East South Central	518	3.0	502	83	-0.11%
Middle Atlantic	680	4.9	662	168	-0.18%
Mountain	359	2.0	350	48	-0.08%
New England	182	1.3	170	31	-0.12%

	Number of Facilities	*Number of Treatments 2014 (in millions)*	*Number of Facilities with QIP Score*	*Number of Facilities Expected to Receive a Payment Reduction*	*Payment Reduction (percent change in total ESRD payments)*
Pacific	760	5.6	745	104	-0.09%
South Atlantic	1,386	9.3	1,340	352	-0.18%
West North Central	455	2.1	426	64	-0.09%
West South Central	841	5.8	816	167	-0.13%
US Territories[2]	47	0.3	46	24	-0.48%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,305	3.5	1,202	220	-0.15%
4,000-9,999 treatments	2,239	10.8	2,207	444	-0.13%
Over 10,000 treatments	2,514	25.3	2,484	612	-0.16%
Unknown	206	0.3	130	37	-0.29%

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3]Based on claims and CROWNWeb data through December 2014.

b. Alternatives Considered

In section III.G.2.c.ii of the CY 2016 ESRD PPS proposed rule, we proposed to adopt the Full-Season Influenza Vaccination reporting measure. Under this proposed measure, data on patient immunization status would be entered into CROWNWeb for each qualifying patient treated at the facility during the performance period. We considered proposing to collect patient immunization data using the CDC's Surveillance for Dialysis Patient Influenza Vaccination module within the NHSN; however, the proposed measure's data sources are administrative claims and "electronic clinical data" which the Measure Justification Form explains will be collected via CROWNWeb (MAP #XDEFM). Because the measure specifications reviewed by the Measure Applications Partnership do not include NHSN as a data source for this measure, we decided not to propose to use the NHSN system to collect patient-level influenza vaccination data for this measure at this time.

We ultimately decided to have facilities report data for this measure in CROWNWeb rather than using an alternative data source, for two main reasons. First, the data elements needed for this measure have already been developed in CROWNWeb and will appear in a new release soon. Second, facilities are already familiar with the use and functionality of CROWNWeb because they are using it to report data for other measures in the ESRD QIP, and we believe that familiarity with CROWNWeb will reduce the burden of reporting data for the Full Season Influenza reporting measure.

As discussed in section III.H.2.c.ii above, based on comments received, we decided not to finalize the Full-Season Influenza Vaccination reporting measure at this time.

C. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 31 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 31 Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS for CY 2016	
Category	**Transfers**
Annualized Monetized Transfers	$10 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$ 0 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2018[20]	
Category	**Transfers**
Annualized Monetized Transfers	$-11.8 million
Category	**Costs**
Annualized Monetized ESRD Provider Costs	$19 thousand
ESRD QIP for PY 2019	
Category	**Transfers**
Annualized Monetized Transfers	$-15.5 million
From Whom to Whom	Federal government to ESRD providers
Category	**Costs**
Annualized Monetized ESRD Provider Costs	N/A

VII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354) (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. Approximately 15 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $38.5 million in any 1 year. Individuals and States are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at http://www.sba.gov/content/small-business-size-standards (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 15 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 27. Using the definitions in this ownership category, we consider the 594 facilities that are independent and the 377 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates finalized in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 0.4 percent increase in payments for CY

2016. An independent facility (as defined by ownership type) is also estimated to receive a 0.2 percent increase in payments for CY 2016.

We estimate that of the 495 ESRD facilities expected to receive a payment reduction in the PY 2019 ESRD QIP, 84 are ESRD small entity facilities. We present these findings in Table 27 ("Estimated Distribution of PY 2019 ESRD QIP Payment Reductions") and Table 28 ("Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2019") above. We estimate that the payment reductions will average approximately $7,797 per facility across the 495 facilities receiving a payment reduction, and $7,509 for each small entity facility. Using our estimates of facility performance, we also estimated the impact of payment reductions on ESRD small entity facilities by comparing the total estimated payment reductions for 958 small entity facilities with the aggregate ESRD payments to all small entity facilities. We estimate that there are a total of 958 small entity facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.07 percent in PY 2019.

Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities. We solicited comment on the RFA analysis provided.

In addition, section 1102(b) of the Social Security Act (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. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding.

While there are 139 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 139 rural hospital-based dialysis facilities will experience an estimated 1.1 percent decrease in payments. As a result, this final rule is not estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

VIII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 is approximately $144 million. This final rule does not include any mandates that will impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $144 million.

IX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

X. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

XI. Files Available to the Public via the Internet

In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules were available in the **Federal Register**. However, the Addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these Addenda to the annual proposed and final rules will be available only through the Internet on the CMS Web site. The Addenda to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) rules are available at: http://www.cms.gov/ESRDPayment/PAY/list.asp. Readers who experience any problems accessing any of the Addenda to the proposed and final rules of the ESRD PPS that are posted on the CMS Web site identified above should contact Michelle Cruse at 410-786-7540.

List of Subjects in 42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C. 1395g; 42 U.S.C. 1395l(a), (i), and (n); 42 U.S.C. 1395x(v); 42 U.S.C. 1395hh; 42 U.S.C. 1395rr; 42 U.S.C. 1395tt; 42 U.S.C. 1395ww; sec. 124 of Pub. L. 106-113, 113 Stat. 1501A-332; sec. 3201 of Pub. L. 112-96, 126 Stat. 156; sec. 632 of Pub. L. 112-240, 126 Stat. 2354; sec. 217 of Pub. L. 113-93, 129 Stat. 1040; and sec. 204 of Pub. L. 113-295, 128 Stat. 4010.

2. Section 413.174 is amended by revising paragraph (f)(6) to read as follows:

§413.174 Prospective rates for hospital based and independent ESRD facilities.

* * * * *

(f) * * *

(6) Effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in §413.230 and separate payment will no longer be provided.

3. Section 413.232 is amended by—

a. Revising paragraph (c)(2).

b. Removing paragraph (d).

c. Redesignating paragraphs (e), (f), (g), and (h) as paragraphs (d), (e), (f), and (g)

respectively.

d. Revising newly redesignated paragraph (e).

e. In newly redesignated paragraph (g) introductory text, the reference “paragraph (f)” is removed and the reference “paragraph (e)” is added in its place.

f. In newly redesignated paragraph (g)(1), the reference “paragraph (f)” is removed and the reference “paragraph (e)” is added in its place.

The revision reads as follows:

§413.232 Low-volume adjustment.

* * * * *

(c) * * *

(2) Five (5) miles or less from the ESRD facility in question.

* * * * *

(e) Except as provided in paragraph (f) of this section, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor that the facility meets all the criteria established in this section, except that, for calendar year 2012, the attestation must be provided by January 3, 2012, for calendar year 2015, the attestation must be provided by December 31, 2014, and for calendar year 2016, the attestation must be provided by December 31, 2015.

* * * * *

4. Add §413.233 to read as follows:

§413.233 Rural facility adjustment.

CMS adjusts the base rate for facilities in rural areas, as defined in §413.231(b)(2).

5. Add §413.234 to read as follows:

§413.234. Drug designation process.

(a) Definitions. For purposes of this section, the following definitions apply:

ESRD PPS functional category. A distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

New injectable or intravenous product. An injectable or intravenous product that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, assigned a Healthcare Common Procedure Coding System code, and designated by CMS as a renal dialysis service under §413.171.

Oral-only drug. A drug or biological with no injectable equivalent or other form of administration other than an oral form.

(b) Drug designation process. Effective January 1, 2016, new injectable or intravenous products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new injectable or intravenous product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product is considered included in the ESRD PPS bundled payment and no separate payment is available.

(2) If the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or intravenous product is used to treat or manage;

(ii) The new injectable or intravenous product is paid for using the transitional drug add-on payment adjustment described in paragraph (c) of this section; and

(iii) The new injectable or intravenous product is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

(c) Transitional drug add-on payment adjustment. (1) A new injectable or intravenous product that is not considered included in the ESRD PPS base rate is paid for using a transitional drug add-on payment adjustment, which is based on pricing methodologies under section 1847A of the Social Security Act.

(2) The transitional drug add-on payment adjustment is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product is available, but not for less than two years.

(3) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

(d) Oral-only drug determination. An oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration.

6. Section 413.237 is amended by revising paragraph (a)(1)(iv) to read as follows:

§413.237 Outliers.

(a) * * *

(1) * * *

(iv) Renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRD-related oral-only drugs effective January 1, 2025.

* * * * *

Dated: October 26, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 27, 2015.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2015-27928 Filed: 10/29/2015 4:15 pm; Publication Date: 11/6/2015]