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42 CFR Part 413

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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 413**

[CMS-1628-P]

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:** Proposed rule.

**SUMMARY:** This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2016. The proposals in this rule are necessary to ensure that ESRD facilities receive accurate Medicare payment amounts for furnishing outpatient maintenance dialysis treatments during calendar year 2016. This rule also proposes to set forth requirements for the ESRD Quality Incentive Program (QIP) for CY 2016. In an effort to incentivize ongoing quality improvement among eligible providers, the ESRD QIP proposes to establish and revise requirements for quality reporting and measurement, including the inclusion of new quality measures for payment year (PY) 2019 and beyond and updates to programmatic policies for the PY 2017 and PY 2018 ESRD QIP.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. E.S.T. on August 25, 2015.

**ADDRESSES:** In commenting, please refer to file code CMS-1628-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1628-P, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the

following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1628-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1810.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Frilling, (410) 786-4507, for issues related to the ESRD PPS, refinement of the case-mix payment adjustments, drug designation process, delay of payment for oral-only drugs and biologicals, Part B payment for self-administered drugs, and reporting of medical director fees on the cost report.

Michelle Cruse, (410) 786-7540, for issues related to the ESRD PPS, refinement of the facility-level payment adjustments, and policy clarifications.

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: Inspection of Public Comments:** All comments received before the close of the comment period are available for

viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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**Addenda Are Only Available Through the Internet on the CMS Web site**

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.

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### Acronyms

Because of the many terms to which we refer by acronym in this proposed 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  
 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  
 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  
 MFP Multifactor Productivity  
 NHSN National Healthcare Safety Network  
 NQF National Quality Forum  
 NQS National Quality Strategy  
 MFP Multifactor Productivity  
 MIPPA Medicare Improvements for Patients and Providers Act of 2008  
 MLR Minimum Lifetime Requirement  
 MSA Metropolitan statistical areas  
 NAMES National Association of Medical Equipment Suppliers  
 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 System  
 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 ESRD PPS, a case-mix adjusted bundled prospective payment system for renal dialysis services furnished by ESRD facilities. This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (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) (Pub. L. 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 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 of the Department of Health and Human Services (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 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. 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. 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 proposes 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. We are proposing to revise 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 and proposing to remove two comorbidity 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, we are also proposing revisions to the other ESRD PPS payment adjustments and a new adjustment based on that regression

analysis. In particular, we are proposing new patient and facility-level adjustment factors. We are also proposing to add an adjustment for rural ESRD facilities. Finally, we are proposing to revise the geographic proximity eligibility criterion for the low-volume payment adjustment (LVPA) and to remove grandfathering from the criteria for the adjustment.

- *Drug designation process:* In accordance with section 217(c) of PAMA, we are proposing a drug designation process for determining when: (1) a product would no longer be considered an oral-only drug and (2) including new injectable and intravenous renal dialysis service drugs and biologicals in the bundled payment under the ESRD PPS.

- *Update to the ESRD PPS base rate for CY 2016:* The proposed CY 2016 ESRD PPS base rate is \$230.20. 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 (1.000332), and a refinement budget-neutrality adjustment factor (0.959703), so that total projected PPS payments in CY 2016 are equal to what the payments would have been in CY 2016 had we not implemented the refinement. The proposed CY 2016 ESRD PPS base rate is  $\$230.20 (\$239.43 \times 1.0015 \times 1.000332 \times 0.959703 = \$230.20)$ .

- *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 are not proposing any changes to the application of the wage index floor and we propose to continue to apply the current wage index floor (0.400) to areas with wage index values below the floor.

- *Update to the outlier policy:* Consistent with our proposal to annually update the outlier policy using the most current data, we are proposing to update 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 would decrease from \$54.35 to \$49.99 and the MAP amount would decrease from \$43.57 to \$37.82, as compared to CY 2015 values. For adult beneficiaries, the fixed-dollar loss amount would decrease from \$86.19 to \$85.66 and the MAP amount would decrease from \$51.29 to \$48.15.

The 1 percent target for outlier payments was not achieved in CY 2014. 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 percent outlier percentage.

#### 2. ESRD QIP

This rule proposes to set 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 proposing 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—on the grounds that a more broadly applicable measure for the topic has become available. We are proposing to replace these measures with a single comprehensive Dialysis Adequacy clinical measure. Additionally, we are proposing to adopt two new reporting measures: (1) The Ultrafiltration Rate reporting measure and (2) the Full-Season Influenza Vaccination reporting measure.

- *Reinstating the In-Center Hemodialysis Consumer Assessment of Healthcare Providers (ICH CAHPS) Attestation:* Beginning with PY 2017, we are proposing to reinstate 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 would 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 proposing to revise the Small Facility Adjuster (SFA). We have developed an equation for determining the SFA that does not rely upon a pooled within-facility standard error, but nonetheless 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 VII of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

#### 1. Impacts of the Proposed ESRD PPS

The impact chart in section VII.B.1.a of this proposed 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 0.3 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.5 percent increase in payments compared with freestanding facilities with an estimated 0.2 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately \$20 million from CY 2015 to CY 2016. This reflects a \$10 million increase from the payment rate update and a \$10 million increase due to the updates to the outlier threshold amounts. As a result of the projected 0.3 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 0.3 percent in CY 2016, which translates to approximately \$10 million.

#### 2. Impacts of the Proposed ESRD QIP

The overall economic impact of the ESRD QIP is an estimated \$11.8 million in PY 2018 and \$14.6 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.<sup>1</sup> In PY 2019, we expect the total payment reductions to be approximately \$3.8 million, and the costs associated with the collection of information requirements for the proposed Ultrafiltration Rate and Full-Season Influenza Vaccination reporting measures to be approximately \$10.7 million for all ESRD facilities.

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

<sup>1</sup> 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.

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

### A. Background

#### 1. Statutory Background

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) 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. 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. 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 our other payment policies are included in regulations at 42 CFR

subpart H. 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).

### 3. 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 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. Specifically, in that rule, we finalized the following:

- *Update to the ESRD PPS base rate for CY 2015.* An ESRD PPS base rate of \$239.43 per treatment for renal dialysis

services. This amount reflected a 0.0 percent update to the payment rate as required by section 1881(b)(14)(F)(i) of the Act, as amended by section 217(b)(2) of PAMA, and the application of the wage index budget-neutrality adjustment factor of 1.001729.

- *Rebasing and revision of the end-stage renal disease bundled market basket.* For CY 2015, we rebased and revised the end-stage renal disease bundled (ESRDB) market basket, which entailed an update to the base year of the ESRDB market basket from 2008 to 2012. The base year update resulted in a shift in relative costs from prescription drugs to compensation. Additionally, we changed the price measure for pharmaceuticals from a more general index Producer Price Index (PPI) Pharmaceuticals for Human Use, Prescription) to a blend of two indices, (78 percent PPI Biological Products, Human Use and 22 percent PPI Vitamin, Nutrient, and Hematinic Preparations). The revision also refined the price measure used for compensation costs to better reflect the occupational mix in the ESRD setting. As a result of the update to the cost weights from 2008 to 2012, the labor-related share increased by about 9 percent.

- *Labor-Related Share.* As a result of the ESRDB market basket rebasing and revision, described above, the CY 2015 labor-related share was finalized at 50.673 percent. This change to the labor-related share had a significant impact on payments for certain ESRD facilities located in low wage areas. Therefore, we implemented the labor-related share of 50.673 with a 2-year transition for all facilities. The labor-related share for CY 2015 was 46.205.

- *Outlier Policy.* For CY 2015, we used CY 2013 claims data to update the outlier services' fixed-dollar loss and Medicare Allowable Payment (MAP) amounts. As a result, we updated the fixed-dollar loss amount for pediatric patients from \$54.01 to \$54.35, and increased the MAP amount from \$40.49 to \$43.57. For adult patients, we updated the fixed-dollar loss amount from \$98.67 to \$86.19 and increased the MAP amount from \$50.25 to \$51.29.

- *Wage Index.* We adjusted wage indices using the most current hospital wage data available for the areas in which ESRD facilities are located. For CY 2015, we implemented the new core-based statistical area (CBSA) delineations, as described in the February 28, 2013 OMB Bulletin No. 13-01, for all ESRD facilities with a 2-year transition (79 FR 66136 through 66142). In addition, we continued our policy for the gradual phase-out of the wage index floor and reduced the wage

index floor value to 0.40, as finalized in our CY 2014 ESRD PPS final rule (78 FR 72173 through 72174).

- *Timing of the Implementation of ICD-10.* Section 212 of PAMA provides that the Secretary may not adopt ICD-10-CM 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). We finalized a policy that the ESRD PPS will continue to use ICD-9-CM through September 30, 2015, and will require the use of ICD-10-CM beginning October 1, 2015 for purposes of reporting the co-morbidity payment adjustments. For CY 2015, we corrected several typographical errors and omissions in the ICD-9-CM to ICD-10-CM crosswalk tables that may be viewed in the CY 2015 ESRD PPS final rule at 79 FR 66155 through 66159.

- *Low-Volume Payment Adjustment.* We clarified the eligibility criteria for the low-volume payment adjustment (LVPA) and amended the supporting regulations in the Code of Federal Regulations (CFR).

- *Payment for Oral-only Drugs under the ESRD PPS.* Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not implement the policy under section 42 CFR 413.174(f)(6) (relating to oral-only ESRD-related drugs in the ESRD prospective payment system), prior to January 1, 2024. Accordingly, we amended the dates in 42 CFR 413.174(f)(6) and 42 CFR 413.237(a)(1)(iv) from January 1, 2016 to January 1, 2024.

### B. Provisions of the Proposed Rule

#### 1. Analysis and Proposed 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), we published our proposed ESRD PPS design and implementation strategy in the **Federal Register** on September 29, 2009 (74 FR 49922). We received over 1400 comments from dialysis facilities, Medicare beneficiaries, physician groups, and other stakeholders in response to our proposals. In consideration of these comments we finalized the case mix and facility-level adjustments for the ESRD PPS in our CY 2011 ESRD PPS final rule (75 FR 49030). For a complete discussion of public comments and our 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 (CY 2006 through 2008).

Section 632(c) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 11-240) requires the Secretary, by not 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. While section 632(c) of ATRA only requires us to analyze and make appropriate revisions to the case-mix payment adjustments, we believe that because we are performing a regression analysis that updates all of the payment multipliers with updated data we should also update the low-volume payment adjustment. Also, as discussed in section II.B.1.d.iii, we analyzed rural areas as a payment variable in our regression analysis and are proposing to implement a new adjustment for this facility characteristic.

For purposes of analyzing and proposing revisions to the payment adjusters included in this proposed rule,

we have updated the two-equation methodology using CY 2012 and 2013 Medicare cost report and claims data. These are the latest available cost reports and claims given the time necessary for the preparation of this proposed rule. The decision to use those 2 years for this proposed rule is because 2011 was the first year under the new bundled payment system. In addition, the FDA "black box" warning for Erythropoiesis-Stimulating Agents (ESA) was issued during 2011. These two factors may have been associated with changing practice patterns since 2011. Updating the regression analysis using the most recent claims and cost report data allows the proposed case-mix adjustment model to reflect practice patterns that have prevailed under the incentives of the expanded bundled payment system.

In this rule we propose to reduce the number of comorbidities to which payment adjusters apply and add an adjustment for rural facilities. Our rationale for proposing to eliminate two of the comorbidities for which we will make payment adjustments is discussed in section II.B.1.c.i.4 of this proposed rule. The measures of resource use, specified as the dependent variables for developing the payment model in each of the two equations, are also explained below.

##### ii. Dependent Variables

###### (1) Average Cost per Treatment for Composite Rate Services

For purposes of this proposed rule, we measured resource use, including time on a dialysis machine for the maintenance dialysis services included in the current bundle of composite rate services, using only ESRD facility data obtained from the Medicare cost reports for independent ESRD facilities and hospital-based ESRD facilities. 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 13A, 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 be consistent with existing methods of adjusting for case-mix, 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 outlier 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 (RTC), *A Design for a Bundled End Stage Renal Disease Prospective Payment System*. This document is available on the CMS Web site 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 this 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 independent), were specifically included to obtain more 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 independent 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.

#### c. Analysis and Revision of the Payment Adjustments

As required by section 632(c) of ATRA, we have analyzed and are proposing revisions to the following case mix payment adjustments. As explained above, because we are conducting a regression analysis of all of the costs associated with furnishing renal dialysis services, we are also proposing revisions to the facility-level adjustment for low-volume facilities.

#### 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 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 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 proposed 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.

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. We believe that the regression analysis we 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. The CY 2016 proposed payment multipliers presented below in Table 1 and in Table 4 in section II.B.1.f.i of this proposed rule are reflective of the regression analysis based upon CY 2012–2013 Medicare cost reports and claims data.

TABLE 1—CY 2016 PROPOSED PAYMENT MULTIPLIERS FOR AGE

Age	Current payment multipliers	Proposed payment multipliers
18–44 .....	1.171	1.257
45–59 .....	1.013	1.068
60–69 .....	1.000	1.070
70–79 .....	1.011	1.000
80+ .....	1.016	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<sup>2</sup>) for malnourished patients were

independent variables in the regression analysis that predicted variations in payments for renal dialysis services and 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, 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 this proposed rule, we analyzed both BSA and low BMI (<18.5kg/m<sup>2</sup>) 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 1.020, which implies a 2.0 percent elevated cost for every 0.1 m<sup>2</sup> 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<sup>0.425</sup> \* Height<sup>0.725</sup> \* 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<sup>2</sup>).

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, we are proposing to update the BSA Medicare national average from 1.87m<sup>2</sup> to 1.90 m<sup>2</sup> 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<sup>2</sup> 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 1.90m<sup>2</sup>, we propose 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 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<sup>2</sup>. 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 this proposed rule, we continue to find low BMI to be a strong predictor of cost variation among ESRD patients. The payment adjustment would be 1.017 as indicated in Table 4 in section II.B.1.f.i of this proposed rule, reflective of the regression analysis based upon CY 2012-2013 Medicare cost report and claims data.

#### (3) 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 499090), 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 this proposed rule, we find that the onset of dialysis continues to be a strong predictor of cost variation among ESRD patients. The updated payment adjustment would be 1.327 as indicated in Table 4 in section II.B.1.f.i of this proposed rule.

#### (4) 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 adjusters 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 adjusters: 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 for 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, 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 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 2 below, effective January 1, 2011.

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

Acute comorbidity category	Current payment multiplier	Proposed payment multiplier
Pericarditis .....	1.114	1.040
Bacterial Pneumonia .....	1.135	.....
Gastrointestinal Tract Bleeding w/Hemorrhage	1.183	1.082

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. Of the three acute comorbidity categories, we were unable to corroborate the diagnoses of bacterial pneumonia on ESRD facility claims with the presence of a diagnosis on claims from another Medicare setting because of significant under-reporting of bacterial pneumonia in these settings.

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 treatment protocols where many physicians and Medicare 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 adjusters continue to be strong predictors of cost variation among ESRD patients based on the regression analysis conducted for this proposed rule. 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. In consideration of stakeholder concerns about the burden associated with meeting the documentation requirements for bacterial pneumonia, however, we are proposing to eliminate the case-mix payment adjustment for the comorbidity category of bacterial pneumonia beginning in CY 2016. 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 an X-ray or sputum culture.

Based upon the regression analysis of CY 2012 through 2013 Medicare claims and cost report data, where comorbidities are measured only on 72x claims, the updated payment adjustment for pericarditis would be 1.040 and the adjustment for gastrointestinal tract bleeding with hemorrhage would be 1.082 as indicated in Table 4 in section II.B.1.f.i of this proposed rule.

**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 adjusters 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	Current payment multiplier	Proposed payment multiplier
Hereditary Hemolytic or Sickle Cell Anemias .....	1.072	1.192
Myelodysplastic Syndrome .....	1.099	1.095
Monoclonal Gammopathy .....	1.024	—

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 bill type 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 comorbid payment adjustment to apply, Medicare requires a positive serum test and a bone marrow biopsy test. We believe that billing inconsistency may result from poor compliance with these payment policy guidelines. 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 therefore forgo the payment adjustment all together.

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 for this proposed rule, using CY 2013 ESRD PPS claims and cost report data, we find that all of the chronic comorbid payment adjusters continue to be strong predictors of cost variation among ESRD patients and accordingly, we will 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, we are proposing to eliminate the case mix payment adjustment for the comorbid condition of monoclonal gammopathy

beginning in CY 2016. We no longer believe that it is appropriate to require the patient to submit to an invasive and painful procedure in order to make a payment adjustment to their ESRD facility. 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 as indicated in Table 4 in section II.B.1.f.i of this proposed rule. These adjustment amounts reflect the regression analysis based upon CY 2012 and 2013 Medicare claims data.

**d. Proposed 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 this proposed rule, 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 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. The regression analysis indicates a payment multiplier of 1.239 percent as indicated in Table 4 in section II.B.1.f.i of this proposed rule. Accordingly, we propose a new 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. 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 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) completed 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 as discussed in section II.B.1.a of this proposed rule, we reviewed the LVPA eligibility criteria and are proposing 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.

We are proposing 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 propose 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 are soliciting 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.

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 is the best data available. The CY 2014 cost reports will not be available until later this year. 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 may not match the facilities currently receiving the LVPA because we are unable to analyze 2014 cost reports of LVPA facilities at this 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 based on 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 and 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 are proposing 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 facilities 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 propose 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 are soliciting comment 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 are considering whether a transition would be appropriate and are requesting 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 areas 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 this 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. Accordingly, we propose a payment multiplier of 1.008 as indicated in Table 4 in section II.B.1.f.i of this proposed rule. This 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 define 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 propose to add a new § 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. We believe that 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 because measure. We believe that while the magnitude of the payment multiplier is small, rural facilities would still benefit from the adjustment and, therefore, we propose a 1.008 facility-level payment multiplier under the ESRD PPS for rural areas. We solicit 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://medpac.gov/documents-reports>. 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 this 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 in this rule, 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 outside 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 Web site: <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 are soliciting comments on establishing a larger payment adjustment outside of the regression analysis. We note 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 are soliciting 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.

e. Proposed 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 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 PD or HD. While the composite rate Medicare Allowable Payment (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 (\$48.09 versus \$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 purposes of regression analysis, we are not proposing any changes to the formula used to establish the pediatric payment multipliers and will continue to apply the computations of  $MultEB = P * C * (WCR + WSB * MultSB)$ , 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 CY 2011 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 reflect a proposed 8.21 percent increase to account for the overall difference in average payments per treatment for pediatric patients. The proposed updated pediatric SB and EB multipliers are shown below in Table 5.

f. Proposed Refinement Payment Multipliers

i. Proposed Adult Case-Mix and Facility-Level Payment Adjustments

TABLE 4—CY 2016 PROPOSED ADULT CASE-MIX AND FACILITY-LEVEL PAYMENT ADJUSTMENTS

	PY2011 Final Rule (based on 2006–2008 data)		PY2016 NPRM (based on 2012–2013 data)			
	% of Medicare dialysis treatments on average	Expanded bundle payment multiplier	% of Medicare dialysis treatments on average	Composite rate multipliers based on Freestanding and Hospital-based facilities	Separately billable multipliers	Expanded bundle payment multiplier
Age:						
18–44 .....	13.5	1.171	12.8	1.308	1.044	1.257
45–59 .....	26.8	1.013	27.8	1.084	1.000	1.068
60–69 .....	23.8	1.000	25.8	1.086	1.005	1.070
70–79 .....	22.9	1.011	21.1	1.000	1.000	1.000
80+ .....	13.0	1.016	12.4	1.145	0.961	1.109
Body surface area (per 0.1 m <sup>2</sup> ) <sup>3</sup> .....		1.020		1.039	1.000	1.032
Underweight (BMI < 18.5) .....	4.0	1.025	3.3	1.000	1.090	1.017
Time since onset of renal dialysis < 4 months .....	4.8	1.510	4.0	1.307	1.409	1.327
Facility low volume status .....	1.8	1.189	1.7	1.368	0.955	1.239
Comorbidities: <sup>4</sup>						
Pericarditis (acute) .....	0.4	1.114	0.1	1.000	1.209	1.040
Gastro-intestinal tract bleeding (acute) .....	1.1	1.183	0.5	1.000	1.426	1.082
Bacterial pneumonia (acute) .....	2.0	1.135				

TABLE 4—CY 2016 PROPOSED ADULT CASE-MIX AND FACILITY-LEVEL PAYMENT ADJUSTMENTS—Continued

	PY2011 Final Rule (based on 2006–2008 data)		PY2016 NPRM (based on 2012–2013 data)			
	% of Medicare dialysis treatments on average	Expanded bundle payment multiplier	% of Medicare dialysis treatments on average	Composite rate multipliers based on Freestanding and Hospital-based facilities	Separately billable multipliers	Expanded bundle payment multiplier
Hereditary hemolytic or sickle cell anemia (chronic) .....	2.0	1.072	0.1	1.000	1.999	1.192
Myelodysplastic syndrome (chronic) .....	1.6	1.099	0.3	1.000	1.494	1.095
Monoclonal gammopathy (chronic) .....	1.2	1.024	.....	.....	.....	.....
Rural .....	—	—	15.0	1.015	0.978	1.008

ii. Proposed Pediatric Case-Mix Payment Adjustments

TABLE 5—CY 2016 PROPOSED PEDIATRIC CASE-MIX PAYMENT ADJUSTMENTS

Cell	Patient characteristics		PY 2011 Final rule (based on 2006–2008 data)		PY 2016 NPRM (based on 2012 and 2013 data)		
	Age	Modality	Population %	Payment multiplier	Population %	Separately billable multiplier	Expanded bundle payment multiplier
1 .....	<13	PD .....	20.58	1.033	27.62	0.410	1.063
2 .....	<13	HD .....	16.57	1.219	19.23	1.406	1.306
3 .....	13–17	PD .....	18.20	1.067	20.19	0.569	1.102
4 .....	13–17	HD .....	44.66	1.277	32.96	1.494	1.327

2. Proposed 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 proposed 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. Proposed 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 propose to use the CY 2012-based ESRDB market basket as finalized and described in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136) to compute the CY 2016 ESRDB market basket increase factor and labor-related

share based on the best available data. Consistent with historical practice, we estimate the ESRDB market basket update based on IHS Global Insight (IGI), Inc.’s forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Using this methodology and the IGI forecast for the first quarter of 2015 of the CY 2012-based ESRDB market basket (with historical data through the fourth quarter of 2014), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2016 ESRDB market basket increase factor is 2.0 percent. As required by section 1881(b)(14)(F)(i)(I) of the Act as amended by section 217(b)(2) of PAMA, we must 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 propose 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) but was applied in CY 2015 using a 2-year transition.

### iii. Proposed Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute 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, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market basket and MFP. 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.

Beginning with the CY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the 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/MedicareProgramRatesStats/MarketBasketResearch.html*. Although we discuss the IGI changes to the MFP proxy series in this proposed rule, 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.

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. We invite public comment on these proposals.

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

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by the productivity adjustment. For CY 2016, section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, requires the Secretary to implement a 1.25 percentage point reduction to the ESRDB market basket increase factor in addition to the productivity adjustment.

As a result of these provisions, the proposed CY 2016 ESRD market basket increase is 0.15 percent. The proposed ESRDB market basket percentage increase factor for CY 2016 is 2.0 percent, which is based on the 1st quarter 2015 forecast of the CY 2012-based ESRDB market basket. This market basket percentage is then reduced by the 1.25 percent, as required by the section 1881(b)(14)(F)(i)(I). The market basket percentage increase is then further reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2016) of 0.6 percent, which is also based on IGI's 1st quarter 2015 forecast. As is our general practice, if more recent data is subsequently available (for example, a more recent estimate of the market basket or MFP adjustment), we will use such data to determine the CY 2016 market basket update and MFP adjustment in the CY 2016 ESRD PPS final rule.

### b. The Proposed 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.

For CY 2016, 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 proposed CY 2016 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed 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) (0.8699). 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 ESRD 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 are proposing 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 are not proposing 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 would be 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](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.” In the CY 2015 ESRD PPS final rule (79 FR 40226) and this proposed rule, 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.

Likewise, 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.

#### 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 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 issuance 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 would use the existing methodology for determining outlier payments by applying outlier services payment multipliers that resulted from the updated regression analyses performed for this proposed rule. The updated outlier services payment multipliers are represented by the updated separately billable payment multipliers presented in Table 4 for patients age 18 years and older and in Table 5 for patients age <18 years. We used these updated outlier services payment multipliers to calculate the predicted outlier service MAP amounts and projected outlier payments for CY 2016.

For CY 2016, we propose 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 propose 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 recognize 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 is reflective of relatively stable ESA use. We have included Table 6 (Total Medicare ESA Utilization in the ESRD Population) 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 <sup>1</sup>
<b>Total ESA Utilization</b>						
Epogen (×100,000) .....	2,083,893	2,075,217	1,655,778	1,319,383	1,262,186	1,143,405
Darbepoetin (×100,000) .....	533	496	379	280	242	291

TABLE 6—TOTAL MEDICARE ESA UTILIZATION IN THE ESRD POPULATION—Continued

	2009	2010	2011	2012	2013	2014 <sup>1</sup>
<b>ESA Utilization per Session</b>						
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

<sup>1</sup> 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 are not proposing any change to the methodology used to compute the MAP or fixed-dollar loss amounts. Rather, we will continue to update the outlier services MAP

amounts and fixed-dollar loss amounts to reflect the utilization of outlier services reported on 2014 claims. For this proposed rule, the outlier services MAP amounts and fixed dollar loss amounts were updated using the 2014 claims from the March 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 proposed estimates for this rule. The estimates for the proposed 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

	<i>Column I</i> Final outlier policy for CY 2015 (based on 2013 data price inflated to 2015)*		<i>Column II</i> Proposed 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	\$38.87	\$50.20
Adjustments:				
Standardization for outlier services .....	1.1145	0.9878	0.9929	0.9788
MIPPA reduction .....	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount .....	43.57	51.29	37.82	48.15
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold .....	54.35	86.19	49.99	85.66
Patient months qualifying for outlier payment .....	6.3%	6.3%	7.7%	6.4%

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; \$85.66) is slightly lower 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 \$48.15. For pediatric patients, the fixed dollar loss amount also fell, from \$54.35 to \$49.99. Likewise, the adjusted average MAP for outlier services fell from \$43.57 to \$37.82.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2016 will be 6.4 percent for adult patients and 7.7 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 continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

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, outlier payments represented approximately 0.9 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 policy. We note that recalibration of the fixed-dollar loss amounts in this proposed rule would 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 would 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.

We note 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. With regard to the suggestion that we eliminate the outlier adjustment altogether, we note that, 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 erythropoiesis stimulating agents 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 patient, we believe an outlier policy, even a small one, is an important payment adjustment to provide under the ESRD PPS. We are not proposing 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 proposed 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 percent of total ESRD PPS payments.

We understand the industry's frustration that payments under the outlier policy have not reached 1 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 percent outlier policy. We would not increase the base rate to account for years where outlier payments were less than 1 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 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. However, we have learned in our discussions with ESRD facilities that many facilities are not willing to 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 in sections II.C.1 and II.C.2 of this proposed rule, respectively.

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 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 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 productivity adjustment which is discussed in section II.B.2.a.iv of this proposed rule.

ii. Annual Payment Rate Update for CY 2016

We are proposing an ESRD PPS base rate for CY 2016 of \$230.20. This update reflects 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 is 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 CY 2016 is 0.6, thus 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 are not

proposing 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 is 1.000332.

*Refinement Budget-Neutrality*

*Adjustment Factor:* In order to implement the refinement in a budget-neutral manner, we are proposing to adjust the ESRD PPS base rate by a budget-neutrality adjustment factor so that total projected PPS payments in CY 2016 are equal to what the payments would have been in CY 2016 had we not implemented the refinement. 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, we are proposing a 4 percent reduction (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 impact of the adjusters on the base rate arises from changes in the age adjustments.

In summary, we are proposing 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.

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 are proposing 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, would 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. Stakeholder Comments From the CY 2015 ESRD PPS Proposed and Final Rules

In the CY 2015 ESRD PPS proposed rule (79 FR 40235), we sought stakeholder comments on the potential components of a drug designation process. While we did not directly address these comments in our CY 2015 final rule, we committed to considering the comments in formulating our drug designation process proposal in CY 2016. We were encouraged by the consensus among stakeholders regarding the significant and fundamental elements of a drug designation process and the recommendation that CMS rely upon the rulemaking process when considering any change to the ESRD PPS to account for new injectable and intravenous drugs or biologicals. We contemplated these comments in the development of the drug designation process proposed below.

We note that commenters largely emphasized the additional costs associated with furnishing new injectable and intravenous renal dialysis services and encouraged CMS to use the most recent year of data for pricing and utilization when adding new injectable drugs and biologicals to the bundled payment. Specifically, an industry association and many of its members offered a 7-principle drug designation process that included:

- A clear definition of what drugs and biologicals are in the ESRD PPS.
- A criterion related to the frequency with which a drug or biological may be used.
- A criterion for determining when drugs or biologicals are equivalent or interchangeable with existing products that are already in the bundle.
- Reliance upon rulemaking whenever making changes to the bundle.
- A transition for adding new drugs and biologicals to the ESRD bundle.
- Tracking of costs of new drugs and biologicals before adding them to the ESRD bundle.
- An increase in the bundled rate to cover the costs of providing such drugs and biologicals.

#### b. 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 our CY 2011 ESRD PPS final rule (75 FR 49030 through 49214) and codified our 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(3) 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 at 42 CFR 413.171(3) 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 discuss in section II.B.4 of this proposed 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 that 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 said that we evaluated each drug and biological to identify its category by indication or mode of action. We also explained that categorizing drugs and biologicals 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 *not* considered used for the treatment of ESRD (75 FR 49049–49050), categories that are *always* considered used for the treatment of ESRD (75 FR 49050), and categories of drugs that *may be* used for the treatment of ESRD but are also commonly used to treat other conditions (75 FR 49051). Those drugs and biologicals that were identified as *not* used for the treatment of ESRD were not considered renal dialysis services and therefore these drugs were not included in computing the base rate. The categories of drugs and biologicals that are 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). We note that 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 66149–66150). 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).

Regarding why we chose to identify ESRD drugs and biologicals by category rather than in a specific list, in response to a commenter's request to provide a specific list of ESRD-only drugs, we explained that 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 of 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 C in the Appendix of the final rule (75 FR 49210). This list is located at the following address: <http://www.gpo.gov/fdsys/pkg/FR-2010-08-12/pdf/2010-18466.pdf>.

We emphasized that any drug or biological 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 biological 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. We grouped the injectable and intravenous drugs and biologicals by action, specifically, into functional categories. In past rules we have referred to these categories as drug categories but we believe the term functional categories is more precise and better reflects how we use the

categories. We propose to define this term in 42 CFR 413.234(a) later in this discussion. 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.a of this proposed rule, which reflects changes in the drug price indices. In addition, we have 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 was made. We are proposing 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.

#### c. Proposed Drug Designation Process

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

In accordance with section 217(c)(2) of PAMA, we propose 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 propose 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. 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. 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 payment methodology, which is currently ASP+6 percent.

If, however, 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 propose 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 in section II.B.3.c.ii 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 propose 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. 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 Web site at [http://www.cms.gov/medicare/coding/MedHCPCSGenInfo/Application\\_Form\\_and\\_Instructions.html](http://www.cms.gov/medicare/coding/MedHCPCSGenInfo/Application_Form_and_Instructions.html). We would designate injectable and intravenous products as renal dialysis services under the ESRD PPS by analyzing the FDA labeling information, the HCPCS application information, and studies submitted as part of these two

standardized processes. A change request would be issued to include new drugs added to the functional categories.

We propose to define 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 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. As discussed above, we have established 12 functional categories that are used to treat conditions associated with ESRD, which are displayed in Table 8 below.

TABLE 8—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 propose 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).

ii. Transitional Drug Add-On Payment Adjustment

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 payment amount. Where a new injectable or intravenous product is used to treat or manage a condition for which there is not a functional category,

we propose 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. 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 believe that a 2-year timeframe is necessary for adequate data collection, rate-setting and regulation development. Two 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. The minimum 2-year period

also allows 1 year for payment of the adjustment before the beginning of a rulemaking cycle in which we could propose to add the drug to the bundled payment. For these reasons, we believe 2 years is the minimum amount of time necessary to pay the adjustment. The proposed regulation text for the transitional drug add-on payment adjustment is at § 413.234(c).

We believe paying a transitional drug add-on payment adjustment for new injectable and intravenous products will 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 propose 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 ASP methodology. We believe 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 will 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 would issue sub-regulatory billing and payment guidance along with the payment modifier in conjunction with our final rule guidance. Under our proposed regulations at § 413.234(c), following payment of the transitional drug add-on payment adjustment, we would propose to modify the ESRD PPS base rate, if appropriate, to account for the new injectable or intravenous product.

We note 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. While a new injectable drug or biological being paid under 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. However, 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.

### 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. We propose 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 propose 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 propose to codify this process in our regulations at 42 CFR 413.234(d).

We note that the FDA has well defined standards for identifying all drug dosages and forms of administration that are approved for use in the United States and this list may be viewed at [www.FDA.gov/developmentapprovalprocess.gov](http://www.FDA.gov/developmentapprovalprocess.gov).

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), we 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. If injectable or intravenous forms of phosphate binders or calcimimetics are approved by the FDA, under our proposed drug designation process at § 413.234(b)(1), 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 are proposing that we would not 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. 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, 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 payment amount. We propose 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

propose 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 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.

### 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 in the same rule. 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.

On December 19, 2014, section 204 of ATRA 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.” 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 are proposing 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. We also are proposing 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 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.

#### 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 (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) (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. We recognize 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.

We also 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 believe that 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, beginning in CY 2016 we propose to

eliminate the RCE limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports. We note 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 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.

### *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 all of 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—End-Stage Renal Disease, Section 20.2 Laboratory Services, 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 labs 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.

Following publication of the CY 2011 ESRD PPS final rule, we 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 macro vascular complication of the diabetes. Commenters believe these varying perspectives among practitioners can translate into inconsistent billing practices.

Stakeholders have also 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.

While we recognize stakeholders' concerns, for CY 2016, we are reiterating our policy 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 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.

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. 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 medically necessary for the treatment of ESRD, and have those tests included and paid under the ESRD PPS, we are not proposing a specific list of laboratory services that are always considered furnished for the treatment of ESRD.

We are, however, soliciting 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 9 is the list of laboratory tests that is used for the CB requirements. 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. Stakeholder comments will assist us in determining whether any of the

laboratory services included in the current list generally are not furnished for ESRD treatment.

In the context of this clarification, we are proposing 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. However, 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 believe that the proposal to remove the lipid panel is consistent with the clarification provided in this rule that laboratory services included in Table 9 and 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 solicit comment on this proposal.

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 .....	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

TABLE 9—LABORATORY SERVICES SUBJECT TO ESRD CONSOLIDATED BILLING—Continued

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

Although we are not proposing to change our policy related to payment for ESRD-related laboratory services under the ESRD PPS, we are clarifying 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. Laboratory services that are 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 are soliciting comment on this clarification.

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.
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

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 proposed 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 × 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 × 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.

c. Reporting of Composite Rate Drugs

As we indicated 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.

**III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2019**

*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 proposed rule discusses each of these elements and our proposals for their application to PY 2019 and future years of the ESRD QIP.

*B. 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 (*i.e.*, Medicare effective date).

### C. Proposal To Use 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 welcome 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 seek comments on this proposal.

### D. 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](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 Web site ([www.qualitynet.org](http://www.qualitynet.org)).

We welcome 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>.

### E. Proposed Revision to the Requirements for the PY 2017 ESRD QIP

#### 1. Proposal To Modify the Small Facility Adjuster 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 propose 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

$$L \leq n_i < C, \text{ let } w_i = \frac{n_i}{C}$$

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  $\bar{P}$ , the facility will not receive an adjustment.

• For the standardized ratio measures, such as the SRR and STTrR 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.<sup>2</sup>

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 [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061\\_TechnicalSpecifications.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html). Table 12 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 12—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≥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 12 indicate, fewer facilities received an adjustment under the proposed small facility adjuster methodology, because small facilities with performance rates above

the 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.

<sup>2</sup>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, 268–286, 1993. Ahmed SE.

Combining Poisson means. *Communications in Statistics: Theory and Methods*, 20, 771–789, 1991.

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 [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061\\_TechnicalSpecifications.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html). Table 13 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 13—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 propose to modify the methodology for determining the small facility adjustment as explained above.

We seek comments on this proposal.

**2. Proposal To Reinstate 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 propose 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 seek comments on this proposal.

*F. Proposed Requirements for the PY 2018 ESRD QIP*

1. Estimated 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). At this time, we do not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks because we do not yet have complete data from CY 2014. Nevertheless, we are able to estimate these numerical values based on the most recent data available. For the Vascular Access Type and Hypercalcemia clinical measures, this data comes from the period of January

through December 2014. For the SRR and STrR clinical measures, this data comes from the period of January through December 2013. In Table 14, we have provided the estimated numerical values for all of the finalized PY 2018 ESRD QIP clinical measures, except the ICH CAHPS clinical measure, because the performance standards for that measure will be calculated using CY 2015 data. We will publish updated values for the clinical measures, using data from the first part of CY 2015, in the CY 2016 ESRD PPS final rule.

TABLE 14—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 .....	53.52% .....	79.67% .....	66.02%.
% Catheter .....	17.44% .....	2.73% .....	9.24%.
Kt/V.			
Adult Hemodialysis .....	89.83% .....	98.22% .....	95.07%.
Adult Peritoneal Dialysis .....	74.68% .....	96.50% .....	88.67%.
Pediatric Hemodialysis .....	50.00% .....	96.90% .....	89.45%.
Pediatric Peritoneal Dialysis .....	43.22% .....	88.39% .....	72.60%.
Hypercalcemia .....	3.86% .....	0.00% .....	1.13%.
NHSN Bloodstream Infection SIR .....	1.811 .....	0 .....	0.861.
Standardized Readmission Ratio .....	1.261 .....	0.649 .....	0.998.
Standardized Transfusion Ratio .....	1.488 .....	0.451 .....	0.915.
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 propose to substitute the PY 2017 performance

standard, achievement threshold, and/or benchmark for that measure.

We seek comments on this proposal.

2. Proposed 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 six-month period as a measure score. In order to avoid such an undue impact on facility scores, we propose that, beginning with the PY 2018 ESRD QIP, if a facility

treats no eligible patients in one of the two six-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 seek comments on this proposal.

3. Proposed 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 are proposing 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 estimate that a facility must meet or exceed a minimum TPS of 39 for PY 2018. For all of the clinical measures except the SRR, STTr, and ICH CAHPS clinical measures, these data come from CY 2014. The data for the SRR and STTr 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 are proposing 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 15 below.

TABLE 15—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2018 BASED ON THE MOST RECENTLY AVAILABLE DATA FROM CY 2014

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 seek comments on these proposals.

#### 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 propose 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 propose 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 propose 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 propose 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 seek comments on these proposals.

*G. Proposed Requirements for the PY 2019 ESRD QIP*

1. Proposed 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 [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061\\_Technical\\_Specifications.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical_Specifications.html) and a summary of our topped-out analysis results appears in Table 16 below.

TABLE 16—PY 2018 CLINICAL MEASURES USING CROWNWEB AND MEDICARE CLAIMS DATA

Measure	N	75th percentile	90th percentile	Std. Error	Statistically indistinguishable	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 <sup>1</sup> .....	N/A. <sup>1</sup>
VAT: Fistula <sup>2</sup> .....	5763	73.3	79.7	0.15	No .....	0.14 .....	No.
VAT: Catheter <sup>3</sup> .....	5744	5.4	2.7	0.10	No .....	<0.01 .....	Yes.
Hypercalcemia <sup>2</sup> .....	6042	0.33	0.0	0.03	No .....	<0.01 .....	Yes.

<sup>1</sup> Insufficient data

<sup>2</sup> Medicare claims data from CY 2014 were used in these calculations.

<sup>3</sup> CROWNWeb data from CY 2014 was used in this calculation.

As the information presented in Table 16 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 are proposing 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), 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 propose 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 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 seek comments on this proposal.

2. Proposed Measures for the PY 2019 ESRD QIP  
 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 17 below. In accordance with our policy to

continue using measures unless we propose to remove or replace them, (77 FR 67477), we will continue to use 12 of these measures in the PY 2019 ESRD QIP. As noted above, we are proposing to remove four of these 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 17—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 ≥ 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 <sup>1</sup>	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.
N/A	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 <sup>2</sup>	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 <sup>3</sup>	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 <sup>4</sup>	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 <sup>5</sup>	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.

<sup>1</sup> We note that this measure is based upon a current NQF-endorsed bloodstream infection measure (NQF#1460).

<sup>2</sup> We note that this measure is based upon a current NQF-endorsed serum phosphorus measure (NQF #0255).

<sup>3</sup> We note that this measure is based upon a current NQF-endorsed pain assessment and follow-up measure (NQF #0420).

<sup>4</sup> We note that this measure is based upon a current NQF-endorsed clinical depression screening and follow-up measure (NQF #0418).

<sup>5</sup> We note that this measure is based upon an NQF-endorsed HCP influenza vaccination measure (NQF #0431).

b. Proposed New 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.<sup>3</sup>

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

<sup>3</sup> <https://www.qualityforum.org/map/>

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.

We are proposing 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:  $\text{spKt/V} \geq 1.2$  (calculated from the last measurement of the month)
- For pediatric (age < 18 years) peritoneal dialysis patients:  $\text{Kt/V urea} > 1.8$  (dialytic + residual, measured within the past six months)
- For adult (age > 18 years) peritoneal dialysis patients:  $\text{Kt/V urea} > 1.7$  (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](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html).

We seek comments on our proposal to adopt this measure beginning with the PY 2019 ESRD QIP.

#### c. Proposed New Reporting Measures 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,<sup>4</sup> 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 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

<sup>4</sup> 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.

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 are proposing to adopt the Ultrafiltration Rate reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

We are proposing 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 propose 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 propose 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](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html).

We seek comments on this proposal.

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<sup>5</sup> and 226,000 hospitalizations annually.<sup>6</sup> 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.<sup>7</sup> 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 adult populations in the United States,<sup>8</sup> 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.<sup>9</sup> 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 are proposing 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 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 are proposing 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 are proposing 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 propose 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

<sup>5</sup> 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>.

<sup>6</sup> 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.

<sup>7</sup> 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.

<sup>8</sup> <http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives> (Healthy People 2020 IID–12.11 and IID–12.12).

<sup>9</sup> 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.

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 are proposing 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](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html).

We seek comments on this proposal.

### 3. Proposed 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 are proposing 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 are proposing 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 seek comments on these proposals.

### 4. Proposed 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 are proposing 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 seek comments on these proposals.

#### 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. Proposed 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 are not proposing 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 are not proposing any changes to these policies.

For the Ultrafiltration Rate reporting measure, we propose 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 propose 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 seek comments on these proposals.

### 5. Proposal for 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 propose 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).

We seek comment on this proposal.

#### 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 propose 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 propose 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 seek comment on this proposal.

#### 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 seek comments on this proposal.

#### d. Proposal for 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 are not proposing 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 are not proposing any changes to these policies.

With respect to the Ultrafiltration Rate reporting measure, we are proposing 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 are proposing 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:

$$\left[ \frac{(\text{No. patients for whom facility reports vacc. status during the performance period})}{(\text{No. of eligible patients during the performance period})} \right]$$

We seek comments on these proposals.

#### 6. Weighting the Clinical Measure Domain and Total Performance Score

##### i. Proposal for 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 are proposing 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 propose to use the following weighting system in Table 18 below for calculating a facility's Clinical Measure Domain score beginning in PY 2019.

TABLE 18—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 seek comments on this proposal for weighting a facility's Clinical Measure Domain score.

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 are therefore not proposing 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 are also not proposing 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.

7. Proposed 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 are not proposing to change these minimum data policies for the measures that we have proposed to continue including in the PY 2019 ESRD QIP measure set.

For the proposed Dialysis Adequacy clinical measure, we propose 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 propose 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 propose 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 propose 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.

We seek comments on these proposals.

Table 19 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 19—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 (Reporting) ..	11 qualifying patients .....	Before July 1, 2017 .....	N/A.
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.

#### 8. Proposed 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 propose 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 recognize that we are not proposing 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 have not proposed such a policy because no measures in the proposed PY 2019 measure set meet this criterion. However, 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 are not proposing 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 seek comments on this proposal.

#### H. 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 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 [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061\\_TechnicalSpecifications.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html).

We invite comment on this policy that we are considering for adoption in the ESRD QIP in the future.

#### *I. 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 intend to publish the methodology for this study in the second half of the year, and encourage all interested parties to review this methodology and submit any comments using the process outlined on the Web page.

#### **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](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 health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual’s care. Health IT that facilitates the secure, efficient and effective sharing and use of 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 Draft Version 1.0 (draft Roadmap) (available at <http://www.healthit.gov/>

[sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf](http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf)) which describes barriers to interoperability across the current health IT landscape, the desired future state that the industry believes will be necessary to enable a learning health system, and a suggested path for moving from the current state to the desired future state. In the near term, the draft Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Moreover, the vision described in the draft Roadmap significantly expands the types of electronic health information, information sources and information users well beyond clinical information derived from electronic health records (EHRs). This shared strategy is intended to reflect important actions that both public and private sector stakeholders can take to enable nationwide interoperability of electronic health information such as: (1) Establishing a coordinated governance framework and process for nationwide health IT interoperability; (2) improving technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhancing incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarifying privacy and security requirements that enable interoperability.

In addition, ONC has released the draft version of the 2015 Interoperability Standards Advisory (available at <http://www.healthit.gov/standards-advisory>), 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 requirement 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 proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2016. However, the changes that are being proposed do not impose any new information collection requirements.

##### *C. Additional Information Collection Requirements*

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, this proposed 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.”<sup>10</sup> 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.<sup>11</sup> Therefore, we believe it is reasonable to 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 patients.<sup>12</sup> The mean hourly wage of a Medical Records and Health Information Technician is \$18.68 per hour.<sup>13</sup> 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.<sup>14</sup> 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.

**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.

**c. Data Validation Requirements for the PY 2018 ESRD QIP**

Section III.F.4 in this proposed rule outlines our data validation proposals for PY 2018. Specifically, we propose to randomly sample records from 300 facilities as part of our continuing pilot data-validation program. Each sampled facility would 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 × 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 × \$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 propose 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. We estimate the burden associated with this measure to be the time and effort necessary for facilities to collect and submit the information required for the ultrafiltration rate reporting measure. We estimated that approximately 6,264 facilities will treat 773,737 ESRD patients nationwide in PY 2019. The ultrafiltration rate reporting measure has 12 elements per patient per year, and we estimate it will take facilities approximately 0.042 hours (2.5 minutes) to submit data for each qualifying patient each month. Therefore, the estimated total annual burden associated with reporting this measure in PY 2019 is approximately 389,963 hours (773,737 ESRD patients nationwide × 12 data elements/year × 0.042 hours per element), or 62 hours per facility. We anticipate that Medical Records and Health Information Technicians or similar administrative staff will be responsible for this reporting. We therefore believe the cost for all ESRD facilities to comply with the reporting requirements associated with the ultrafiltration rate reporting measure would be approximately \$9,924,558 (389,963 × \$25.45/hour), or \$1,584 per facility. The burden associated with these requirements is captured in an information collection request currently available for review and comment, OMB control number 0938–NEW.

**e. Proposed Full-Season Influenza Vaccination Reporting Measure**

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. We estimate the burden associated with this measure to be the time and effort necessary for facilities to collect and submit the information required for this measure. We estimated that approximately 6,264 facilities will treat 773,737 ESRD patients nationwide in PY 2019. The Full-Season Influenza Vaccination reporting measure has just 1 element per patient per year, and we estimate it will take facilities approximately 0.042 hours, or 2.5 minutes, to submit this data for each patient on an annual basis. Therefore, the estimated total annual burden associated with reporting this measure in PY 2019 is approximately 32,497

<sup>10</sup> <http://www.bls.gov/bls/infohome.htm>.

<sup>11</sup> <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

<sup>12</sup> <http://www.bls.gov/ooh/healthcare/registered-nurses.htm>.

<sup>13</sup> <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html>.

<sup>14</sup> [http://www.whitehouse.gov/omb/circulars\\_a076\\_a76\\_incl\\_tech\\_correction](http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction).

hours (737,773 ESRD patients nationwide  $\times$  1 element/year  $\times$  0.042 hours/element), or 5 hours per facility. Again, we anticipate that Medical Records and Health Information Technicians or similar administrative staff will be responsible for this reporting. In total, we stated that we believe the cost for all ESRD facilities to comply with the reporting requirements associated with the Full-Season Influenza Vaccination reporting measure would be approximately \$827,049 (32,497 hours  $\times$  \$25.45/hour), or \$132 per facility. The burden associated with these requirements is captured in an information collection request currently available for review and comment, OMB control number 0938—NEW.

## VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## VII. 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 proposed regulations, and the Departments have provided the following assessment of their impact. We solicit comments on the regulatory impact analysis provided.

#### 2. Statement of Need

This rule proposes a number of routine updates and several policy changes to the ESRD PPS in CY 2016. The proposed routine updates include the CY 2016 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Other proposed 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.a.iv 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 of this proposed rule. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2016.

This rule proposes to implement requirements for the ESRD QIP, including a proposal to adopt a measure set for the PY 2019 program, as directed by section 1881(h) of the Act. Failure to propose requirements for the PY 2019 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2018. In

addition, proposing 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 proposed revisions to the ESRD PPS will result in an increase of approximately \$20 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, 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.<sup>15</sup> For PY 2019, we estimate that the proposed requirements related to the ESRD QIP will cost approximately \$10.7 million dollars, and the payment reductions will result in a total impact of approximately \$3.8 million across all facilities, resulting in a total impact from the proposed ESRD QIP of approximately \$14.6 million.

### 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 proposed rule, we used the December 2014 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

<sup>15</sup> 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.

updates to the ESRD PPS base rate are described in section II.B.2 of this

proposed rule. Table 20 shows the impact of the estimated CY 2016 ESRD

payments compared to estimated payments to ESRD facilities in CY 2015.

TABLE 20—IMPACT OF PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2016 PROPOSED RULE

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2016 changes in outlier policy (percent)	Effect of 2016 changes in wage indexes, CBSA (per-cent)designations and labor share (percent)	Effect of 2016 changes in payment rate update (percent)	Effect of 2016 proposed refinement changes to payment rate (percent)	Effect of total 2016 proposed changes (refinement and routine updates to the payment rate) (percent)
	A	B	C	D	E	F	G
All Facilities .....	6,264	40.0	0.1	0.0	0.15	0.0	0.3
Type:							
Freestanding .....	5,812	37.7	0.1	0.0	0.15	0.0	0.2
Hospital based .....	452	2.3	0.1	0.1	0.16	0.1	0.5
Ownership Type:							
Large dialysis organization .....	4,380	28.5	0.1	-0.1	0.15	0.1	0.3
Regional chain .....	926	6.0	0.1	0.2	0.15	-0.3	0.2
Independent .....	584	3.6	0.1	0.1	0.15	-0.1	0.2
Hospital based <sup>1</sup> .....	374	1.9	0.1	0.0	0.16	0.4	0.7
Geographic Location:							
Rural .....	1,239	5.9	0.1	-1.2	0.15	1.0	0.0
Urban .....	5,025	34.1	0.1	0.2	0.15	-0.2	0.3
Census Region:							
East North Central .....	1,036	5.8	0.1	-0.3	0.15	0.2	0.1
East South Central .....	518	3.0	0.1	-1.2	0.15	0.7	-0.2
Middle Atlantic .....	680	4.9	0.1	0.9	0.15	-0.3	0.8
Mountain .....	359	2.0	0.1	-0.1	0.15	-0.1	0.1
New England .....	182	1.3	0.1	1.1	0.15	-0.6	0.7
Pacific <sup>2</sup> .....	760	5.6	0.1	1.4	0.15	-0.8	0.8
Puerto Rico and Virgin Islands .....	47	0.3	0.1	-4.0	0.15	-0.2	-3.9
South Atlantic .....	1,386	9.3	0.1	-0.4	0.15	0.3	0.2
West North Central .....	455	2.1	0.1	-0.6	0.15	0.4	0.0
West South Central .....	841	5.8	0.1	-0.7	0.15	0.2	-0.2
Facility Size:							
Less than 4,000 treatments <sup>3</sup> .....	1,305	3.5	0.1	-0.3	0.15	0.4	0.3
4,000 to 9,999 treatments .....	2,239	10.8	0.1	-0.3	0.15	0.1	0.1
10,000 or more treatments .....	2,514	25.3	0.1	0.2	0.15	-0.1	0.3
Unknown .....	206	0.3	0.1	0.1	0.15	-0.2	0.1
Percentage of Pediatric Patients:							
Less than 2% .....	6,156	39.6	0.1	0.0	0.15	0.0	0.3
Between 2% and 19% .....	42	0.4	0.1	-0.1	0.15	0.4	0.5
Between 20% and 49% .....	14	0.0	0.1	-0.2	0.15	0.4	0.4
More than 50% .....	52	0.0	0.1	0.0	0.15	0.5	0.7

<sup>1</sup> Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

<sup>2</sup> Includes Facilities located in Guam, American Samoa, and the Northern Mariana Islands.

<sup>3</sup> Of the 1,305 Facilities with less than 4,000 treatments, only 385 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 7.0 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 proposed changes to the outlier payment policy described in section II.B.2.c of this proposed 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 0.1 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2016 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed CY 2016 wage indexes, 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 4.0 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 1.4 percent increase due to these proposed updates.

Column E shows the effect of the ESRD PPS payment rate update of 0.15 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2016 of 2.0 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 0.6 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 1.0 percent increase.

Column G reflects the overall impact (that is, the effects of the proposed outlier policy changes, the proposed 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 0.3 percent increase in estimated payments in 2016. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive a 3.9 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 0.2 percent to an increase of 0.8 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 proposed 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 \$8.7 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.5 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 0.3 percent overall increase in the proposed ESRD PPS payment amounts in CY 2016, we estimate that there will be an increase in beneficiary co-insurance payments of

0.3 percent in CY 2016, which translates to approximately \$10 million.

e. Alternatives Considered

1. CY 2016 ESRD PPS

In section II.B.1.c.i of this proposed rule, we propose updated payment multipliers for five age groups resulting from our regression analysis. In section II.B.2.d.ii, we propose a regression budget-neutrality adjustment to account for the overall effects of the refinement. We are proposing a 4 percent reduction (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 and indicate 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.ii of this proposed rule, we are proposing to modify the eligibility criteria for the low-volume payment adjustment by excluding facilities of common ownership that are located within 5

road miles from one another. We considered proposing a geographic proximity criterion of 10 road miles; however, this approach negatively impacted rural facilities which are important to ensure access of 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 proposing to use to determine a facility's TPS for PY 2019 is described in section III.G.9 of this proposed 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 8 percent or 495 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 21 shows the overall estimated distribution of payment reductions resulting from the PY 2019 ESRD QIP.

TABLE 21—ESTIMATED DISTRIBUTION OF PY 2019 ESRD QIP PAYMENT REDUCTIONS

Percentage reduction	Frequency	Percent	Cumulative frequency	Cumulative percent
0 .....	5509	91.76	5509	91.76
0.5 .....	430	7.16	5939	98.92
1 .....	41	0.68	5980	99.60
1.5 .....	18	0.30	5998	99.90
2 .....	6	0.10	6004	100.00

Note: This table excludes 260 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 22.

TABLE 22—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—June 2013 .....	July 2013—Dec 2013.
Hypercalcemia .....	Jan 2013—Dec 2013 .....	Jan 2014—Dec 2014.

TABLE 22—DATA USED TO ESTIMATE PY 2019 ESRD QIP PAYMENT REDUCTIONS—Continued

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance Period
SRR .....	Jan 2012– Dec 2012 .....	Jan 2013—Dec 2013.
STrR .....	Jan 2012– Dec 2012 .....	Jan 2013—Dec 2013.

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.G.9 of this proposed 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 proposed 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 495 facilities estimated to receive a reduction is approximately \$3.85 million (\$3,859,742). Further, we estimate that the total costs associated with the collection of information requirements for PY 2019 described in section III.C.1 of this proposed rule would be approximately \$10.7 million for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately \$14.6

million (\$10,751,607 + \$3,859,742 = \$14,611,249) in PY 2019, as a result of the PY 2019 ESRD QIP.

Table 23 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 23—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2019

	Number of facilities	Number of treatments 2013 (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	6,004	495	–0.04
Facility Type:					
Freestanding .....	5,812	37.7	5,614	464	–0.04
Hospital-based .....	452	2.3	390	31	–0.06
Ownership Type:					
Large Dialysis .....	4,380	28.5	4,259	356	–0.04
Regional Chain .....	926	6.0	888	55	–0.03
Independent .....	584	3.6	538	56	–0.07
Hospital-based (non-chain) .....	374	1.9	319	28	–0.07
Facility Size:					
Large Entities .....	5,306	34.5	5,147	411	–0.04
Small Entities <sup>1</sup> .....	958	5.5	857	84	–0.07
Rural Status:					
(1) Yes .....	1,332	6.5	1,257	66	–0.03
(2) No .....	4,932	33.5	4,747	429	–0.05
Census Region:					
Northeast .....	861	6.2	825	50	–0.03
Midwest .....	1,490	7.9	1,386	112	–0.05
South .....	2,744	18.1	2,655	243	–0.05
West .....	1,112	7.5	1,085	77	–0.04
US Territories <sup>2</sup> .....	57	0.4	53	13	–0.16
Census Division:					
East North Central .....	1,036	5.8	962	86	–0.05
East South Central .....	518	3.0	500	48	–0.06
Middle Atlantic .....	680	4.9	658	43	–0.03
Mountain .....	359	2.0	348	25	–0.04
New England .....	182	1.3	167	7	–0.02
Pacific .....	760	5.6	744	53	–0.04
South Atlantic .....	1,386	9.3	1,337	143	–0.06
West North Central .....	455	2.1	424	26	–0.03
West South Central .....	841	5.8	818	52	–0.03
US Territories <sup>2</sup> .....	47	0.3	46	12	–0.17
Facility Size (# of total treatments):					
Less than 4,000 treatments .....	1,305	3.5	1,185	109	–0.07
4,000–9,999 treatments .....	2,239	10.8	2,211	166	–0.04

TABLE 23—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2019—  
Continued

	Number of facilities	Number of treatments 2013 (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)
Over 10,000 treatments .....	2,514	25.3	2,491	203	-0.04
Unknown .....	206	0.3	117	17	-0.11

<sup>1</sup> Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.

<sup>2</sup> Includes Puerto Rico and Virgin Islands.

<sup>3</sup> Based on claims and CROWNWeb data through December 2014.

b. Alternatives Considered

In section III.G.2.c.ii of this proposed rule, we are proposing 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 Measures Application Partnership do not include NHSN as a data source for this measure, we have 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.

C. Accounting Statement

As required by OMB Circular A-4 (available at [http://www.whitehouse.gov/omb/circulars\\_a004\\_a-4](http://www.whitehouse.gov/omb/circulars_a004_a-4)), in Table 24 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 24—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

ESRD PPS for CY 2016	
Category	Transfers
Annualized Monetized Transfers .....	\$20 million.
From Whom to Whom .....	Federal government to ESRD providers.
Category	Transfers
Increased Beneficiary Co-insurance Payments .....	\$ 10 million.
From Whom to Whom .....	Beneficiaries to ESRD providers.
ESRD QIP for PY 2018 <sup>16</sup>	
Category	Transfers
Annualized Monetized Transfers .....	\$ - 11.6 million.
Category	Costs
Annualized Monetized ESRD Provider Costs .....	\$19 thousand.
ESRD QIP for PY 2019	
Category	Transfers
Annualized Monetized Transfers .....	\$ - 3.8 million.
From Whom to Whom .....	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs .....	\$10.7 million.

<sup>16</sup> 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 values presented here capture those previously finalized impacts plus the collection of information requirements related for PY 2018 presented in this notice of proposed rulemaking.

## VIII. 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 20. Using the definitions in this ownership category, we consider the 584 facilities that are independent and the 374 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 proposed in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 0.7 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 21 ("Estimated Distribution of PY 2019 ESRD QIP Payment Reductions") and Table 23 ("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 proposed rule would not have a significant economic impact on a substantial number of small entities. We solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 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 proposed 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 0.1 percent decrease in payments. As a result, this proposed rule is not estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

## IX. 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 proposed rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of \$141 million.

## X. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed 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 proposed 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.

## XI. Congressional Review Act

This proposed 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 proposed rule was reviewed by the Office of Management and Budget.

## XII. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet and is posted on the CMS Web site at <http://www.cms.gov/ESRDPayment/PAY/list.asp> In addition to the Addenda, limited data set (LDS) files are available for purchase at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html>. Readers who experience any problems accessing the Addenda or LDS files, 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 proposes to amend 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:** Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub.L. 106–113 (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, and sec. 204 of Pub. L. 113–295.

■ 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. In newly redesignated paragraph (e), the reference “paragraph (g)” is removed and the reference “paragraph (f)” is added in its place.

■ 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) 5 miles or less from the ESRD facility in question.

\* \* \* \* \*

■ 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) 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 ASP pricing methodology.

(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) 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: June 23, 2015.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: June 24, 2015.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

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