DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 411, 413 and 414

[CMS–1614–P]

RIN 0938–AS13

Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

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) 2015. This rule also proposes to set forth requirements for the ESRD quality incentive program (QIP), including payment years (PYs) 2017 and 2018. This rule also proposes to make a technical correction to remove outdated terms and definitions. In addition, this rule proposes to set forth the methodology for adjusting Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment amounts using information from the Medicare DMEPOS Competitive Bidding Program (CBP); make alternative payment rules for DME and enteral nutrition under the Medicare DMEPOS CBP; clarify the statutory Medicare hearing aid coverage exclusion and specify devices not subject to the hearing aid exclusion; update the definition of minimal self-adjustment regarding what specialized training is needed by suppliers to provide custom fitting services if they are not certified orthotists; clarify the Change of Ownership (CHOW) and provides for an exception to the current requirements; revise the appeal provisions for termination of a contract and notification to beneficiaries under the Medicare DMEPOS CBP, and add a technical change related to submitting bids for infusion drugs under the Medicare DMEPOS CBP.

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 September 2, 2014.

ADDRESSES: In commenting, please refer to file code CMS–1614–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–1614–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–1614–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 21244–1850.

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, the ESRD PPS CY 2015 Base Rate and Payment for Frequent Hemodialysis.

Michelle Cruse, (410) 786–7540, for issues related to the ESRD PPS and the Low Volume Payment Adjustment.

Karen Reinhardt, (410) 786–0189, for issues related to the ESRD PPS and the Outlier Payment Policy.

Wendy Tucker, (410) 786–3004, for issues related to the ESRD PPS and Wage Index.

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

Anita Segar, (410) 786–4614, for issues related to the ESRD QIP.

Christopher Molling (410) 786–6399 and Hafsa Vahora (410) 786–7899 for issues related to the methodology for making national price adjustments based upon information gathered from the DMEPOS CBP.

Sandhya Gilkerson, (410) 786–4085, for issues related to the alternative payment methodologies under the CBP.

Sandhya Gilkerson, (410) 786–4085 and Michelle Peterman, 410–786–2581 for issues related to the clarification of the statutory Medicare hearing aid coverage exclusion.

Michelle Peterman, (410) 786–2591 for issues related to the definition of minimal self-adjustment at 414.402.

Janae James (410) 786–0801 for issues related to CHOW and breach of contract appeals.

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 Stephanie Frilling at 410–786–4507.

Table of Contents

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

Acronyms

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

AHRQ—Agency for Healthcare Research and Quality
ANOVA—Analysis of Variance
ANPRM—Advanced Notice of Proposed Rulemaking
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
CBA—Competitive Bidding Area
CBP—Competitive Bidding Program
CBSA—Core based statistical area
CCN—CMS Certification Number
CDC—Centers for Disease Control and Prevention
CfC—Conditions for Coverage
CHOW—Change of Ownership
CKD—Chronic Kidney Disease
CPAP—Continuous positive airway pressure
CY—Calendar Year
DFC—Dialysis Facility Compare
DME—Durable Medical Equipment
DMEPOS—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
ESA—Erythropoiesis stimulating agent
ESRD—End-Stage Renal Disease
ESRDB End-Stage Renal Disease bundled
ESRD PPS— End-Stage Renal Disease Prospective Payment System
FDA—Food and Drug Administration
GEM—General Equivalence Mappings
HCP—Healthcare Personnel
HD—Hemodialysis
HAIs—Healthcare-Acquired Infections
HCPCS—Healthcare Common Procedure Coding System
HCFA—Health Care Financing Administration
HLM—Hierarchical Logistic Modeling
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
IOLs—Intraocular Lenses
IPPS—Inpatient Prospective Payment System
ICH CAHPS—In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Services
IUR—Inter-unit reliability
MAC—Medicare Administrative Contractor
MAP—Medicare Allowable Payment
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 Health Safety Network
NQF—National Quality Forum
NQS—National Quality Strategy
OBRA—Omnibus Budget Reconciliation Act
OMB—Office of Management and Budget
P&O—Prosthetics and orthotics
PAMA—Protecting Access to Medicare Act of 2014
PC—Product category
PD—Peritoneal Dialysis

PEN—Parenteral and enteral nutrition
PFS—Physician Fee Schedule
QIP—Quality Incentive Program
RMA—Reporting Measure Adjuster
RSPA—Regional single payment amounts
RUL—Reasonable useful lifetime
SAF—Standard Analysis File
SHR—Standardized Hospitalization Ratio Admissions
SMR—Standardized Mortality Ratio
SPA—Single payment amount
STrR—Standardized Transfusion Ratio
TENS—Transcutaneous electrical nerve stimulation
TEP—Technical Expert Panel
TPS—Total Performance Score
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) 2015. 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 (Pub. L. 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. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2011, to reduce the single payment amount to reflect the Secretary's 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. And finally, 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). PAMA section 217 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 interpret 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 what the market basket update will be for CY 2015 (0.0 percent) and how it will be reduced in CYs 2016 through 2018. Section 217(a)(1) of PAMA amends section 632(b)(1) of ATRA, which now provides 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(a)(2) further amends section 632(b)(1) of ATRA by adding a sentence that provides: ''Notwithstanding section 1881(b)(14)(A)(ii) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(A)(ii)), implementation of the policy described in the previous sentence shall be based on data from the most recent year available.'' Finally, PAMA section 217(c) provides that, as part of the CY 2016 ESRD PPS rulemaking, the Sectary 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.

As discussed further below, section 212 of PAMA provides that the Secretary may not adopt ICD–10 prior to October 1, 2015. HHS has announced that it intends to issue an interim final rule that will require use of ICD–10 beginning October 1, 2015 and will require the continued use of ICD–9–CM through September 30, 2015. Therefore, the ESRD PPS will continue to use ICD–9 through September 30, 2015 and will require use of ICD–10 beginning October 1, 2015 for purposes of the comorbidity payment adjustment.

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

This rule also proposes to set forth requirements for the ESRD Quality Incentive Program (QIP), including for payment years (PYs) 2017 and 2018. 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.

3. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

This proposed rule proposes a methodology for making national price adjustments to payments for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) paid under fee schedules based upon information gathered from the DMEPOS competitive bidding programs (CBPs) and proposes to phase in special payment rules in a limited number of competitive bidding areas (CBAs) under the CBP for certain, specified DME and enteral nutrition. This rule proposes to clarify the statutory Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act and the regulation at 42 CFR 411.15(d) to further specify the scope of this exclusion and to note certain devices excepted from the hearing aid exclusion. In addition, this rule proposes to update the definition of minimal self-adjustment at § 414.402 to note the specialized training that is needed by suppliers to provide custom fitting services if they are not certified orthotists. Finally, this rule proposes a revision to the Change of Ownership (CHOW) policy in the current regulations to allow a product category to be severed from a competitive bidding contract and transferred to a new contract when a contract supplier sells a distinct line of business to a qualified successor entity.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2015:* For CY 2015, we are proposing an ESRD PPS base rate of $239.33. This amount reflects 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 proposed wage index budget-neutrality adjustment factor of 1.001306 to the CY 2014 ESRD PPS base rate of $239.02.

- *Rebasing and revision of the ESRD bundled (ESRDB) market basket:* For CY 2015, we are proposing to rebase and revise the ESRDB market basket so the cost weights and price proxies would reflect the mix of goods and services that underlie ESRD bundled operating and capital costs for CY 2012. We note that if PAMA had not been enacted the proposed 2012-based ESRDB market basket update less productivity for CY

2015 would have been 1.6 percent, or (2.0 percent less 0.4 percentage point).

• *Update to the labor-related share:* Because the cost distributions would change significantly as a result of the proposed ESRDB market basket revision, the proposed labor-related share would be 50.673 percent compared to the current labor-related share of 41.737 percent. The change to the labor-related share would have a significant impact on payments for certain ESRD facilities, specifically those ESRD facilities that have low wage index values. Therefore, for CY 2015 we are proposing a 2-year transition, in which the CY 2015 payment would be based on a 50/50 blended labor-related share that would apply to all ESRD facilities. ESRD facilities would receive 50 percent of their current labor-related share and 50 percent of their revised labor-related share. Specifically, we would apply a labor-related share of 46.205 ((41.737+50.673)/2 = 46.205). For CY 2016, the labor-related share would be based on 100 percent of the revised labor-related share.

• *Update to the wage index and wage index floor:* We adjust wage indices on an annual basis using the most current hospital wage data to account for differing wage levels in areas in which ESRD facilities are located. In CY 2015, we are not proposing any changes to the application of the wage index budget-neutrality adjustment factor and will continue to apply the budget-neutrality adjustment to the base rate for the ESRD PPS. We will continue our policy for the gradual phase-out of the wage index floor and reduce the wage index floor values to 0.40, as finalized in the CY 2014 ESRD PPS final rule (78 FR 72173–72174).

• *Update to the Core-Based Statistical Areas (CBSA):* For CY 2015, we are proposing to implement 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 addition, we are proposing to implement a 2-year transition, under which a 50/50 blended wage index would apply to all ESRD facilities for CY 2015. Specifically, facilities would receive 50 percent of their CY 2015 wage index based on the CBSA delineations for CY 2014 and 50 percent of their CY 2015 wage index based on the proposed new CBSA delineations. In CY 2016, facilities' wage index values would be based 100 percent on the new CBSA delineations.

• *Update to the outlier policy:* We are updating the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments (MAPs) for adult patients for CY 2015 using 2013 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries would increase from $54.01 to $56.30 and the MAP amount would increase from $37.29 to $40.05, as compared to CY 2014 values. For adult beneficiaries, the fixed-dollar loss amount would decrease from $98.67 to $85.24 and the MAP amount would increase from $51.97 to $52.61. The 1 percent target for outlier payments was not achieved in CY 2013. We believe using CY 2013 claims data to update the outlier MAP and fixed dollar loss amounts for CY 2015 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage.

• *Clarification for the low-volume payment adjustment (LVPA):* We are clarifying two policies regarding MAC verification and proposing conforming changes to the LVPA regulation. The first clarification explains that MACs can consider supporting data from hospital-based ESRD facilities to verify the facility's total treatment count. The second clarification explains that MACs can add or prorate treatment counts from non-standard cost reporting periods (those that are not 12-month periods) where there is a change in ownership that does not result in a new Provider Transaction Access Number.

• *Continued use of ICD–9–CM codes and corrections to the ICD–10–CM codes eligible for the comorbidity payment adjustment:* Section 212 of PAMA provides that the Secretary may not adopt ICD–10 prior to October 1, 2015. HHS has announced that it intends to issue an interim final rule that will require use of ICD–10 beginning October 1, 2015 and will require the continued use of ICD–9–CM through September 30, 2015. Therefore, the ESRD PPS will continue to use ICD–9 through September 30, 2015 and will require use of ICD–10 beginning October 1, 2015 for purposes of the comorbidity payment adjustment. For CY 2015, we are correcting several typographical errors and omissions in the Tables that appeared in the CY 2014 ESRD PPS final rule.

2. ESRD QIP

This rule proposes to implement requirements for the ESRD QIP, including measure sets for PYs 2017 and 2018.

• *PY 2017 Measure Set:* For PY 2017, we are proposing to remove one measure from the ESRD QIP, the Hemoglobin Greater than 12 g/dL clinical measure, on the grounds that it is ''topped out''. We are also proposing to adopt the Standardized Readmission Ratio (SRR) clinical measure, which evaluates care coordination.

• *PY 2018 Measure Set:* For PY 2018, we are proposing to adopt two new clinical measures—the Standardized Transfusion Ratio (STrR) and Pediatric Peritoneal Dialysis Adequacy—and three new reporting measures: (1) Pain Assessment and Follow-Up; (2) Clinical Depression Screening and Follow-Up; and (3) National Healthcare Safety Network (NHSN) Healthcare Personnel Influenza Vaccination. We are also proposing to transition the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey reporting measure to a clinical measure.

• *Revision to the ICH CAHPS Reporting Measure:* Beginning with the PY 2017 program year, we are proposing to revise the ICH CAHPS reporting measure to determine facility eligibility for the measure based on the number of survey-eligible patients treated during the ''eligibility period'', which we propose to define as the Calendar Year (CY) that immediately precedes the performance period. Survey-eligible patients are defined in the ICH CAHPS measure specifications available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html* and *https://ichcahps.org*.

• *Revision to the NHSN Bloodstream Infection in Hemodialysis Outpatients Clinical Measure:* Beginning with the PY 2016 program year, we are proposing to revise the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure to calculate facility performance using the Adjusted Ranking Metric (ARM).

• *Revision to the Mineral Metabolism Reporting Measure:* Beginning with the PY 2018 program year, we are proposing to revise the Mineral Metabolism reporting measure to allow facilities to submit both serum phosphorus and plasma phosphorus measurements.

• *Extraordinary Circumstances Exemption:* Beginning with the PY 2017 ESRD QIP, we are proposing to exempt dialysis facilities from all requirements of the ESRD QIP clinical and reporting measures during the months in which they are forced to close due to a natural disaster or other extraordinary circumstances.

• *New Scoring Methodology for PY 2018:* For PY 2018, we are proposing to use a new scoring methodology for the ESRD QIP. This proposed scoring methodology would assign facility Total Performance Scores (TPS) on the basis of two domains, the Clinical Measure

Domain and the Reporting Measure Domain. Facility scores on clinical measures in the Clinical Measure Domain would be divided into subdomains that align with National Quality Strategy (NQS) domains and weighted according to the number of measures in a subdomain, facility experience with the measure, and the measure's alignment with CMS priorities for quality improvement. These weighted scores would be summed to produce a facility's Clinical Measure Domain score. Facility scores on reporting measures in the Reporting Measure Domain would be summed and calculated to produce a facility's Reporting Measure Adjuster, which would be subtracted from the facility's Clinical Measure Domain score to produce a facility's TPS.

3. DMEPOS

• *The methodology for making national price adjustments based upon information gathered from the DMEPOS CBPs:* As required by the MIPPA, this rule proposes methodologies for using information from the DMEPOS CBP to adjust the fee schedule amounts for DME in areas where CBPs are not implemented. The rule proposes to use the same methodologies to adjust the fee schedule amounts for enteral nutrition and off-the shelf (OTS) orthotics in areas where CBPs are not implemented.

• *Phase in of special payment rules in a limited number of CBAs under the CBP for certain, specified DME and enteral nutrition.* This rule proposes to phase-in special payment rules for certain DME and enteral nutrition under the DMEPOS CBP in a limited number of CBAs.

• *Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act:* This rule proposes to modify the regulation at § 411.15 to address the scope of the statutory hearing aid exclusion and note the types of devices that are not subject to the hearing aid exclusion.

• *Definition of minimal self-adjustment at § 414.402:* This rule proposes to update the regulation to indicate what specialized training is needed to provide custom fitting services if suppliers are not certified orthotists.

• *Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business:* This proposed rule proposes to establish an exception under the CHOW rules to allow CMS to sever a product category from a contract, incorporate the product category into a new contract, and transfer the new contract to a qualified new owner under certain specific circumstances.

• *Termination of a Competitive Bidding Contract:* This rule proposes to clarify the effective date for terminations of competitive bidding contracts, which impacts the deadline for which contract suppliers must notify its beneficiaries of the termination.

C. Summary of Costs and Benefits

In section XII.B 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 XII.B.1.a of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2015 compared to estimated payments in CY 2014. The overall impact of the CY 2015 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 0.3 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately $30 million from CY 2014 to CY 2015. This reflects a $0 million change from the payment rate update and a $30 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 2015, which translates to approximately $10 million.

2. Impacts for ESRD QIP

The overall economic impact of the ESRD QIP is an estimated $11.9 million in PY 2017 and $7.2 million in PY 2018. In PY 2017, we expect the total payment reductions to be approximately $11.9 million, and the costs associated with the collection of information requirements for the validation of NHSN data feasibility study to be approximately $27 thousand for all ESRD facilities. In PY 2018, we expect the total payment reductions to be approximately $7 million, and the costs associated with the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure to be approximately $248 thousand for all ESRD facilities.

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

3. Impacts for DMEPOS

a. Proposed methodology for making national price adjustments to DMEPOS fee schedule amounts based upon information gathered from the DMEPOS competitive bidding programs

The proposed regulation proposes to adjust Medicare fee schedule amounts for items subject to DMEPOS CBPs beginning January 1, 2016, using information from the DMEPOS CBPs to be applied to items in non-competitive bidding areas. It is estimated that these adjustments would save over $7 billion for the 5-year period beginning January 1, 2016, and ending December 30, 2020. The estimated savings are primarily derived from price reductions for items. It is expected that most of the economic impact would result from reduced payment amounts. The ability of suppliers to furnish items is not expected to be impacted.

b. Proposed phase in of special payment rules under the competitive bidding program for certain DME and enteral nutrition

We believe that the proposed special payment rules for certain DME and enteral nutrition under the DMEPOS CBPs would not have a significant impact on beneficiaries and suppliers. Contract suppliers are responsible for furnishing items and services needed by the beneficiary, and the cost to suppliers for furnishing these items and services does not change based on whether or not the equipment and related items and services are paid for separately under a capped rental payment method. Because the supplier's bids would reflect the cost of furnishing items in accordance with the new payment rules, we expect the overall savings to generally be the same as they are under the current payment rules.

Furthermore, the proposed special payment rules would be phased under a limited number of areas first to evaluate their impact on the program, beneficiaries, and suppliers, including costs, quality, and access. Expanded use of the special payment rules in other areas or for other items would be addressed in future rulemaking.

c. Proposed clarification of the statutory Medicare hearing aid coverage exclusion stipulated at section 1862(a)(7) of the Act

This proposed rule proposes to clarify the scope of the Medicare coverage exclusion for hearing aids and withdraw coverage of bone anchored hearing aids. This proposal would not have a significant fiscal impact on the Medicare program, because the

Medicare program expenditures for bone anchored hearing aids during the period CY2005 through CY 2013 are less than $9,000,000. This proposed rule, if finalized, would provide further guidance about coverage of DME with regard to the statutory hearing aid exclusion. The proposed rule, if finalized, would leave unchanged coverage of cochlear implants and brain stem implants, which are not considered hearing aids.

d. Proposed update of the definition of minimal self-adjustment at 42 CFR 414.402

The proposed rule proposes to update the definition of minimal self-adjustment to make clear that minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or a physician as defined in section 1861(r) of the Act, a treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, an occupational therapist as defined in 42 CFR 484.4, or physical therapist as defined in 42 CFR 484.4 in compliance with all applicable Federal and State licensure and regulatory requirements. If finalized, this revised definition would impact suppliers furnishing custom fitted orthotics that do not have this expertise. These suppliers would be required to hire an individual with expertise. For example, according to the Bureau of Labor Statistics Occupational Employment Statistics May 2013 the median pay for a certified orthotist is $30.27 an hour. The impact will vary according to the caseload of custom fitted orthotics provided by an individual supplier.

e. Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business

This rule proposes to clarify the CHOW rules in order to limit disruption to the normal course of business for DME suppliers. This rule proposes to establish an exception under the current CHOW rules to allow CMS to sever a product category from a contract, incorporate the product category into a new contract, and transfer the new contract to a qualified new owner under certain specific circumstances. This proposed clarification would impact businesses in a positive way by allowing them to conduct everyday transactions with less disruption from our rules and regulations.

II. Calendar Year (CY) 2015 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

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

On August 12, 2010, we published in the **Federal Register** a final rule (75 FR 49030 through 49214) in which we implemented a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis services beginning January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA. On November 10, 2011, we published in the **Federal Register** a final rule (76 FR 70228 through 70316) in which we made a number of routine updates for CY 2012, implemented the second year of the transition to the ESRD PPS, made several policy changes and clarifications, and made technical changes. On November 9, 2012, we published in the **Federal Register** a final rule (77 FR 67450 through 67531) in which we made a number of routine updates for CY 2013, implemented the third year of the transition to the ESRD PPS, and made several policy changes and reiterations.

On December 2, 2013, we published in the **Federal Register** a final rule (78 FR 72156 through 72253) titled, Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (hereinafter referred to as the CY 2014 ESRD PPS final rule). In that final rule, for the ESRD PPS, we made a number of routine updates for CY 2014, implemented the fourth and final year of the transition, implemented sections 632(a) and (b)(1) of ATRA, 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 $239.02 per treatment for renal dialysis services. This amount reflected the CY 2014 ESRD bundled (ESRDB) market basket update of 3.2 percent minus a multifactor productivity adjustment of 0.4 percent, that is, a 2.8 percent increase. This amount also reflected the application of the wage index budget-neutrality adjustment of 1.000454, the home dialysis training add-on budget neutrality adjustment factor of 0.999912, and the portion of the drug utilization adjustment that was transitioned for CY 2014, or $8.16.
- *Update to the wage index floor.* A 0.05 reduction to the CY 2014 and CY 2015 wage index floor values, which resulted in a wage index floor value of 0.45 for CY 2014 and a wage index floor value of 0.40 for CY 2015 under the ESRD PPS.
- *Update to the outlier policy.* Using CY 2012 claims data to update the outlier Medicare Allowable Payments (MAPs) and fixed dollar loss amounts for CY 2014, which resulted in updated fixed dollar loss amounts for adult and pediatric patients and MAPs for adult patients. Specifically, for pediatric beneficiaries, we finalized a fixed-dollar loss amount of $54.01 and a MAP amount of $40.49. For adult beneficiaries, we finalized a fixed-dollar loss amount of $98.67 and a MAP amount of $50.25.
- *The application of ICD–10–CM diagnosis codes to the comorbidity payment adjustment.* We discussed and provided a crosswalk from ICD–9–CM to ICD–10–CM for codes that are subject to the comorbidity payment adjustment. We finalized a policy under which all ICD–10–CM codes to which ICD–9–CM codes that are eligible for the comorbidity payment adjustment crosswalk are eligible for the comorbidity payment adjustment beginning on October 1, 2014 with two exceptions. As discussed further below, however, section 212 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) provides that the Secretary may not adopt ICD–10 prior to October 1, 2015. HHS has announced that it intends to issue an interim final rule that will require use of ICD–10 beginning October 1, 2015 and will continue to require use of ICD–9–CM through September 30, 2015. Accordingly, we plan to continue to require facilities to utilize ICD–9–CM codes to identify comorbidities eligible for the comorbidity payment adjustment through September 30, 2015, and then to use ICD–10–CM codes beginning October 1, 2015.
- *The self-dialysis and home dialysis training add-on adjustment.* An increase to the self-dialysis and home dialysis training add-on adjustment from $33.44 to $50.16.
- *The delay in payment for oral-only ESRD-related drugs and biologicals until January 1, 2016.* We also delayed payment for oral-only ESRD-related drugs under the ESRD PPS until January 1, 2016. As discussed further below, section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not include oral-only ESRD-related drugs for payment

under the ESRD PPS prior to January 1, 2024.

B. Routine Updates and Proposed Policy Changes to the CY 2015 ESRD PPS

1. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we discussed the development 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 for projected outlier payments and 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 Medicare Allowable Payment (MAP) for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and regulations at § 413.230, the ESRD PPS base rate is adjusted for the patient-specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, as well as applicable outlier payments or training payments.

a. Changes to the Drug Utilization Adjustment

i. The Drug Utilization Adjustment Finalized in the CY 2014 ESRD PPS Final Rule

Section 1881(b)(14)(I) of the Act, as added by section 632(a) of the American Taxpayer Relief Act of 2012 (ATRA), required that, for services furnished on or after January 1, 2014, the Secretary shall make reductions to the single payment for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs) by comparing per patient utilization data from 2007 with such data from 2012. Section 1881(b)(14)(I) further required that in making the reductions, the Secretary take into account the most recently available data on Average Sales Prices (ASP) and changes in prices for drugs and biologicals reflected in the ESRD market basket percentage increase factor under section 1881(b)(14)(F). Consistent with these requirements, in CY 2014, we finalized a payment adjustment to the CY 2014 ESRD PPS base rate that reflected the change in utilization of ESRD-related drugs and biologicals from CY 2007 to CY 2012.

Specifically, we finalized the drug utilization adjustment amount of $29.93 per treatment, and finalized a policy to implement this amount over a 3- to 4-year transition period. For CYs 2014 and 2015, we stated that we would implement the transition by offsetting the payment update by a portion of the reduction amount necessary to create an overall impact of a zero percent for facilities from the previous year's payments. For example, in CY 2014 we finalized a per treatment drug utilization adjustment amount for the first transition year of $8.16 or 3.3 percent, which represented the CY 2014 ESRDB market basket update minus productivity and other impacts to create an overall impact of zero percent. For a complete discussion of the methodology for computing the drug adjustment please see the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170).

ii. PAMA Changes to the Drug Utilization Adjustment

On April 1, 2014, Congress enacted PAMA. Section 217(b), titled Mitigation of the Application of Adjustment to ESRD Bundled Payment Rate to Account for Changes in the Utilization of Certain Drugs and Biologicals, amends section 1881(b)(14)(I) of the Act by inserting ''and before January 1, 2015'' after January 1, 2014. This amendment effectively eliminates the remaining years of the drug utilization adjustment transition. In its place, the PAMA amendments to section 1881(b)(14)(F)(i) dictate what the market basket increase factor will be for 2015 and how it will be reduced in 2016 through 2018. In particular, PAMA section 217(b)(2)(C) amended section 1881(b)(14)(F)(i) by adding subclause (III), which provides that ''[n]otwithstanding subclauses (I) and (II), in order to accomplish the purposes of subparagraph (I) with respect to 2015, the increase factor described in subclause (I) for 2015 shall be 0.0 percent.'' We interpret subclause (III) to mean that the market basket increase factor less the productivity adjustment for 2015 is 0.0 percent. The PAMA amendments also provide for a payment reduction in lieu of the drug utilization adjustment in 2016 through 2018. In particular, PAMA section 217(b)(2)(ii) further amends section 1881(b)(14)(i)(I) by adding at the end the following new sentence, '' In order to accomplish the purpose of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the increase factor described in the preceding sentence 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.'' We interpret this provision as requiring us to reduce the market basket increase factor for 2016 through 2018 by the percentages prescribed in the statute.

b. Payment Rate Update for CY 2015

As discussed in section II.B.2 of this proposed rule, 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, provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the rate of increase in the ESRD market basket, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. If PAMA had not stipulated a 0.0 percent payment update for CY 2015, we would have proposed a payment update of 1.6 percent, (a 2.0 percent ESRDB market basket update less a 0.4 percent productivity adjustment). In accordance with section 1881(b)(14)(F)(i)(III) of the Act, as added by PAMA section 217(b)(2)(C), however, we propose a 0.0 percent update to the CY 2014 ESRD PPS base rate of $239.02 for CY 2015.

c. CY 2015 ESRD PPS Wage Index Budget Neutrality Adjustment

For CY 2015 we propose to apply the wage index budget-neutrality adjustment factor of 1.001306 to the unadjusted CY 2014 and CY 2015 ESRD PPS base rate (that is, $239.02), yielding a proposed CY 2015 ESRD PPS wage-index budget-neutrality adjusted base rate of $239.33 ($239.02 × 1.001306 = $239.33).

d. Labor-Related Share

As discussed in section II.2.e, as part of the proposed ESRDB market basket rebasing and revision, we are proposing to update the labor-related share value from 41.737 percent to 50.673 percent. We note that some ESRD facilities are adversely affected by this proposal. For example, rural facilities and facilities located in CBSA areas with wage indexes below 1 will experience reduced payments due to an increase in the labor-related share, while other facilities located in CBSA area where wage indices are above 1 will experience increased payments. While we are proposing the new labor-related share under the ESRD PPS payment system computed at 50.673 percent, we propose to implement this value using a 2-year 50/50 blend transition.

Therefore, for CY 2015 we propose to apply 50 percent of the value of the current labor-related share under the ESRD PPS (41.737) and 50 percent of the value of the new labor-related share, (50.673), add the values together and divide by two, for a CY 2015 labor-related value of 46.205 ((41.737 + 50.673)/2 = 46.205). Beginning in CY 2016 we propose to apply 100 percent of the proposed labor-related share value of 50.673 percent. We propose to continue to apply a labor-related share value of 50.673 percent until such time in the future the ESRDB market basket is again rebased in computing a wage index-adjusted base rate for ESRD facilities. We believe that this approach is similar to the 50/50 blend transition proposed for the CY 2015 wage indexes and discussed in section II.3.c of this rule and that a 2- year transition is necessary to allow ESRD facilities time to adjust to the new labor related-share value.

We note that we considered implementing the computed labor related share value of 50.673 for CY 2015, but that would have increased the CY 2015 proposed wage index budget neutrality factor to 1.002081. This increase would have resulted in a decrease in CY 2015 Medicare payments to rural facilities of 1.3 percent, and an increase to urban facilities 0.5 percent. When we apply the transition labor-related share value of 46.205, the disparity in impacts for rural and urban facilities is reduced to less than 1.0 percent. Specifically, rural facilities would experience a decrease in payments of 0.5 percent and urban facilities would experience an increase in payments of 0.4 percent. (For more information of the CY 2015 Impact of Proposed Changes in Payments to ESRD Facilities for CY 2015 ESRD proposed rule, see section XV of this rule). Therefore, we believe a 2-year transition strikes an appropriate balance between ensuring that ESRD PPS payments are as accurate and stable as possible while giving facilities time to adjust to the new labor-related share factor.

In summary, we propose a CY 2015 ESRD PPS base rate update of $239.33. This reflects a 0.0 percent payment update consistent with section 1881(b)(14)(F)(i)(III), as added by section 217(b)(2) of PAMA. This base rate reflects the CY 2015 proposed wage index budget neutrality factor of 1.001306, and a labor-related share value of 46.205.

2. ESRD Bundled Market Basket and Labor-Related Share

a. Background

In accordance with section 1881(b)(14)(F)(i) of the 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 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.

In the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162), we established an ESRD Bundled market basket using CY 2008 as the base year. This market basket was used to annually update the ESRD base rate payments for CY 2012, CY 2013, and CY 2014. In this CY 2015 ESRD PPS proposed rule, we are proposing to revise and rebase the ESRDB market basket to a base year of CY 2012. We note that PAMA dictates a market basket update for CY 2015 of 0.0 percent and a reduction to the market basket updates in CYs 2016 through 2018 (by 1.25 percentage points for each of 2016 and 2017 and by 1 percentage point for 2018).

The term ''market basket'' refers to the mix of goods and services needed to produce ESRD care, and is also commonly used to denote the input price index that includes both weights (mix of goods and services) and price factors. The term ''ESRDB market basket'' as used in this proposed rule refers to the ESRDB input price index.

The proposed CY 2012-based ESRDB market basket represents the costs of operating and capital-related costs. The percentage change in the ESRDB market basket reflects the average change in the price of a fixed set of goods (both operating and capital) and services purchased by ESRD facilities in providing renal dialysis services. For further background information, see the CY 2011 final rule with comment period (75 FR 49151 through 49162).

For purposes of the ESRDB PPS, the ESRDB market basket is a fixed-weight (Laspeyres-type) price index. A Laspeyres-type index compares the cost of purchasing a specified mix of goods and services in a selected base period to the cost of purchasing that same group of goods and services at current prices. The effects on total expenditures resulting from changes in the quantity or mix of goods and services purchased subsequent or prior to the base period are, by design, not considered.

We construct the market basket in three steps. The first step is to select a base period and estimate total base period expenditure shares for mutually exclusive and exhaustive spending categories. We use total costs for operating and capital expenses. These shares are called ''cost'' or ''expenditure'' weights. The second step is to match each expenditure category to a price/wage variable, called a price proxy. We draw these price proxy variables from publicly available statistical series published on a consistent schedule, preferably at least quarterly. The final step involves multiplying the price series for each spending category by the cost weight for that category. The sum of these products (that is, weights multiplied by proxy index levels) for all cost categories yields the composite index level of the market basket for a given quarter or year. Repeating the third step for other quarters and years produces a time series of market basket index levels, from which we can calculate rates of growth.

The market basket represents a fixed-weight index because it answers the question of how much more or less it would cost, at a later time, to purchase the same mix of goods and services that was purchased in the base period.

We are proposing to use CY 2012 as the base year for the proposed rebased and revised ESRDB market basket cost weights. The cost weights for this proposed ESRDB market basket are based on the cost report data for independent ESRD facilities. We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2012 = 100. Source data included CY 2012 Medicare cost reports (Form CMS–265–11), supplemented with 2012 data from the U.S. Census Bureau's Services Annual Survey (SAS). Medicare cost reports from hospital-based ESRD providers were not used to construct the proposed ESRDB market basket because data from independent ESRD facilities tend to better reflect the actual cost structure faced by the ESRD facility itself, and are not influenced by the allocation of overhead over the entire institution, as can be the case with hospital-based providers. This approach is consistent with our standard methodology used in the development of other market baskets.

Consistent with our discussion in the CY 2011 final rule with comment period

(75 FR 49153), and as further discussed below, to implement section 1881(b)(14)(F)(i) of the Act we propose to revise and rebase the market basket so the cost weights and price proxies reflect the mix of goods and services that underlie ESRD bundled operating and capital costs for CY 2012.

b. Rebasing and Revision of the ESRD Bundled Market Basket

The terms ''rebasing'' and ''revising'', while often used interchangeably, actually denote different activities. Rebasing means shifting the base year for the structure of costs of the input price index (for example, for this proposed rule, we propose to shift the base year cost structure from CY 2008 to CY 2012). Revising means changing data sources, cost categories, price proxies, and/or methodology used in developing the input price index. We are proposing both to rebase and revise the ESRDB market basket to reflect CY 2012 total cost data.

We selected CY 2012 as the new base year because 2012 is the most recent year for which relatively complete Medicare cost report (MCR) data are available. In developing the proposed market basket, we reviewed ESRD expenditure data from ESRD MCRs (CMS Form 265–11) for CY 2012 for each freestanding ESRD facility that reported expenses and payments. The CY 2012 cost reports are those with cost reporting periods beginning on or after January 1, 2012 and before December 31, 2012. We propose to maintain our policy of using data from freestanding ESRD facilities because freestanding ESRD data reflect the actual cost structure faced by the ESRD facility itself. In contrast, expense data for a hospital-based ESRD reflect the allocation of overhead over the entire institution. Due to this method of allocation, the expenses of each hospital-based component may be skewed.

We developed cost category weights for the proposed CY 2012-based ESRDB market basket in two stages. First, we derived base weights for nine major categories (Wages and Salaries, Employee Benefits, Medical Supplies, Lab Services, Housekeeping & Operations, Pharmaceuticals, Administrative and General, Capital-Related Building & Fixed Equipment, and Capital-Related Machinery) from the ESRD MCRs. Second, we are proposing to divide the Administrative & General cost category into further detail using 2012 U.S. Census Bureau Services Annual Survey (SAS) Data for the industry Kidney Dialysis Centers (NAICS 621492). We apply the 2012 distributions from the SAS data to the 2012 ''Administrative & General'' cost weight to yield the more detailed 2012 cost weights. This is similar to the methodology we used to break the 2008-based Administrative & General Costs into more detail for the ESRDB market basket as detailed in the CY 2011 ESRD final rule (75 FR 49154 through 49159). The main difference is that in the 2008-based market basket we relied on data from the U.S. Census Bureau Business Expenses Survey (BES). The BES data was the predecessor to the SAS. The Census Bureau SAS data are published annually, with the most recent data available being 2012. For more information on the SAS data, see *http://www.census.gov/services/sas/about_the_surveys.html*.

We are proposing to include a total of 20 detailed cost categories for the proposed CY 2012-based ESRDB market basket, which is four more cost categories than the CY 2008-based ESRDB market basket. In addition, we are proposing to further decompose both the Wages and Salaries and Employee Benefits cost categories into four more detailed cost categories reflecting the occupational mix of full time equivalents (FTEs) at ESRD facilities. The four detailed occupational categories that will underlie both Wages and Salaries and Employee Benefits are: (1) Health-related workers; (2) Management workers; (3) Administrative workers; and (4) Service workers. Having more detailed cost categories for these compensation costs enables them to be proxied more precisely. We are also proposing to collapse the Professional Fees and All Other Services cost categories into single categories rather than splitting those categories into Labor-Related and Non-Labor-Related Services. We will continue to assume that 87 percent of Professional Fees are labor-related costs and will be included in the proposed labor-related share. In addition, we are proposing to revise our labels for All Other Materials to Medical Materials and Supplies, Laboratories to Lab Services, and All Other Labor-Related/Non Labor-Related to All Other Goods and Services. A more thorough discussion of our proposals is provided below.

i. Cost Category Weights

Using Worksheets A and B from the CY 2012 Medicare cost reports, we first computed cost shares for nine major expenditure categories: Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Lab Services, Administrative and General (A&G), Housekeeping and Operations, Capital-Related Building & Equipment, and Capital-Related Machinery. Edits were applied to include only cost reports that had total costs greater than zero. In order to reduce potential distortions from outliers in the calculation of the cost weights for the major expenditure categories, cost values for each category less than the 5th percentile or greater than the 95th percentile were excluded from the computations. The resulting data set included information from approximately 4,700 independent ESRD facilities' cost reports from an available pool of 5,333 cost reports. Expenditures for the nine cost categories as a proportion of total expenditures are shown in Table 1.

Table 1 presents the proposed CY 2012-based ESRDB and CY 2008-based ESRDB market basket major cost weights as derived directly from the MCR data. Following the table, we describe the sources of the major category weights and their subcategories in the proposed CY 2012-based ESRDB market basket.

TABLE 1—PROPOSED CY 2012-BASED ESRDB MARKET BASKET MAJOR COST WEIGHTS

Cost category	Proposed CY 2012-based ESRDB market basket	CY 2008-based ESRDB market basket
Wages and Salaries	31.839%	26.338%
Employee Benefits	6.570%	5.163%
Pharmaceuticals	16.510%	26.358%
Supplies	10.097%	9.726%
Lab Services	1.532%	0.356%
Housekeeping & Operations	3.785%	3.604%
Administrative & General (residual)	17.419%	17.594%
Capital-related Building & Fixed Equipment	8.378%	7.910%

TABLE 1—PROPOSED CY 2012-BASED ESRDB MARKET BASKET MAJOR COST WEIGHTS—Continued

Cost category	Proposed CY 2012-based ESRDB market basket	CY 2008-based ESRDB market basket
Capital-related Machinery	3.870%	2.951%

Note: Totals may not sum to 100.000% due to rounding.

Some costs are reported on the Medicare cost report but are not included in the ESRD bundled payment. For example, we removed the expenses related to vaccine costs from total expenditures since these are excluded from the ESRD bundled payment, but reported on the Medicare cost report.

We are proposing to expand the expenditure categories developed from the Medicare cost reports to allow for more detailed expenditure decomposition. To expand these cost categories, SAS data were used because the Medicare cost reports do not collect detailed information on the items of interest. Those categories include: benefits for all employees, professional fees, telephone, utilities, and all other goods and services. We chose to separately break out these categories to more accurately reflect ESRD facility costs. We describe below how the initially computed categories and weights from the cost reports were modified to yield the final 2012 ESRDB market basket expenditure categories and weights presented in this proposed rule.

Wages and Salaries

The weight for wages and salaries for direct patient care for 2012 was initially derived from Worksheet B of the Medicare cost report. However, because the cost center for direct patient care salaries does not include all other wage and salary costs for non-health workers and physicians, it was necessary to derive a methodology to include all salaries, not just direct patient care salaries, in order to calculate the appropriate market basket cost weight. This was accomplished in the following steps.

(1) From the trial balance of the cost report (Worksheet A), we computed the ratio of salaries to total costs in each of the following cost centers: housekeeping and operations, employee benefits for direct patient care, Administrative & General, Supplies, Laboratories, and Pharmaceuticals.

(2) We then multiplied the ratios computed in step 1 by the total costs for each corresponding cost center from Worksheet B. This provided us with an estimate of salaries other than direct-patient care for each cost center.

(3) The estimated salaries for each of the cost centers on Worksheet B estimated in step 2 were subsequently summed and added to the direct patient care salary figure (resulting in a new total salaries figure).

(4) The estimated non-direct patient care salaries (see step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

As a result of this process, we moved from an estimated Wages and Salaries cost weight of 23.242 percent (as estimated using only direct patient care salaries as a percent of total costs) to a weight of 31.839 percent (capturing both direct patient care salaries and all other salary costs and, again, dividing that by total costs found on the Medicare cost report), as seen in Table 2.

The final adjustment made to this category is to include contract labor costs. These costs appear on the Medicare cost report; however, they are embedded in the Administrative and General category and cannot be disentangled using the Medicare cost reports alone. To move the appropriate expenses from the A&G category to Wages and Salaries, we used data from the 2012 SAS, which reported 2.3 of total expenses were spent on contract labor costs. We allocated 80 percent of that figure to Wages and Salaries. At the same time, we subtracted that same amount from A&G, where the contract labor expenses would be reported on the cost report. The 80 percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor) from the 2012 MCR data. The resulting cost weight for Wages and Salaries increases to 33.650 percent.

TABLE 2—ESRD WAGES & SALARIES SHARE DETERMINATION

Components	Cost share (%)
08 MCR Salaries Direct Patient Care (DPC)	22.297
08 MCR Additional Salaries Weight (other than DPC)	4.041
08 Wage & Salary Weight normalized after adding separately billable services into the bundle	−1.373
08 Contract Labor (wages) (80% of BES CL share)	1.790
08 Final Wage & Salary Weight	26.755
12 MCR Salaries Direct Patient Care (DPC)	23.242
12 MCR Additional Salaries Weight (other than DPC)	8.597
12 Contract Labor (80% of SAS CL share)	1.811
12 Final Wage & Salary Weight	33.650

Benefits

The Benefits weight was derived from the MCR data for employee benefits for direct patient care and supplemented with data from the 2012 SAS to account for non-direct patient care benefits. The cost report only reflects health-related benefit costs associated with direct patient care; that is, it does not reflect retirement benefits. In order to include the benefits related to non-direct patient care, we estimated this marginal increase from the SAS Benefits weight. Unlike the MCR, data the SAS benefits share includes expenses related to the retirement and pension benefits. In order to be consistent with the cost report definitions we do not want to include the costs associated with retirement and pension benefits in the cost share weights. These costs are relatively small compared to the costs for the health related benefits, accounting for only 2.7 percent of the total benefits costs as reported on the SAS. Our method produced a Benefits

(both direct patient care and non-direct patient care) weight that was 1.824 percentage points larger (8.394 vs. 6.570) than the Benefits weight for direct patient care calculated directly from the cost reports. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.824 percentage point for Benefits from the residual category.

The final adjustment made to this category is to include contract labor costs. Once again, these costs appear on the Medicare cost report; however, they are embedded in the Administrative and General category and cannot be disentangled using the Medicare cost report alone. We applied 20 percent of total contract labor costs, as estimated using the SAS, to the Benefits cost weight calculated from the cost reports. The resulting cost weight for Benefits increases to 8.847 percent.

The Table 3 compares the 2008-based Benefits cost share derivation as detailed in the CY 2011 ESRD final rule (75 FR 49155–49156) to the proposed 2012-based Benefits cost share derivation as explained above.

TABLE 3—ESRD BENEFIT SHARE DETERMINATION

Components	Cost share (percent)
08 MCR Benefits	5.163
08 BES Additional Benefits Weight (Health only)	1.143
08 Contract Labor (20% of BES benefits share)	0.448
08 Final Benefit Weight	6.754
12 MCR Benefits	6.570
12 SAS Additional Benefits Weight (Health only)	1.824
12 Contract Labor (20% of SAS benefits share)	0.453
12 Final Benefit Weight	8.847

Utilities

We developed a weight for Utility expenses using the 2012 SAS data, as utilities are not separately identified on the Medicare cost report. The SAS data reports the percentage of expenses for 'purchased fuels (except motor fuels)', 'purchased electricity', and 'water, sewer, refuse, and other utilities.' We applied these ratios to the administrative and general cost share (net of contract labor and additional benefits). The resulting Electricity, Fuel (Natural Gas), and Water and Sewerage weights in the proposed 2012 ESRDB market basket are 0.973, 0.101, and 0.765 percent, respectively; together these categories yield a combined Utilities cost weight of 1.838 percent.

Pharmaceuticals

The proposed ESRDB market basket includes expenditures for all drugs, including formerly separately billable drugs and ESRD-related drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We were able to calculate an expenditure weight for pharmaceuticals directly from the following cost centers on Worksheet B: columns 11 'Drugs Included in Composite Rate'; 12 'ESAs'; 13 'ESRD-Related Drugs; and drug expenses reported on line 5 column 10, 'Non-ESRD related drugs.' The Non-ESRD related drugs would include drugs and biologicals, administered during dialysis for non-ESRD related conditions as well as oral-only drugs. Since these are costs to the facility for providing ESRD treatment to the patient we propose to include them in the drug cost share weight. Vaccine expenditures, which are mandated as separately reimbursable, were excluded when calculating this cost weight. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these drugs are excluded from other prospective payment systems, we exclude them from the proposed ESRDB market basket, as well.

Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of non-direct patient care salaries and benefits associated with the applicable drug cost centers referenced above. This resulted in a proposed ESRDB market basket weight for Pharmaceuticals of 16.510 percent. ESA expenditures accounted for 12.383 percentage points of the Pharmaceuticals weight, and all other drugs accounted for the remaining 4.127 percentage points (.438 percent for Drugs Included in Composite Rate, 3.534 percent for ESRD-Related Drugs, and 0.155 percent for Non-ESRD related drugs).

The 9-percentage point decrease in the pharmaceutical share between 2008 and 2012 (25.052 percent to 16.510 percent) is due largely to the drop in drug utilization. The drug percentage of the base rate used in 2011 was about 31 percent; however, the analysis conducted for the drug utilization adjustment showed that the drug portion of the base rate in 2014 would have fallen to only be 22 percent of the base rate had it been fully implemented. The cost report data corroborate the drop in drug costs for facilities over the same time frame.

Supplies

We calculated the weight for Supplies included in the bundled rate using the costs reported in the Supplies cost center (column 7 on Worksheet B) of the Medicare cost report. This total was divided by total expenses to derive a weight for the Supplies component in the ESRDB market basket. Finally, to avoid double-counting, the weight for the Supplies category was reduced to exclude the estimated share of non-direct patient care salaries and benefits associated with this cost center. The resulting proposed 2012-based ESRDB market basket weight for Supplies is 10.097 percent.

Lab Services

We calculated the weight for Lab Services included in the bundled rate using the costs reported in the Laboratory cost center (column 8 on Worksheet B) of the Medicare cost report. This total was divided by total expenses to derive a weight for the Lab component in the ESRDB market basket. Finally, to avoid double-counting, the weight for the Lab services category was reduced to exclude the estimated share of non-direct patient care salaries and benefits associated with this cost center. The resulting proposed 2012-based ESRDB market basket weight for Lab Services is 1.532 percent.

The cost weight for lab services is substantially lower than the 2008 ESRDB market basket lab weight of 5.497 percent. This is due to the change in the method used to determine lab costs. In 2008, we relied on MCR data for the cost share weight; however, the majority of lab services were performed by labs outside of the dialysis facility and those costs were not reported on the MCR. Therefore, in the 2008 ESRDB market basket we inflated the expenses reported for labs in ESRD facilities to reflect the use from other provider types. This adjustment factor was estimated based on the lab payment to dialysis facilities relative to the lab fee payment to other providers. For the rebased ESRDB market basket, the 2012 cost report data represents the expenses under the bundled payment system, and all of the expenses related to lab fees (whether in house or contracted through an outside lab) are reported in the MCR data.

Housekeeping & Operations

We calculated the weight for Housekeeping and Operations included in the bundled rate using the costs reported on worksheet A, column 8,

lines 3 & 4 of the Medicare Cost Report. This total was divided by total expenses to derive a weight for the Housekeeping and Operations component in the ESRDB market basket. Finally, to avoid double-counting, the weight for the Housekeeping & Operations category was reduced to exclude the estimated share of non-direct patient care salaries and benefits associated with this cost center. The resulting proposed 2012-based ESRDB market basket weight for Housekeeping and Operations is 3.785 percent.

Administrative and General (A&G)

We computed the proportion of total A&G expenditures using the A&G cost center data from Worksheet B (column 9) of the Medicare cost reports. As described above, we exclude contract labor from this cost category and apportion these costs to the salary and benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude salaries and benefits associated with the A&G cost center and the additional benefits for non-direct patient care. The resulting A&G cost weight is 13.331 percent. This A&G cost weight is then fully apportioned to derive detailed cost weights for Utilities, Telephone, Professional Fees, and All Other Goods and Services.

Professional Fees

A separate weight for Professional Fees was developed using the 2012 SAS data. Professional fees include fees associated with the following: purchased professional & technical services (such as accounting, bookkeeping, legal, management, consulting, and other professional services fees) and purchased advertising & promotional services. To estimate professional fees, we first calculated the ratio of SAS professional fees to SAS expenses that match the A&G expenses from the cost reports. We then applied this ratio to the A&G total cost weight to estimate the proportion of ESRD facility professional fees. The resulting weight for the proposed 2012-based ESRDB market basket is 0.617 percent. An estimated 87 percent of the expenses are considered labor-related and subsequently included in the proposed labor-related share, which is described in more detail below.

Telephone

Because telephone service expenses are not separately identified on the Medicare cost report, we developed a Telephone Services weight using the 2012 SAS expenses. We estimated a ratio of telephone services expenses to total administrative and general expenses from SAS. We applied this ratio to the total A&G cost weight from the cost reports to estimate the proportion of ESRD facility telephone expenses. The resulting proposed 2012-based ESRDB market basket cost weight for Telephone Services is 0.468 percent.

All Other Goods and Services

A separate weight for All Other Goods and Services was developed using the 2012 SAS data. All other Goods and Services include expenses for purchased software, professional liability insurance, data processing and other purchased computer services, and all other operating expenses not otherwise captured. We estimated a ratio of All Other Goods and Services expenses to Total Administrative and General expenses from SAS. We then applied this ratio to the total A&G cost weight from the cost reports to estimate the cost weight for ESRD facility All Other Goods and Services. The resulting proposed 2012-based ESRDB market basket cost weight for All Other Goods and Services is 10.407 percent.

Capital

We developed a market basket weight for the Capital category using data from Worksheet B of the Medicare cost reports. Capital-related costs include depreciation and lease expense for buildings, fixtures, movable equipment, property taxes, insurance, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. Because housekeeping as well as operation & maintenance costs are included in the Worksheet B cost center for Capital-Related costs (Worksheet B, column 2), we excluded the costs for these two categories and developed a separate expenditure category for housekeeping & operations, as detailed above. Similar to the methodology used for other market basket cost categories with a salaries component, we computed a share for non-direct patient care salaries and benefits associated with the Capital-related Machinery cost center. We used Worksheet B to develop two capital-related cost categories, one for Buildings and Equipment (based on worksheet B column 2 less housekeeping & operations), and one for Machinery (based on worksheet B column 4). We reasoned this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Equipment could move differently than those associated with Machinery, we felt that separate price proxies would be more appropriate. The resulting proposed 2012-based ESRDB market basket weights for Capital-related Buildings and Equipment and Capital-related Machinery are 8.378 and 3.870 percent, respectively.

Table 4 lists all of the cost categories and cost weights in the proposed CY 2012 ESRDB market basket compared to the cost categories and cost weights in the CY 2008 ESRDB market basket.

TABLE 4—COMPARISON OF THE PROPOSED CY 2012–BASED ESRDB MARKET BASKET COST CATEGORIES & WEIGHTS AND THE CY 2008–BASED ESRDB MARKET BASKET COST CATEGORIES & WEIGHTS.

2008 Cost category	2008 Cost weight (percent)	Proposed 2012 cost weight (percent)	Proposed 2012 cost category
Total	100.000	100.000	Total.
Compensation	33.509	42.497	Compensation.
Wages and Salaries	26.755	33.650	Wages and Salaries.
Employee Benefits	6.754	8.847	Employee Benefits.
Utilities	1.264	1.839	Utilities.
Electricity	0.621	0.973	Electricity.
Natural Gas	0.127	0.101	Natural Gas.
Water and Sewerage	0.516	0.765	Water and Sewerage.
All Other Materials	39.765	28.139	Medical Materials and Supplies.
Pharmaceuticals	25.052	16.510	Pharmaceuticals.
Supplies	9.216	10.097	Supplies.

TABLE 4—COMPARISON OF THE PROPOSED CY 2012–BASED ESRDB MARKET BASKET COST CATEGORIES & WEIGHTS AND THE CY 2008–BASED ESRDB MARKET BASKET COST CATEGORIES & WEIGHTS.—Continued

2008 Cost category	2008 Cost weight (percent)	Proposed 2012 cost weight (percent)	Proposed 2012 cost category
Lab Services	5.497	1.532	Lab Services.
All Other Services	15.929	15.277	All Other Goods and Services.
Telephone	0.597	0.468	Telephone Service.
Housekeeping and Operations	2.029	3.785	Housekeeping and Operations.
Labor-Related Services	2.768		
Prof. Fees: Labor-related	1.549	0.617	Professional Fees (Labor-related and NonLabor-related services).
All Other Labor-related	1.219		
NonLabor-Related Services	10.535	10.407	All Other Goods and Services.
Prof. Fees: Nonlabor-related	0.224		
All Other Nonlabor-related	10.311		
Capital Costs	9.533	12.248	Capital Costs.
Capital Related-Building and Equipment	7.459	8.378	Capital Related-Building and Equipment.
Capital Related-Machinery	2.074	3.870	Capital Related-Machinery.

Note: Totals may not sum to 100.000 percent due to rounding.

ii. Proposed Price Proxies for the CY 2012 ESRDB Market Basket

After developing the cost weights for the proposed CY 2012-based ESRDB market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. We base the price proxies on Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the North American Classification System (NAICS) and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs were available.

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

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 7 lists all price proxies for the proposed revised and rebased ESRDB market basket. Below is a detailed explanation of the price proxies used for each cost category weight.

Wages and Salaries

We will continue using an ECI blend for wages and salaries in the proposed 2012-based ESRDB market basket. However, we are proposing to expand the number of occupation categories and associated ECIs from two to four based on FTE data from ESRD Medicare Cost Reports and the availability of ECIs from BLS. We calculated weights for the Wages and Salaries sub-categories using 2012 FTE data and associated 2012 Average Mean Wage data from the Bureau of Labor Statistics' Occupational Employment Statistics.

Wages and Salaries—Health Related

We are proposing to continue using the ECI for Wages & Salaries for Hospitals (All Civilian) (BLS series code #CIU1026220000000I). Of the two health-related ECIs that we considered (''Hospitals'' and ''Health Care and Social Assistance''), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the

Health Care and Social Assistance NAICS sector (62).

The Wages and Salaries—Health Related subcategory weight within the Wages and Salaries cost category is 80percent. The ESRD Medicare Cost Report FTE categories used to define the Wages and Salaries—Health Related subcategory include ''Physicians,'' ''Registered Nurses,'' ''Licensed Practical Nurses,'' ''Nurses' Aides,'' ''Technicians,'' and ''Dieticians.''

The current 2008-based ESRD Market Basket uses the ECI for Wages & Salaries for Hospitals (All Civilian) for 50 percent of Wages and Salaries.

Wages and Salaries—Management

We propose using the ECI for Wages & Salaries for Management, Business, and Financial (Private Industry) (BLS series code #CIU2020000110000I). We feel this ECI is the most appropriate price proxy to measure the price growth of management functions at ESRD facilities. Furthermore, we regularly use this ECI-wages for management, business, and financial in our other market baskets, such as the MEI.

The Wages and Salaries—Management subcategory weight within the Wages and Salaries cost category is 8 percent. The ESRD Medicare Cost Report FTE category used to define the Wages and Salaries—Management subcategory is ''Management.''

Wages and Salaries—Administrative

We propose using the ECI for Wages & Salaries for Office and Administrative Support (Private Industry) (BLS series code #CIU2020000220000I). We feel this ECI is the most appropriate price proxy to measure the price growth of administrative support at ESRD facilities. Furthermore, we regularly use this ECI for administrative wages in our other market baskets, such as the MEI.

The Wages and Salaries—Administrative subcategory weight within the Wages and Salaries cost category is 7 percent. The ESRD Medicare Cost Report FTE category used to define the Wages and Salaries—Administrative subcategory is ''Administrative.''

Wages and Salaries—Services

We propose using the ECI for Wages & Salaries for Service Occupations (Private Industry) (BLS series code #CIU2020000300000I). We feel this ECI is the most appropriate price proxy to measure the price growth of all other non-health related, non-management, and non-administrative service support at ESRD facilities. Furthermore, we regularly use this ECI for all other service wages in our other market baskets, such as the MEI.

The Wages and Salaries—Services subcategory weight within the Wages and Salaries cost category is 6 percent. The ESRD Medicare Cost Report FTE categories used to define the Wages and Salaries—Services subcategory are ''Social Workers'' and ''Other.''

Table 5 lists the four ECI series and the corresponding weights used to construct the proposed ECI blend for wages and salaries. We feel this new ECI blend is the most appropriate price proxy to measure the growth of wages and salaries faced by ESRD facilities.

TABLE 5—ECI BLEND FOR WAGES AND SALARIES IN THE PROPOSED 2012 BASED ESRDB MARKET BASKET

Cost category	ECI Series	Weight (%)
Wages and Salaries—Health Related	ECI—Wages & Salaries—Hospital (All Civilian)	80
Wages and Salaries—Management	ECI—Wages & Salaries—Management, Business, and Financial (Private Industry).	7
Wages and Salaries—Administrative	ECI—Wages & Salaries—Office and Administrative Support (Private Industry)	7
Wages and Salaries—Services	ECI—Wages & Salaries—Service Occupations (Private Industry)	6

The current 2008-based ESRDB market basket uses a 50 percent/50 percent blend of the ''ECI—Wages & Salaries—Hospital (All Civilian)'' and the ''ECI—Wages and Salaries—Healthcare and Social Assistance'' for the wages and salaries ECI blend.

Benefits

We will continue using an ECI blend for Benefits in the proposed 2012-based ESRDB market basket; however, we are proposing to expand the number of occupation categories and associated ECIs from two to four based on the components of the proposed Wage and Salaries ECI blend.

Benefits—Health Related

We are proposing to continue using the ECI for Benefits for Hospitals (All Civilian) to measure price growth of this subcategory. The ECI for Benefits for Hospitals is calculated using the ECI for Total Compensation for Hospitals (BLS series code # CIU1016220000000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the wages and salaries price proxy section.

Benefits—Management

We propose using the ECI for Benefits for Management, Business, and Financial (Private Industry) to measure price growth of this subcategory. The ECI for Benefits for Management, Business, and Financial is calculated using the ECI for Total Compensation for Management, Business, and Financial (BLS series code # CIU2010000110000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the wages and salaries price proxy section.

Benefits—Administrative

We propose using the ECI for Benefits for Office and Administrative Support (Private Industry) to measure price growth of this subcategory. The ECI for Benefits for Office and Administrative Support is calculated using the ECI for Total Compensation for Office and Administrative Support (BLS series code # CIU2010000220000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the wages and salaries price proxy section.

Benefits—Services

We propose using the ECI for Benefits for Service Occupations (Private Industry) to measure price growth of this subcategory. The ECI for Benefits for Service Occupations is calculated using the ECI for Total Compensation for Service Occupations (BLS series code # CIU2030000300000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the wages and salaries price proxy section.

We feel the new benefits ECI blend is the most appropriate price proxy to measure the growth of prices faced by

ESRD facilities. Table 6 lists the four ECI series and the corresponding weights used to construct the proposed benefits ECI blend.

TABLE 6—BENEFITES ECI BLEND IN THE PROPOSED 2012–BASED ESRDB MARKET BASKET

Cost category	ECI Series	Weight (%)
Benefits—Health Related	ECI—Benefits—Hospital (All Civilian)	80
Benefits—Management	ECI—Benefits—Management, Business, and Financial (Private Industry)	7
Benefits—Administrative	ECI—Benefits—Office and Administrative Support (Private Industry)	7
Benefits—Services	ECI—Benefits—Service Occupations (Private Industry)	6

The current 2008-based ESRDB market basket uses a 50 percent/50 percent blend of the ''ECI—Benefits—Hospital (All Civilian)'' and the ''ECI—Benefits—Healthcare and Social Assistance'' for the benefits ECI blend.

Electricity

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

Natural Gas

We propose to continue using the PPI for Commercial Natural Gas (BLS series code #WPU0552) to measure the price growth of this cost category. This is the same proxy used in the current 2008-based ESRDB market basket.

Water and Sewerage

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

Pharmaceuticals

We propose to change the price proxy used for the pharmaceuticals cost category. A recent Health and Human Services Office of the Inspector General (OIG) report titled ''Update: Medicare Payment for End Stage Renal Disease Drugs'' recommended that CMS consider updating the ESRD payment bundle using a factor that takes into account drug acquisition costs. CMS had responded to this recommendation by stating that we would consider these findings in the continual evaluation of the ESRD market basket, particularly during the next rebasing and revising of the market basket index.[1]

Drug acquisition cost data is neither publicly available nor the methods used to determine it transparent, and, therefore, wouldn't meet our price proxy criteria of relevance, reliability, transparency, and public availability. However, after considering several viable options that do meet the criteria we are proposing to use the PPI: Vitamin, Nutrient, and Hematinic Preparations (BLS series code #WPU063807). This index includes drugs that are most similar to ESAs and other drugs used in the ESRD setting, such as iron supplements. The definition of a hematinic is a medicine that increases the hemoglobin content of the blood, and these types of drugs are used to treat iron-deficiency anemia essential for normal erythropoiesis.

We believe the PPI: Vitamin, Nutrient, and Hematinic Preparations to be the most technically appropriate index available to measure the price growth of the pharmaceuticals cost category in the proposed 2012-based ESRDB market basket. The current 2008-based ESRDB market basket uses the PPI: Pharmaceuticals for Human Use.

Supplies

We propose using the PPI for Surgical and Medical Instruments (BLS series code #WPU1562) since it excludes orthopedic, prosthetic, ophthalmic, and dental type medical equipment and devices, which are not likely to be used extensively in the ESRD setting. The types of equipment under Surgical and Medical Instruments, particularly blood transfusion and IV equipment, seem most similar to the medical equipment and supplies that would be used in the ESRD setting. The current 2008-based ESRDB market basket uses the PPI for Medical, Surgical, and Personal Aid Devices.

Lab Services

We propose to continue using the PPI for Medical Laboratories (BLS series code #PCU621511621511) to measure the price growth of this cost category. This is the same proxy used in the current 2008-based ESRDB market basket.

Telephone Service

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

Housekeeping and Operations

We propose to continue using the PPI for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category. This is the same proxy used in the current 2008-based ESRDB market basket.

Professional Fees

We propose to continue using the ECI (Compensation) for Professional and Related Occupations (Private Industry) (BLS series code # CIU2010000120000I) to measure the price growth of this cost category. This is the same proxy used in the current 2008-based ESRDB market basket.

All Other Goods and Services

We propose using the PPI for Finished Goods less Foods and Energy (BLS series code #WPUFD4131) as the price proxy for the All Other Goods and Services cost category. This PPI series is used in most of CMS' other market baskets to measure the expenses for the residual category of all other goods and services. It is more consistent with the purchase of items at a wholesale rather than a consumer level. The current 2008-based ESRDB market basket (specifically, the ''All Other Non Labor-Related Services'' cost category) uses the CPI–U, All Items less Foods and Energy.

Capital-Related Building and Equipment

We propose using the PPI for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120) as it represents the types of fixed capital expenses most likely faced by ESRD facilities. We also use this proxy in the MEI as the fixed capital proxy for physicians. We believe the PPI for Lessors of Nonresidential Buildings is more appropriate as fixed capital expenses in both the ESRD and physician office setting should be more congruent with trends in business office space costs rather than residential costs. The current 2008-based ESRDB market

[1] *http://oig.hhs.gov/oei/reports/oei-03-12-00550.asp.*

basket uses the CPI for Owners' Equivalent Rent of Residences.

Capital Related Machinery

We propose to continue using the PPI for Electrical Machinery and Equipment (BLS series code #WPU117) to measure the price growth of this cost category. This is the same proxy used in the current 2008-based ESRDB market basket.

Table 7 shows all the proposed price proxies for the proposed CY 2012-based ESRDB Market Basket.

TABLE 7—PROPOSED PRICE PROXIES FOR THE CY 2012-BASED ESRDB MARKET BASKET

Cost category	Price proxy	Cost weight %
Compensation		42.497
Wages and Salaries		33.650
Health-related Wages	ECI—Wages & Salaries—Hospital (Civilian)	26.920
Management Wages	ECI—Wages & Salaries—Management, Business, and Financial (Private)	2.356
Administrative Wages	ECI—Wages & Salaries—Office and Administrative Support (Private)	2.356
Service Wages	ECI—Wages & Salaries—Service Occupations (Private)	2.019
Employee Benefits		8.847
Health-related Benefits	ECI—Benefits—Hospital (Civilian)	7.078
Management Benefits	ECI—Benefits—Management, Business, and Financial (Private)	0.619
Administrative Benefits	ECI—Benefits—Office and Administrative Support (Private)	0.619
Service Benefits	ECI—Benefits—Service Occupations (Private)	0.531
Utilities		1.839
Electricity	PPI—Commercial Electric Power	0.973
Natural Gas	PPI—Commercial Natural Gas	0.101
Water and Sewerage	CPI—Water and Sewerage Maintenance	0.765
Medical Materials and Supplies		28.139
Pharmaceuticals	PPI—Vitamin, Nutrient, and Hematinic Preparations	16.510
Supplies	PPI—Surgical and Medical Instruments	10.097
Lab Services	PPI—Medical Laboratories	1.532
All Other Goods and Services		15.277
Telephone Service	CPI—Telephone Services	0.468
Housekeeping and Operations	PPI—Cleaning and Building Maintenance Services	3.785
Professional Fees	ECI—Compensation—Professional and Related Occupations (Private)	0.617
All Other Goods and Services	PPI—Finished Goods less Foods and Energy	10.407
Capital Costs		12.248
Capital Related Building and Equipment	PPI—Lessors of Nonresidential Buildings	8.378
Capital Related Machinery	PPI—Electrical Machinery and Equipment	3.870
Total		100.000

Note: Totals may not sum to 100.000% due to rounding.

iii. Proposed Market Basket Estimate for the CY 2015 ESRDB PPS Update

As discussed previously in this proposed rule, beginning with the CY 2015 ESRD PPS update, we are proposing to adopt the CY 2012-based ESRDB market basket as the appropriate market basket of goods and services for the ESRD PPS.

Based on the IHS Global Insight, Inc. (IGI) first quarter 2014 forecast with history through the fourth quarter of 2013, the most recent estimate of the proposed CY 2012-based ESRDB market basket for CY 2015 is 2.0 percent. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the CMS market baskets. Based on IGI's first quarter 2014 forecast with history through the fourth quarter of 2013, the estimate of the current CY 2008-based ESRDB market basket for CY 2015 is 2.7 percent.

Table 8 compares the proposed CY 2012-based ESRDB market basket and the CY 2008-based ESRDB market basket percent changes. For the historical period between CY 2011 and CY 2013, the average difference between the two market baskets is -1.8 percentage points. This is primarily the result of the lower pharmaceutical cost share combined with the proposed revised price proxy for the pharmaceutical cost category. For the CY 2014 and CY 2015 forecasts, the difference in the market basket forecasts are mainly driven by the same factors as in the historical period; however, it is important to note that the differences between the two market baskets are projected to be smaller as the growth in the price proxy for the pharmaceutical category are projected to grow at more similar growth rates in the projected period than the growth rates in the recent historical period.

TABLE 8—PROPOSED CY 2012-BASED ESRDB MARKET BASKET AND CY 2008 BASED ESRDB MARKET BASKET, PERCENT CHANGES: 2011–2015

Calendar Year (CY)	Proposed Rebased CY 2012-based ESRDB Market Basket	CY 2008-Based ESRDB Market Basket
Historical data.		
CY 2011	1.2	2.8
CY 2012	1.4	3.4
CY 2013	1.1	3.0
Average CY 2011–2013	1.3	3.1
Forecast:		
CY 2014	1.8	2.3

TABLE 8—PROPOSED CY 2012-BASED ESRDB MARKET BASKET AND CY 2008 BASED ESRDB MARKET BASKET, PERCENT CHANGES: 2011–2015—Continued

Calendar Year (CY)	Proposed Rebased CY 2012-based ESRDB Market Basket	CY 2008-Based ESRDB Market Basket
CY 2015	2.0	2.7

Source: IHS Global Insight, Inc. 1st quarter 2014 forecast with historical data through 4th quarter 2013.

c. 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 multifactor productivity (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. We note that the proposed and final methodology for calculating and applying the MFP adjustment to the ESRD payment update is similar to the methodology used in other payment systems, as required by section 3401 of the Affordable Care Act.

The projection of MFP is currently produced by IGI. The details regarding the methodology for forecasting MFP and how it is applied to the market basket were finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70234). Using this method and the IGI forecast for the first quarter of 2014 of the 10-year moving average of MFP, the CY 2015 MFP factor we would have proposed is 0.4 percent. As discussed further below, however, section 1881(b)(F)(i)(III) of the Act, as added by section 217(b)(2) of PAMA, requires the Secretary to implement a 0.0 percent payment update in CY 2015.

d. Calculation of the Proposed ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2015

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 2015, section 1881(b)(14)(F)(i)(III) of the Act, as added by section 217(b)(2) of PAMA, requires the Secretary to implement a 0.0 percent ESRDB market basket increase to the ESRD PPS base rate. In addition, we interpret the reference to ''[n]otwithstanding subclause (III)'' that was added to amended section 1881(b)(14)(F)(i)(III) as precluding the application of the multi-factor productivity (MFP) adjustment in 2015. As a result of these provisions, the proposed CY 2015 ESRD market basket increase is 0.0 percent. We note that if PAMA had not been enacted the proposed 2012-based ESRDB market basket update less productivity for CY 2015 would have been 1.6 percent, or 2.0 percent less 0.4 percentage point.

e. Labor-Related Share

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of Wages and Salaries, Benefits, Professional Fees, Labor-related Services, and a portion of the Capital share from a given market basket.

We propose to use the proposed 2012-based ESRDB market basket costs to determine the proposed labor-related share for ESRD facilities of 50.673 percent, as shown in Table 9 below. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, 87 percent of the weight for Professional Fees (details discussed below), and 46 percent of the weight for Capital-related Building and Equipment expenses (details discussed below). We note that this is a similar methodology used to compute the labor-related share used from CY 2011 through CY 2014.

TABLE 9—PROPOSED CY 2015 LABOR-RELATED SHARE AND CY 2014 ESRDB LABOR-RELATED SHARE

Cost category	Proposed CY 2015 ESRDB labor-related share (percent)	CY 2014 ESRDB labor-related share (percent)
Wages	33.650	26.755
Benefits	8.847	6.754
Housekeeping and operations	3.785	2.029
Professional fees (labor-related)	0.537	2.768
Capital labor-related	3.854	3.431
Total	50.673	41.737

The labor-related share for Professional Fees (87 percent) reflects the proportion of ESRD facilities' professional fees expenses that we believe vary with local labor market. We conducted a survey of ESRD facilities in 2008 to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD facility's local labor market. Thus, we are proposing to

include 87 percent of the cost weight for Professional Fees in the labor-related share, the same percentage as used in prior years.

The labor-related share for capital-related expenses (46 percent of ESRD facilities' adjusted Capital-related Building and Equipment expenses) reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages. Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

3. The Proposed CY 2015 ESRD PPS Wage Indices

a. Background

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. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized for the ESRD PPS the use of the Office of Management and Budget's (OMB) Core-Based Statistical Areas (CBSAs)-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.*

We also finalized that we would use the urban and rural definitions used for the Medicare IPPS but without regard to geographic reclassification authorized under section 1886(d)(8) and (d)(10) of the Act. In the CY 2012 ESRD PPS final rule (76 FR 70239), we finalized that, under the ESRD PPS, we will continue to utilize the ESRD PPS wage index methodology, first established under the basic case-mix adjusted composite rate payment system, for updating the wage index values using the OMB's CBSA-based geographic area designations to define urban and rural areas.

b. Proposed Implementation of New Labor Market Delineations

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 37246–37252) and Census Bureau data.'' In this CY 2015 ESRD PPS proposed rule, when referencing the new OMB geographic boundaries of statistical areas, we are using 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 proposed rule, we proposed to implement 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 28054 through 28055).

Similarly, in this CY 2015 ESRD PPS proposed rule, we are proposing to implement 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. We believe that the most current CBSA delineations accurately reflect the local economies and wage levels of the areas where facilities are located, and we believe that it is important for the ESRD PPS to use the latest CBSA delineations available in order to maintain an up-to-date payment system that accurately reflects the reality of populations shifts and labor market conditions. We have reviewed our findings and impacts relating to the new CBSA delineations using the most recent data available at the time of this proposed rule, and have concluded that there is no compelling reason to further delay the implementation of the CBSA delineations as set forth in OMB Bulletin 13–01.

In order to implement these changes for the ESRD PPS, it is necessary to identify the new labor market area delineation for each county and facility in the country. For example, if we adopt the new CBSA delineations, 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. Because the wage index of urban areas is typically higher than that of rural areas, ESRD facilities currently located in rural counties that would become urban if we adopt the new CBSA delineations would generally experience an increase in their wage index values. We have identified 105 counties and 113 facilities that would move from rural to urban status if we adopt the new CBSA delineations beginning in CY 2015. Table 10: (CY 2015 Proposed Rural to Urban CBSA Crosswalk) shows the CBSA delineations for CY 2014 and the rural wage index values proposed for CY 2015 based on those delineations, compared to the proposed CBSA delineations for CY 2015 and the proposed urban wage index values for CY 2015 based on the new delineations, and the percentage change in these values for those counties that would change from rural to urban if we adopt the new CBSA delineations. If we adopt the new OMB delineations illustrated in Table 10 below, approximately 100 facilities would experience an increase in their wage index values.

TABLE 10—CY 2015 PROPOSED RURAL TO URBAN CBSA CROSSWALK

County name	State	ESRD PPS CY 2014 CBSA delineations			Proposed ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
BALDWIN	AL	01	RURAL	0.6981	19300	URBAN	0.7279	4.27
PICKENS	AL	01	RURAL	0.6981	46220	URBAN	0.8288	18.72
COCHISE	AZ	03	RURAL	0.9159	43420	URBAN	0.8970	−2.06
LITTLE RIVER	AR	04	RURAL	0.7265	45500	URBAN	0.7390	1.72
WINDHAM	CT	07	RURAL	1.1292	49340	URBAN	1.1536	2.16
SUSSEX	DE	08	RURAL	1.0248	41540	URBAN	0.9296	−9.29
CITRUS	FL	10	RURAL	0.8010	26140	URBAN	0.7653	−4.46
GULF	FL	10	RURAL	0.8010	37460	URBAN	0.7861	−1.86
HIGHLANDS	FL	10	RURAL	0.8010	42700	URBAN	0.8011	0.01
SUMTER	FL	10	RURAL	0.8010	45540	URBAN	0.8125	1.44
WALTON	FL	10	RURAL	0.8010	18880	URBAN	0.8260	3.12
LINCOLN	GA	11	RURAL	0.7425	12260	URBAN	0.9213	24.08
MORGAN	GA	11	RURAL	0.7425	12060	URBAN	0.9358	26.03
PEACH	GA	11	RURAL	0.7425	47580	URBAN	0.7570	1.95
PULASKI	GA	11	RURAL	0.7425	47580	URBAN	0.7570	1.95
KALAWAO	HI	12	RURAL	0.9953	27980	URBAN	0.9510	−4.45
MAUI	HI	12	RURAL	0.9953	27980	URBAN	0.9510	−4.45
BUTTE	ID	13	RURAL	0.7425	26820	URBAN	0.8966	20.75
DE WITT	IL	14	RURAL	0.8363	14010	URBAN	0.8935	6.84
JACKSON	IL	14	RURAL	0.8363	16060	URBAN	0.8354	−0.11
WILLIAMSON	IL	14	RURAL	0.8363	16060	URBAN	0.8354	−0.11
SCOTT	IN	15	RURAL	0.8454	31140	URBAN	0.8319	−1.60
UNION	IN	15	RURAL	0.8454	17140	URBAN	0.8942	5.77
PLYMOUTH	IA	16	RURAL	0.8483	43580	URBAN	0.8948	5.48
KINGMAN	KS	17	RURAL	0.7838	48620	URBAN	0.8503	8.48
ALLEN	KY	18	RURAL	0.7770	14540	URBAN	0.8403	8.15
BUTLER	KY	18	RURAL	0.7770	14540	URBAN	0.8403	8.15
ACADIA	LA	19	RURAL	0.7608	29180	URBAN	0.7896	3.79
IBERIA	LA	19	RURAL	0.7608	29180	URBAN	0.7896	3.79
ST. JAMES	LA	19	RURAL	0.7608	35380	URBAN	0.8778	15.38
TANGIPAHOA	LA	19	RURAL	0.7608	25220	URBAN	0.9487	24.70
VERMILION	LA	19	RURAL	0.7608	29180	URBAN	0.7896	3.79
WEBSTER	LA	19	RURAL	0.7608	43340	URBAN	0.8347	9.71
ST. MARYS	MD	21	RURAL	0.8586	15680	URBAN	0.8625	0.45
WORCESTER	MD	21	RURAL	0.8586	41540	URBAN	0.9296	8.27
MIDLAND	MI	23	RURAL	0.8232	33220	URBAN	0.7964	−3.26
MONTCALM	MI	23	RURAL	0.8232	24340	URBAN	0.8832	7.29
FILLMORE	MN	24	RURAL	0.9057	40340	URBAN	1.1384	25.69
LE SUEUR	MN	24	RURAL	0.9057	33460	URBAN	1.1162	23.24
MILLE LACS	MN	24	RURAL	0.9057	33460	URBAN	1.1162	23.24
SIBLEY	MN	24	RURAL	0.9057	33460	URBAN	1.1162	23.24
BENTON	MS	25	RURAL	0.7603	32820	URBAN	0.9069	19.28
YAZOO	MS	25	RURAL	0.7603	27140	URBAN	0.7932	4.33
GOLDEN VALLEY	MT	27	RURAL	0.9055	13740	URBAN	0.8718	-3.72
HALL	NE	28	RURAL	0.8957	24260	URBAN	0.9253	3.30
HAMILTON	NE	28	RURAL	0.8957	24260	URBAN	0.9253	3.30
HOWARD	NE	28	RURAL	0.8957	24260	URBAN	0.9253	3.30
MERRICK	NE	28	RURAL	0.8957	24260	URBAN	0.9253	3.30
JEFFERSON	NY	33	RURAL	0.8226	48060	URBAN	0.8417	2.32
YATES	NY	33	RURAL	0.8226	40380	URBAN	0.8783	6.77
CRAVEN	NC	34	RURAL	0.7963	35100	URBAN	0.8547	7.33
DAVIDSON	NC	34	RURAL	0.7963	49180	URBAN	0.8660	8.75
GATES	NC	34	RURAL	0.7963	47260	URBAN	0.9156	14.98
IREDELL	NC	34	RURAL	0.7963	16740	URBAN	0.9123	14.57
JONES	NC	34	RURAL	0.7963	35100	URBAN	0.8547	7.33
LINCOLN	NC	34	RURAL	0.7963	16740	URBAN	0.9123	14.57
PAMLICO	NC	34	RURAL	0.7963	35100	URBAN	0.8547	7.33
ROWAN	NC	34	RURAL	0.7963	16740	URBAN	0.9123	14.57
OLIVER	ND	35	RURAL	0.7125	13900	URBAN	0.7251	1.77
SIOUX	ND	35	RURAL	0.7125	13900	URBAN	0.7251	1.77
HOCKING	OH	36	RURAL	0.8315	18140	URBAN	0.9499	14.24
PERRY	OH	36	RURAL	0.8315	18140	URBAN	0.9499	14.24
COTTON	OK	37	RURAL	0.7824	30020	URBAN	0.7948	1.58
JOSEPHINE	OR	38	RURAL	1.0120	24420	URBAN	1.0123	0.03
LINN	OR	38	RURAL	1.0120	10540	URBAN	1.0919	7.90
ADAMS	PA	39	RURAL	0.8730	23900	URBAN	1.0142	16.17
COLUMBIA	PA	39	RURAL	0.8730	14100	URBAN	0.9382	7.47
FRANKLIN	PA	39	RURAL	0.8730	16540	URBAN	1.0997	25.97

TABLE 10—CY 2015 PROPOSED RURAL TO URBAN CBSA CROSSWALK—Continued

County name	State	ESRD PPS CY 2014 CBSA delineations			Proposed ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
MONROE	PA	39	RURAL	0.8730	20700	URBAN	0.9406	7.74
MONTOUR	PA	39	RURAL	0.8730	14100	URBAN	0.9382	7.47
UTUADO	PR	40	RURAL	0.4000	10380	URBAN	0.4000	0.00
BEAUFORT	SC	42	RURAL	0.8381	25940	URBAN	0.8807	5.08
CHESTER	SC	42	RURAL	0.8381	16740	URBAN	0.9123	8.85
JASPER	SC	42	RURAL	0.8381	25940	URBAN	0.8807	5.08
LANCASTER	SC	42	RURAL	0.8381	16740	URBAN	0.9123	8.85
UNION	SC	42	RURAL	0.8381	43900	URBAN	0.8275	−1.26
CUSTER	SD	43	RURAL	0.8343	39660	URBAN	0.9075	8.77
CAMPBELL	TN	44	RURAL	0.7387	28940	URBAN	0.7039	−4.71
CROCKETT	TN	44	RURAL	0.7387	27180	URBAN	0.7775	5.25
MAURY	TN	44	RURAL	0.7387	34980	URBAN	0.9053	22.55
MORGAN	TN	44	RURAL	0.7387	28940	URBAN	0.7039	−4.71
ROANE	TN	44	RURAL	0.7387	28940	URBAN	0.7039	−4.71
FALLS	TX	45	RURAL	0.7917	47380	URBAN	0.8202	3.60
HOOD	TX	45	RURAL	0.7917	23104	URBAN	0.9412	18.88
HUDSPETH	TX	45	RURAL	0.7917	21340	URBAN	0.8356	5.55
LYNN	TX	45	RURAL	0.7917	31180	URBAN	0.8870	12.04
MARTIN	TX	45	RURAL	0.7917	33260	URBAN	0.8973	13.34
NEWTON	TX	45	RURAL	0.7917	13140	URBAN	0.8541	7.88
OLDHAM	TX	45	RURAL	0.7917	11100	URBAN	0.8308	4.94
SOMERVELL	TX	45	RURAL	0.7917	23104	URBAN	0.9412	18.88
BOX ELDER	UT	46	RURAL	0.8877	36260	URBAN	0.9259	4.30
AUGUSTA	VA	49	RURAL	0.7694	44420	URBAN	0.8357	8.62
BUCKINGHAM	VA	49	RURAL	0.7694	16820	URBAN	0.9087	18.11
CULPEPER	VA	49	RURAL	0.7694	47894	URBAN	1.0418	35.40
FLOYD	VA	49	RURAL	0.7694	13980	URBAN	0.8504	10.53
RAPPAHANNOCK	VA	49	RURAL	0.7694	47894	URBAN	1.0418	35.40
STAUNTON CITY	VA	49	RURAL	0.7694	44420	URBAN	0.8357	8.62
WAYNESBORO CITY	VA	49	RURAL	0.7694	44420	URBAN	0.8357	8.62
COLUMBIA	WA	50	RURAL	1.0932	47460	URBAN	1.0974	0.38
PEND OREILLE	WA	50	RURAL	1.0932	44060	URBAN	1.1467	4.89
STEVENS	WA	50	RURAL	1.0932	44060	URBAN	1.1467	4.89
WALLA WALLA	WA	50	RURAL	1.0932	47460	URBAN	1.0974	0.38
FAYETTE	WV	51	RURAL	0.7391	13220	URBAN	0.8037	8.74
RALEIGH	WV	51	RURAL	0.7391	13220	URBAN	0.8037	8.74
GREEN	WI	52	RURAL	0.9074	31540	URBAN	1.1190	23.32

The wage index values of rural areas are typically lower than that of urban areas. Therefore, ESRD facilities located in a county that is currently designated as urban under the ESRD PPS wage index that would become rural if we adopt the new CBSA delineations may experience a decrease in their wage index values. We have identified 39 counties and 29 ESRD facilities that would move from urban to rural status if we adopt the new CBSA delineations beginning in CY 2015. Table 11: (CY 2015 Proposed Urban to Rural CBSA Crosswalk) shows the CBSA delineations for CY 2014 and the proposed urban wage index values for CY 2015 based on those delineations, compared with the proposed CBSA delineations and wage index values for CY 2015 based on those delineations, and the percentage change in these values for those counties that would change from urban to rural if we adopt the new CBSA delineations. If we adopted the new CBSA delineations illustrated in Table 11 below, approximately 30 facilities would experience a decrease in their wage index values.

TABLE 11—CY 2015 PROPOSED URBAN TO RURAL CBSA CROSSWALK

County name	State	ESRD PPS CY 2014 CBSA delineations			Proposed ESRD PPS CY 2015 CBSA delineations			Change in value (%)
		CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
GREENE	AL	46220	URBAN	0.8336	01	RURAL	0.6930	−16.9
FRANKLIN	AR	22900	URBAN	0.7593	04	RURAL	0.7265	−4.3
POWER	ID	38540	URBAN	0.9707	13	RURAL	0.7425	−23.5
FRANKLIN	IN	17140	URBAN	0.8942	15	RURAL	0.8454	−5.5
GIBSON	IN	21780	URBAN	0.8524	15	RURAL	0.8454	−0.8
GREENE	IN	14020	URBAN	0.9096	15	RURAL	0.8454	−7.1
TIPTON	IN	29020	URBAN	0.9023	15	RURAL	0.8454	−6.3

TABLE 11—CY 2015 PROPOSED URBAN TO RURAL CBSA CROSSWALK—Continued

County name	State	ESRD PPS CY 2014 CBSA Delineations			Proposed ESRD PPS CY 2015 CBSA delineations			Change in value (%)
		CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
FRANKLIN	KS	28140	URBAN	0.9454	17	RURAL	0.7811	−17.4
GEARY	KS	31740	URBAN	0.7225	17	RURAL	0.7811	8.1
NELSON	KY	31140	URBAN	0.8313	18	RURAL	0.7774	−6.5
WEBSTER	KY	21780	URBAN	0.8524	18	RURAL	0.7774	−8.8
FRANKLIN	MA	44140	URBAN	1.0309	22	RURAL	1.1596	12.5
IONIA	MI	24340	URBAN	0.8998	23	RURAL	0.8313	−7.6
NEWAYGO	MI	24340	URBAN	0.8998	23	RURAL	0.8313	−7.6
GEORGE	MS	37700	URBAN	0.7423	25	RURAL	0.7584	2.2
STONE	MS	25060	URBAN	0.8209	25	RURAL	0.7584	−7.6
CRAWFORD	MO	41180	URBAN	0.9457	26	RURAL	0.7827	−17.2
HOWARD	MO	17860	URBAN	0.8349	26	RURAL	0.7827	−6.3
WASHINGTON	MO	41180	URBAN	0.9457	26	RURAL	0.7827	−17.2
ANSON	NC	16740	URBAN	0.9283	34	RURAL	0.7880	−15.1
GREENE	NC	24780	URBAN	0.9405	34	RURAL	0.7880	−16.2
ERIE	OH	41780	URBAN	0.7792	36	RURAL	0.8338	7.0
OTTAWA	OH	45780	URBAN	0.9152	36	RURAL	0.8338	−8.9
PREBLE	OH	19380	URBAN	0.8918	36	RURAL	0.8338	−6.5
WASHINGTON	OH	37620	URBAN	0.8167	36	RURAL	0.8338	2.1
STEWART	TN	17300	URBAN	0.7554	44	RURAL	0.7297	−3.4
CALHOUN	TX	47020	URBAN	0.8504	45	RURAL	0.7909	−7.0
DELTA	TX	19124	URBAN	0.9751	45	RURAL	0.7909	−18.9
SAN JACINTO	TX	26420	URBAN	0.9881	45	RURAL	0.7909	−20.0
SUMMIT	UT	41620	URBAN	0.9548	46	RURAL	0.8993	−5.8
CUMBERLAND	VA	40060	URBAN	0.9556	49	RURAL	0.7573	−20.8
DANVILLE CITY	VA	19260	URBAN	0.7985	49	RURAL	0.7573	−5.2
KING AND QUEEN	VA	40060	URBAN	0.9556	49	RURAL	0.7573	−20.8
LOUISA	VA	40060	URBAN	0.9556	49	RURAL	0.7573	−20.8
PITTSYLVANIA	VA	19260	URBAN	0.7985	49	RURAL	0.7573	−5.2
SURRY	VA	47260	URBAN	0.9156	49	RURAL	0.7573	−17.3
MORGAN	WV	25180	URBAN	0.9113	51	RURAL	0.7249	−20.5
PLEASANTS	WV	37620	URBAN	0.8167	51	RURAL	0.7249	−11.2

We note that facilities in some urban CBSAs could experience a change in their wage index values even though they remain urban because an urban CBSA's boundaries and/or the counties included in that CBSA could change. Table 12 (CY 2015 Proposed Urban to a Different Urban CBSA Crosswalk) shows the CBSA delineations for CY 2014 and urban wage index values for CY 2015 based on those delineations, compared with the proposed CBSA delineations and urban wage index values for CY 2015 based on those delineations, and the percentage change in these values for counties that would remain urban even though the CBSA boundaries and/or counties included in that CBSA would change.

TABLE 12—CY 2015 PROPOSED URBAN TO A DIFFERENT URBAN CBSA CROSSWALK

County name	State	ESRD PPS CY 2014 CBSA delineations			Proposed ESRD PPS CY 2015 CBSA delineations			Change In value (%)
		CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
MARIN	CA	41884	URBAN	1.7049	42034	URBAN	1.7317	1.6
FLAGLER	FL	37380	URBAN	0.8494	19660	URBAN	0.8407	−1.0
DE KALB	IL	16974	URBAN	1.0368	20994	URBAN	1.0347	−0.2
KANE	IL	16974	URBAN	1.0368	20994	URBAN	1.0347	−0.2
MADISON	IN	11300	URBAN	1.0115	26900	URBAN	1.0170	0.5
MEADE	KY	31140	URBAN	0.8313	21060	URBAN	0.7650	−8.0
ESSEX	MA	37764	URBAN	1.0808	15764	URBAN	1.1196	3.6
OTTAWA	MI	26100	URBAN	0.8167	24340	URBAN	0.8832	8.1
JACKSON	MS	37700	URBAN	0.7423	25060	URBAN	0.7927	6.8
BERGEN	NJ	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
HUDSON	NJ	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
MIDDLESEX	NJ	20764	URBAN	1.1085	35614	URBAN	1.2887	16.3
MONMOUTH	NJ	20764	URBAN	1.1085	35614	URBAN	1.2887	16.3
OCEAN	NJ	20764	URBAN	1.1085	35614	URBAN	1.2887	16.3
PASSAIC	NJ	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
SOMERSET	NJ	20764	URBAN	1.1085	35084	URBAN	1.1520	3.9

TABLE 12—CY 2015 PROPOSED URBAN TO A DIFFERENT URBAN CBSA CROSSWALK—Continued

County name	State	ESRD PPS CY 2014 CBSA delineations			Proposed ESRD PPS CY 2015 CBSA delineations			Change In value (%)
		CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
BRONX	NY	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
DUTCHESS	NY	39100	URBAN	1.1576	20524	URBAN	1.1387	−1.6
KINGS	NY	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
NEW YORK	NY	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
ORANGE	NY	39100	URBAN	1.1576	35614	URBAN	1.2887	11.3
PUTNAM	NY	35644	URBAN	1.3136	20524	URBAN	1.1387	−13.3
QUEENS	NY	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
RICHMOND	NY	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
ROCKLAND	NY	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
WESTCHESTER	NY	35644	URBAN	1.3136	35614	URBAN	1.2887	−1.9
BRUNSWICK	NC	48900	URBAN	0.8899	34820	URBAN	0.8641	−2.9
BUCKS	PA	37964	URBAN	1.0934	33874	URBAN	1.0236	−6.4
CHESTER	PA	37964	URBAN	1.0934	33874	URBAN	1.0236	−6.4
MONTGOMERY	PA	37964	URBAN	1.0934	33874	URBAN	1.0236	−6.4
ARECIBO	PR	41980	URBAN	0.4471	11640	URBAN	0.4229	−5.4
CAMUY	PR	41980	URBAN	0.4471	11640	URBAN	0.4229	−5.4
CEIBA	PR	21940	URBAN	0.4000	41980	URBAN	0.4460	11.5
FAJARDO	PR	21940	URBAN	0.4000	41980	URBAN	0.4460	11.5
GUANICA	PR	49500	URBAN	0.4000	38660	URBAN	0.4169	4.2
GUAYANILLA	PR	49500	URBAN	0.4000	38660	URBAN	0.4169	4.2
HATILLO	PR	41980	URBAN	0.4471	11640	URBAN	0.4229	−5.4
LUQUILLO	PR	21940	URBAN	0.4000	41980	URBAN	0.4460	11.5
PENUELAS	PR	49500	URBAN	0.4000	38660	URBAN	0.4169	4.2
QUEBRADILLAS	PR	41980	URBAN	0.4471	11640	URBAN	0.4229	−5.4
YAUCO	PR	49500	URBAN	0.4000	38660	URBAN	0.4169	4.2
ANDERSON	SC	11340	URBAN	0.8775	24860	URBAN	0.9025	2.8
GRAINGER	TN	34100	URBAN	0.7002	28940	URBAN	0.7039	0.5
LINCOLN	WV	16620	URBAN	0.8017	26580	URBAN	0.8773	9.4
PUTNAM	WV	16620	URBAN	0.8017	26580	URBAN	0.8773	9.4

Likewise, ESRD facilities currently located in a rural area may remain rural under the new CBSA delineations but experience a change in their rural wage index value due to implementation of the new CBSA delineations. Table 13 (CY 2015 Proposed Changes to the Statewide Rural Wage Index Crosswalk) shows the CBSA numbers for CY 2014 and the proposed rural statewide wage index values for CY 2015, compared with the proposed statewide rural wage index values for CY 2015, and the percentage change in these values.

TABLE 13—CY 2015 PROPOSED CHANGES TO THE STATEWIDE RURAL WAGE INDEX CROSSWALK

State	ESRD PPS CY 2014 CBSA delineations			Proposed ESRD PPS CY 2015 CBSA delineations			Change in value (%)
	CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
AL	01	RURAL	0.6981	01	RURAL	0.6930	−0.73
AZ	03	RURAL	0.9159	03	RURAL	0.9253	1.03
CT	07	RURAL	1.1292	07	RURAL	1.1337	0.40
FL	10	RURAL	0.8010	10	RURAL	0.8394	4.79
GA	11	RURAL	0.7425	11	RURAL	0.7439	0.19
HI	12	RURAL	0.9953	12	RURAL	1.0276	3.25
IL	14	RURAL	0.8363	14	RURAL	0.8365	0.02
KS	17	RURAL	0.7838	17	RURAL	0.7811	−0.34
KY	18	RURAL	0.7770	18	RURAL	0.7774	0.05
LA	19	RURAL	0.7608	19	RURAL	0.7135	−6.22
MD	21	RURAL	0.8586	21	RURAL	0.8778	2.24
MA	22	RURAL	1.3971	22	RURAL	1.1596	−17.00
MI	23	RURAL	0.8232	23	RURAL	0.8313	0.98
MS	25	RURAL	0.7603	25	RURAL	0.7584	−0.25
NE	28	RURAL	0.8957	28	RURAL	0.8909	−0.54
NY	33	RURAL	0.8226	33	RURAL	0.8208	−0.22
NC	34	RURAL	0.7963	34	RURAL	0.7880	−1.04
OH	36	RURAL	0.8315	36	RURAL	0.8338	0.28
OR	38	RURAL	1.0120	38	RURAL	0.9985	−1.33
PA	39	RURAL	0.8730	39	RURAL	0.8079	−7.46

TABLE 13—CY 2015 PROPOSED CHANGES TO THE STATEWIDE RURAL WAGE INDEX CROSSWALK—Continued

State	ESRD PPS CY 2014 CBSA delineations			Proposed ESRD PPS CY 2015 CBSA delineations			Change in value (%)
	CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
SC	42	RURAL	0.8381	42	RURAL	0.8357	−0.29
TN	44	RURAL	0.7387	44	RURAL	0.7297	−1.22
TX	45	RURAL	0.7917	45	RURAL	0.7909	−0.10
UT	46	RURAL	0.8877	46	RURAL	0.8993	1.31
VA	49	RURAL	0.7694	49	RURAL	0.7573	−1.57
WA	50	RURAL	1.0932	50	RURAL	1.0917	−0.14
WV	51	RURAL	0.7391	51	RURAL	0.7249	−1.92
WI	52	RURAL	0.9074	52	RURAL	0.9120	0.51

While we believe that the new CBSA delineations would result in wage index values that are more representative of the actual costs of labor in a given area, we also recognize that use of the new CBSA delineations would result in reduced payments to some facilities. In particular, approximately 30 facilities would experience reduced payments if we adopt the new CBSA delineations. At the same time, use of the new CBSA delineations would result in increased payments for approximately 100 facilities, while the majority of facilities would experience no change in payments due to the implementation of the new CBSA delineations. We are proposing to implement 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% of the wage index based on the new CBSA delineations in CY 2016.

c. Transition Period

We considered having no transition period and fully implementing the proposed new CBSA delineations beginning in CY 2015, which would mean that all facilities would have payments based on the new delineations starting on January 1, 2015. However, because more facilities would have increased rather than decreased payments beginning in CY 2015, and because the overall amount of ESRD payments would increase slightly due to the new CBSA delineations, the wage index budget neutrality factor would be higher. This higher factor would reduce the ESRD PPS per treatment base rate for all facilities paid under the ESRD PPS, despite the fact that the majority of ESRD facilities are unaffected by the new CBSA delineations. Thus, we believe that it would be appropriate to provide for a transition period to mitigate any resulting short-term instability of a lower ESRD PPS base rate as well as any negative impacts to facilities that experience reduced payments. In addition, we note that for CY 2015, section 1881(b)(14)(F)(i)(III), as added by section 217 of PAMA, requires a 0.0 payment update (for further discussion on this update please see section II.B.1.a.ii of this rule), and thus, there is no possibility of offsetting any reduction, even a slight reduction, to the ESRD PPS base rate in CY 2015.

Therefore, we are proposing a two-year transition blended wage index for all facilities. Facilities would receive 50 percent of their CY 2015 wage index value based on the CBSA delineations for CY 2014 and 50 percent of their CY 2015 wage index value based on the proposed new CBSA delineations. This results in an average of the two values. We propose that facilities' CY 2016 wage index values would be based 100 percent on the new CBSA delineations. We believe a two-year transition strikes an appropriate balance between ensuring that ESRD PPS payments are as accurate and stable as possible while giving facilities time to adjust to the new CBSA delineations.

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. For the CY 2015 ESRD PPS, we propose to use a labor-related share of 50.673 percent, which we propose to transition over a 2-year period with the labor-related share in CY 2015 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 based 100 percent on the new labor-related share. For a complete discussion of the proposed changes in the CY 2015 ESRD PPS market basket and labor-related share, as well as the transition of the labor-related share; please see sections II.B.2.e and XII.B.1.a of this proposed rule.

4. Proposed Revisions 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. Our regulations at 42 CFR 413.237(a)(1) 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 ESRD-related oral-only drugs.

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. The ESRD-related drugs, laboratory tests, and medical/surgical supplies that we would recognize as outlier services were specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. With respect to the outlier policy, Transmittal 2094 identified additional drugs and laboratory tests that may 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.

In the CY 2012 ESRD PPS final rule (76 FR 70246), we eliminated the issuance of a specific list of eligible outlier service drugs which were or would have been separately billable under Medicare Part B prior to January 1, 2011. However, we use separate guidance to continue to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes in order to provide unit prices for calculating imputed outlier services. We also can identify, through our monitoring efforts, items and services that are incorrectly being identified as eligible outlier services in the claims data. Information about these items and services and any updates to the list of renal dialysis items and services that qualify as outlier services are made through administrative issuances, if necessary.

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 Medicare Allowable Payment (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 and 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 CY 2014, the outlier services MAP amounts and fixed dollar loss amounts were based on 2012 data (78FR 72180). Therefore, the outlier thresholds for CY 2014 were based on utilization of ESRD-related items and services furnished under the ESRD PPS. Because of the utilization of epoetin and other outlier services has continued to decline under the ESRD PPS, we lowered the MAP amounts and fixed dollar loss amounts for CYs 2013 and 2014 to allow for an increase in payments for ESRD beneficiaries requiring higher resources.

a. Proposed Changes to the Outlier Services MAP Amounts and Fixed Dollar Loss Amounts

For CY 2015, we are not proposing any changes to the methodology used to compute the MAP or fixed dollar loss amounts. Rather, in this proposed rule, we are updating the outlier services MAP amounts and fixed dollar loss amounts to reflect the utilization of outlier services reported on the 2013 claims using the December 2013 claims file. The impact of this update is shown in Table 14, which compares the outlier services MAP amounts and fixed dollar loss amounts used for the outlier policy in CY 2014 with the updated estimates for this proposed rule. The estimates for the proposed outlier CY 2015 outlier policy, which are included in Column II of Table 14, were inflation-adjusted to reflect projected 2015 prices for outlier services.

TABLE 14—OUTLIERPOLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I Final outlier policy for CY 2014 (based on 2012 data price inflated to 2014) *		*Column II* Proposed outlier policy for CY 2015 (based on 2013 data price inflated to 2015) *	
	Age <18	Age >=18	Age <18	Age >=18
Average outlier services MAP amount per treatment [1]	$37.29	$51.97	$40.05	$52.61
Adjustments.				
Standardization for outlier services [2]	1.1079	0.9866	1.1182	0.9899
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount [3]	$40.49	$50.25	$43.89	$51.04
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold [4]	$54.01	$98.67	$56.30	$85.24
Patient months qualifying for outlier payment	6.7%	5.3%	6.2%	6.3%

* The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect updated prices for outlier services (that is, 2014 prices in Column I and projected 2015 prices in Column II).

[1] Excludes patients for whom not all data were available to calculate projected payments. The outlier services MAP amounts are based on 2013 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that are in place under the ESA claims monitoring policy were applied.

[2] Applied to the average outlier MAP per treatment. Standardization for outlier services is based on existing case mix adjusters for adult and pediatric patient groups.

[3] This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.

[4] The fixed dollar loss amounts were calculated using 2013 data to yield total outlier payments that represent 1% of total projected payments for the ESRD PPS.

As seen in Table 14, the estimated fixed dollar loss amount that determines the CY 2015 outlier threshold amount for adults (Column II) is lower than that used for the CY 2014 outlier policy (Column I). The threshold is lower in

spite of the fact that the average outlier services MAP per treatment has increased. Between 2012 and 2013, the variation in outlier services across patients declined among adults. The net result is an increase in the percentage of patient-months qualifying for outlier payment (6.3 percent based on 2013 data versus 5.3 percent based on 2012 data) but a decrease in the average outlier payment per case. The estimated fixed dollar loss amount that determines the CY 2015 outlier threshold amount for pediatric patients (Column II) is higher than that used for the CY 2014 outlier policy (Column I).

For pediatric patients, there was an increase in the overall average outlier service MAP amount between 2012 ($37.29 per treatment as shown in Column I) and 2013 ($40.05 per treatment, as shown in Column II). In addition, there was a continuing tendency in 2013 for a relatively small percentage of pediatric patients to account for a disproportionate share of the total outlier service MAP amounts. The one percent target for outlier payments is therefore expected to be achieved based on a smaller percentage of pediatric outlier cases using 2013 data compared to 2012 data (6.2 percent of pediatric patient months are expected to qualify for outlier payments rather than 6.7 percent). These patterns led to the estimated fixed dollar loss amount for pediatric patients being higher for the outlier policy for CY 2015 compared to the outlier policy for CY 2014. Generally, there is a relatively higher likelihood for pediatric patients that the outlier threshold may be adjusted to reflect changes in the distribution of outlier service MAP amounts. This is due to the much smaller overall number of pediatric patients compared to adult patients, and therefore to the fact that the outlier threshold for pediatric patients is calculated based on data for a much smaller number of pediatric patients compared to adult patients.

We propose to update the fixed dollar loss amounts that are added to the predicted MAP amounts per treatment to determine the outlier thresholds for CY 2015 from $98.67 to $85.24 for adult patients and from $54.01 to $56.30 for pediatric patients compared with CY 2014 amounts. We estimate that the percentage of patient months qualifying for outlier payments under the current policy will be 6.3 percent and 6.2 percent for adult and pediatric patients, respectively, based on the 2013 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 epoetin and other injectable drugs).

b. Outlier Policy Percentage

42 CFR 413.220(b)(4) stipulates that the per treatment base rate is reduced by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments. Based on the 2013 claims, outlier payments represented approximately 0.5 percent of total payments, again falling short of the 1 percent target due to further declines in the use of outlier services. Use of 2013 data to recalibrate the thresholds, which reflect lower utilization of EPO and other outlier services and reduced variation in outlier services among adults, is expected to result in aggregate outlier payments close to the 1 percent target in CY 2015. We believe the proposed update to the outlier MAP and fixed dollar loss amounts for CY 2015 will increase payments for ESRD beneficiaries requiring higher resource utilization and come closer to meeting our 1 percent outlier policy.

We note that recalibration of the fixed dollar loss amounts in this proposed rule for CY 2015 outlier payments results in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but increases payments to providers 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.

C. Restatement of Policy Regarding Reporting and Payment for More Than Three Dialysis Treatments per Week

1. Reporting More Than Three Dialysis Treatments per Week on Claims

Since the composite payment system was implemented in the 1980s, CMS has reimbursed ESRD facilities based upon three hemodialysis treatments per week and allowed for the payment of additional weekly dialysis treatments with medical justification. When a dialysis modality regimen requires more than three weekly dialysis treatments, such as with short, frequent hemodialysis (HD) and peritoneal dialysis (PD) modalities, we apply payment edits to ensure that Medicare payment on the monthly claim is consistent with the three times-weekly dialysis treatment payment limit, which translates to payment for 13 treatments for a 30-day month and 14 treatments for a 31-day month.

Under section 1881(b)(14)(C) of the Act, the ESRD PPS may provide for payment on the basis of renal dialysis services furnished during a week, or month, or such other appropriate unit of payment as the Secretary specifies. In the CY 2011 ESRD PPS final rule (75 FR 49064), CMS finalized the per treatment basis of payment in which ESRD facilities are paid for up to three treatments per week, unless there is medical justification for more than three treatments per week. We codified the per-treatment unit of payment under the ESRD PPS at 42 CFR 413.215(a). Also in the CY 2011 ESRD PPS final rule (75 FR 49078), we explained how we converted patient weeks to HD-equivalent sessions for PD patients. Specifically, we noted that one week of PD was considered equivalent to three HD treatments. For example, a patient on PD for 21 days would have (21/7) x 3 or 9 HD-equivalent sessions. Our policy is that ESRD facilities treating patients on PD or home HD will be paid for up to three HD-equivalent sessions for each week of dialysis, unless there is medical justification for furnishing additional treatments.

Increasingly, some ESRD facilities have begun to offer dialysis modalities where the standard treatment regimen is more than three treatments per week. Also, we have observed a payment variance among Medicare Administrative Contractors (MACs) in processing claims for dialysis treatments for modalities that require more frequent dialysis, resulting in payment of more than 14 treatments per month without medical justification. Lastly, CMS has received several requests for clarification regarding Medicare payment and billing policies for dialysis treatments for modalities requiring more than three treatments per week that are furnished in-facility or in the patient's home. Specifically, ESRD facilities, renal physician groups, and MACs have requested billing guidance regarding whether all of the dialysis treatments furnished to the patient during the billing month should be reported on the claim form, even though the Medicare benefit only provides for payment of three dialysis treatments per week.

For these reasons, we are reiterating our policy with respect to payment for more than three dialysis treatments per week. We note that we are not changing our policy for reporting extra non-medically necessary dialysis sessions. ESRD facility claims should continue to include all dialysis treatments furnished during the month on claims, but payment is limited to three dialysis treatments per week through the payment edits of 13 treatments for a 30-

day month or 14 treatments for a 31-day month. For example, an ESRD facility that furnishes dialysis services to patients who dialyze using modalities requiring shorter, more frequent dialysis (for example, a dialysis regimen of 4, 5, 6 or 7 days a week in-facility or at home), should report all of the patient's dialysis treatments on the monthly claim. However, payment for these services will reflect existing claims processing system edits, and the monthly Medicare payment would mirror the Medicare ESRD benefit of three dialysis treatments per week.

2. Medical Necessity for More Than Three Treatments per Week

Under the ESRD benefit, we have always recognized that some patient conditions benefit from more than three dialysis sessions per week and as such, the Medicare policy for medically necessary additional dialysis treatments was developed. Under this policy, the MACs determine whether additional treatments furnished during a month are medically necessary. While Medicare does not define specific patient conditions that meet the requirements of medical necessity, we do furnish instructions to MACs to consider appropriate patient conditions that would result in a patient's medical need for additional dialysis treatments (for example, excess fluid of five or more pounds). When such patient conditions are indicated with the claim requesting payment, we instruct MACs to consider medical justification and the appropriateness of payment for the additional sessions.

In section 50.A of the Medicare Benefit Policy Manual (Pub. 100–02), we explained our policy regarding payment for hemodialysis-equivalent PD and payment for more than three dialysis treatments per week under the ESRD PPS. We restated that ESRD facilities are paid for a maximum of 13 treatments during a 30 day month and 14 treatments during a 31-day month unless there is medical justification for additional treatments. The only time facilities should seek payment for additional dialysis sessions, including payment for shorter, more frequent modalities, is when the patient has a medical need for additional dialysis and the facility has furnished supporting medical justification for the extra treatments. Modality choice does not constitute medical justification.

D. Delay of Payment for Oral-Only Drugs Under the ESRD PPS

As we discussed in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), section 1881(b)(14)(A)(i) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), 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 that 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 (before the application of this paragraph) 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, which are included under clause (ii) of section 1881(b)(14)(B)), but also all non-injectable oral drugs used for the treatment of ESRD furnished under title XVIII of the Act. We also concluded that, to the extent ESRD-related oral-only drugs do not fall within clause (iii) of the statutory definition of renal dialysis services, such drugs would fall under clause (iv), 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). As such, CMS finalized and promulgated the payment policies for oral-only drugs used for the treatment of ESRD in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), and we defined ''renal dialysis services'' at 42 CFR 413.171(3) as including, among other things ''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).''

Although ESRD-related oral-only drugs are included in the definition of renal dialysis services, in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the PPS until January 1, 2014. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only ESRD-related drugs and biologicals to their patients. Accordingly, 42 CFR 413.174(f)(6) provides 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, the Congress enacted ATRA. Section 632(b) of ATRA states that the Secretary ''may not implement the policy under section 413.176(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system), prior to January 1, 2016.'' Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for ESRD-related oral-only drugs under the ESRD PPS until January 1, 2016, instead of on January 1, 2014, which is the original date we finalized for payment of ESRD-related oral-only drugs under the ESRD PPS. We implemented this delay by revising the effective date for providing payment for oral-only ESRD-related drugs under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2014 to January 1, 2016. In addition, we also changed the date when oral-only drugs would be eligible outlier services under the outlier policy described in 42 CFR 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 provides that the Secretary ''may not implement the policy under section 413.174(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD drugs in the ESRD prospective payment system), prior to January 1, 2024.'' Accordingly, payment for ESRD-related oral-only drugs will not be made under the ESRD PPS prior to January 1, 2024 instead of on January 1, 2016, which is the date we finalized for payment of ESRD-related oral-only drugs under the ESRD PPS in the CY 2014 ESRD PPS final rule (78 FR 72186).

We propose to implement this delay by modifying the effective date for providing payment for oral-only ESRD-related drugs and biologicals under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also propose to change the date in 42 CFR 413.237(a)(1)(iv) regarding outlier payments for oral-only ESRD-related drugs made under the ESRD PPS from January 1, 2016 to January 1, 2024. We continue to believe that oral-only drugs used for the treatment of ESRD are an essential part of the ESRD PPS payment bundle and should be paid for under the ESRD PPS as soon as possible, or beginning January 1, 2024.

In addition to the delay of payment for oral-only ESRD-related drugs, section 217(a)(2) of PAMA further amends section 632(b)(1) of ATRA by adding a new sentence that provides,

''[n]otwithstanding section 1881(b)(14)(A)(ii) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(A)(ii)), implementation of the policy described in the previous sentence shall be based on data from the most recent year available.'' We interpret this provision to mean that we are not to use per patient utilization data from 2007, 2008, or 2009 (whichever has the lowest per patient utilization) as we were required for the original ESRD PPS in implementing payment for oral-only ESRD drugs under the ESRD PPS. We will make proposals consistent with section 632(b)(1) of ATRA, as amended by section 217(a)(2) of PAMA, in future rulemaking.

Section 217(c) of PAMA requires the Secretary, as part of the CY 2016 ESRD PPS rulemaking, to 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 bundled payment under such system.'' Consistent with this statutory requirement, we plan to propose a drug designation process in our CY 2016 rulemaking cycle and we are seeking industry and stakeholder comments on the components and elements of such a process for our consideration next year.

E. ESRD Drug Categories Included in the ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49050), we finalized Table 4, (Renal Dialysis Service ESRD Drug Categories Included in the Final ESRD PPS Base Rate), and have included Table 15 below for the purpose of this discussion. In that rule, we noted that the categories of drugs and biologicals used for access management, anemia management, anti-infectives, bone and mineral metabolism and cellular management would always be considered ESRD-related drugs when furnished to an ESRD patient, and that payment for such drugs would be included in the ESRD PPS payment bundle. As such, beginning January 1, 2011, Medicare no longer makes a separate payment when a drug or biological (except for oral-only ESRD–related drugs for which we are proposing to delay payment under the ESRD PPS until January 1, 2024) identified in the categories listed in the following table is furnished to a Medicare ESRD beneficiary.

TABLE 15—RENAL DIALYSIS SERVICE ESRD DRUG CATEGORIES INCLUDED IN THE FINAL ESRD PPS BASE RATE

Drug category	Rationale for inclusion
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.
Anti-infectives	Vancomycin and daptomycin used to treat access site infections.
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.

In the CY 2011 ESRD PPS final rule (75 FR 49050), we noted that we included the anti-infective drugs of vancomycin and daptomycin because these drugs were routinely furnished for the ESRD-related conditions of access site infections and peritonitis. However, in the CY 2012 ESRD PPS final rule (76 FR 70242 through 70243), we responded to public comments that noted that vancomycin is a common anti-infective drug appropriate for treating infections that are both ESRD- and non-ESRD-related by modifying our policy to eliminate the payment restriction for vancomycin when it is furnished for non-ESRD related conditions. In addition, we finalized the use of CMS payment modifier AY (Item or service furnished to an End Stage Renal Disease (ESRD) patient that is not for the treatment of ESRD) and instructed facilities to append the modifier to the claim reporting vancomycin to indicate that the drug was furnished for reasons other than ESRD. The presence of the AY modifier on the claim allows the MAC to make a separate payment for the drug when it is furnished by the facility to a Medicare beneficiary for reasons other than ESRD.

In the CY 2013 ESRD PPS final rule (77 FR 67461), we further amended this policy to allow ESRD facilities to bill separately for daptomycin when it is furnished to ESRD beneficiaries for reasons other than ESRD. Once again, we instructed facilities to append claims reporting daptomycin furnished for reasons other than ESRD with the AY modifier so that MACs would be able to make a separate payment.

Because we have removed the payment limitation for both vancomycin and daptomycin, and because we believe that anti-infectives are a drug category that may be furnished for both ESRD- and non-ESRD-related reasons, we have updated the list of drug categories that are always considered ESRD-related under the ESRD PPS by removing the drug category for anti-infectives. We have included Table 16 (Renal Dialysis Service ESRD Drug Categories Included in the ESRD PPS Base Rate and Not Separately Payable) below to appropriately recognize the drug categories that are always considered ESRD-related and we confirm that the revised table reflects policy changes made in the CY 2012 and CY 2013 ESRD PPS rulemaking cycles and does not constitute new policy.

Over the past few years, we have received payment and billing inquiries requesting clarification for the payment for drugs represented by one of the drug categories included in the ESRD PPS, but not furnished for the treatment of ESRD. Therefore, we clarify that any drug included in the drug categories of access management, anemia management, bone and mineral metabolism and cellular management is not separately paid by Medicare regardless of why the drug is being furnished. In addition, the facility may not furnish a prescription for such drugs with the expectation that a Medicare Part D payment would be made, as the payment for the drug is included in the ESRD PPS payment bundle.

TABLE 16—RENAL DIALYSIS SERVICE ESRD DRUG CATEGORIES INCLUDED IN THE ESRD PPS BASE RATE AND NOT SEPARATELY PAYABLE

Drug category	Rationale for inclusion
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.

The drug categories that may be separately paid by Medicare when furnished for non-ESRD patient conditions are included in Table 5 (ESRD Drug Categories Included in the ESRD PPS Base Rate But May be Used for Dialysis and non-Dialysis Purposes) (75 FR 49051). This table is included below for the purpose of this discussion. When any drug identified in the drug categories listed in Table 17 (antiemetic, anti-infectives, antipruritic, anxiolytic, excess fluid management, fluid and electrolyte management or pain management), is furnished for the treatment of ESRD, payment for the drug is included in the ESRD PPS payment and may not be paid separately. If a drug represented by a drug category in Table 17 is furnished for reasons other than ESRD, a separate Medicare payment is permitted when the AY modifier is indicated on the claim line reporting the drug for payment.

TABLE 17—ESRD DRUG CATEGORIES INCLUDED IN THE ESRD BASE RATE BUT MAY BE USED FOR DIALYSIS AND NON–DIALYSIS PURPOSES

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.

F. Low-Volume Payment Adjustment

1. Background

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 a result of this provision and the regression analysis conducted for the ESRD PPS, effective January 1, 2011, 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: (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 § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments equals the aggregate 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. This geographic proximity criterion is only applicable to ESRD facilities that were Medicare certified on or after January 1, 2011.

For purposes of determining eligibility for the low-volume payment adjustment (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 cost reporting periods ending in the three years preceding the payment year must report costs for 12-consecutive months.

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) that it qualifies as a low-volume ESRD facility and that it meets all of the requirements specified at 42 CFR 413.232. 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. Further information regarding the administration of the LVPA is provided in CMS Pub. 100–02, Medicare Benefit Policy Manual, chapter 11, section 60.B.1.

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

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required the United States Government Accountability Office (the GAO) to study the LVPA. The GAO examined (1) the extent to which the LVPA targeted low-volume, high-cost facilities that appeared necessary for ensuring access to care; and (2) CMS's implementation of the LVPA, including the extent to which CMS paid the 2011 LVPA to facilities eligible to receive the adjustment. To do this work, the GAO reviewed Medicare claims, facilities' annual cost reports, and data on dialysis facilities' locations to identify and compare facilities that were eligible for the LVPA with those that received the adjustment. The GAO published a report 13–287 on March 1, 2013, entitled, ''End-Stage Renal Disease: CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment''. The report found multiple discrepancies in the identification of low-volume facilities which are summarized below.

a. The GAO's Main Findings

The GAO found that many of the facilities eligible for the LVPA were located near other facilities, indicating that they might not have been necessary for ensuring access to 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, they 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. The GAO calculated that Medicare overpaid an estimated $5.3 million for the LVPA to dialysis facilities that did not meet the eligibility requirements established by CMS. They indicated in their report that the guidance that CMS issued for implementation of the regulatory requirements was sometimes unclear and not always available when needed, and the misunderstanding of LVPA eligibility likely was exacerbated because CMS conducted limited monitoring of the Medicare contractors' administration of LVPA payments.

b. The GAO's Recommendations

In the conclusion of their study, the GAO provided 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: Require Medicare contractors to promptly recoup 2011 LVPA payments that were made in error; investigate any errors that contributed to eligible facilities not consistently receiving the 2011 LVPA and ensure that such errors are corrected; 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 improve the timeliness and efficacy of CMS's monitoring regarding the extent to which Medicare contractors are determining LVPA eligibility correctly and promptly redetermining eligibility when all necessary data become available.

In response to the GAO's recommendations, 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 other 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 provide specific expectations.

3. Clarification of the LVPA Policy

For CY 2015, we are not proposing to make changes to the eligibility criteria for the adjustment or to the magnitude of the adjustment value. In accordance with section 632(c) of ATRA, for CY 2016 we will assess and address other necessary LVPA policy changes when we use updated data and reevaluate all of the patient- and facility-level adjustments together in a regression analysis similar to the analysis that is discussed in the CY 2011 ESRD PPS final rule (75 FR 49083). At this time, we are not proposing to change the criteria in such a way that the number of low-volume facilities would deviate substantially from the number of facilities originally modeled to receive the adjustment in the first year of implementation. This is because of the interaction of the LVPA with other payment adjustments under the ESRD PPS. As discussed in the CY 2011 ESRD PPS final rule (75 FR 49081), we standardized the ESRD PPS base rate to account for the payment variables and it would not be appropriate to make changes to one variable in the regression when it could potentially affect the other adjustments or the standardization factor. However, there are two clarifications under the LVPA policy (discussed below) that we can address in this year's rulemaking that we believe are responsive to stakeholder's concerns and GAO's concern that the LVPA should effectively target low-volume, high cost-facilities.

a. Hospital-Based ESRD Facilities

As stated above, for purposes of determining eligibility for the LVPA, ''treatments'' means total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare) and for peritoneal dialysis (PD) patients, one week of PD is considered equivalent to 3 HD treatments. Once a MAC receives an attestation from an ESRD facility, it reviews the ESRD facility's cost reports to verify that the facility meets the low-volume criteria specified at 42 CFR 413.232(b). Specifically, the ESRD facility cost report is used to verify the total treatment count that an ESRD facility furnishes in its fiscal year, which includes Medicare and non-Medicare treatments. For independent ESRD facilities, this information is provided on Worksheet C of the Form CMS–265–11 form (previously Form CMS–265–94) and for hospital-based ESRD facilities, this information is on Worksheet I–4 of the Form CMS–2552–10.

After the LVPA was implemented, we began hearing concerns from multiple stakeholders, including members of Congress and rural hospital-based ESRD facilities, about the MACs' LVPA eligibility determinations. The stakeholders indicated that because hospital-based ESRD facilities are financially integrated with a hospital, their costs and treatment data are aggregated in the I-series of the hospital's cost report. This means that if there is more than one ESRD facility that is affiliated with a hospital, the cost and treatment data for all facilities are aggregated on Worksheet I–4, typically causing the facilities' treatment counts to exceed the 4,000-treatment criterion.

We have learned that some MACs accepted treatment counts from

hospital-based ESRD facilities other than those provided on the hospital's cost report and, as a result, certain hospital-based ESRD facilities received the LVPA. Other MACs solely used the aggregated treatment counts from the hospital's cost report to verify LVPA eligibility, which resulted in denials for many hospital-based facilities that would have qualified for the adjustment if the MACs had considered other supporting documentation.

We agree with stakeholders that limiting the MAC review to the hospital cost reports for verification of LVPA eligibility for hospital-based ESRD facilities places these facilities at a disadvantage and does not comport with the intent of our policy. We believe it can be necessary for MACs to use other supporting data to verify the treatment counts for individual hospital-based facilities that would meet the eligibility criteria for the LVPA if their treatment counts had not been aggregated with one or more other facilities on their hospitals' cost reports. Because LVPA eligibility is based on cost report information and the individual hospital-based facility treatment counts is the source of the aggregated treatment counts reported in the cost report, however, we continue to believe that cost report data is an integral part of the process of verifying whether a hospital-based facility meets the LVPA eligibility criteria.

For these reasons, we are clarifying that MACs may consider other supporting data, such as a hospital-based facility's total treatment count, along with the facility's cost reports and attestation, to verify it meets the low-volume eligibility criteria provided at 42 CFR 413.232(b). The attestation should continue to be configured around the parent hospital's cost reports, that is, it should be for the same fiscal periods. 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, rather than the hospital's cost report alone, to verify the number of treatments that were furnished by the individual hospital-based facility that is seeking the adjustment. Consistent with this policy clarification, 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.

MACs have discretion as to the format of the attestation and any supporting data, however, the facility must provide the total number of Medicare and non-Medicare treatments for the three cost reporting years preceding the payment year for all of the hospital-based facilities for which treatment counts appear on the hospital's cost report. This will allow MACs to determine which treatments on the cost report were furnished by the individual hospital-based facility that is seeking the LVPA and which treatments were furnished by other affiliated facilities. Finally, we propose to amend the regulation text by adding a new paragraph (h)(1) to § 413.232 to reflect this clarification of current policy under which MACs can verify hospital-based ESRD facilities' eligibility for the LVPA using supporting data in addition to hospital cost reports. We are soliciting comment on the proposed changes at § 413.232(h)(1).

b. Cost Reporting Periods Used for Eligibility

In the CY 2012 ESRD PPS final rule (76 FR 70236), we clarified that for purposes of eligibility under 42 CFR 413.232(b), 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 cost reporting periods ending in the three years preceding the payment year must report costs for 12 consecutive months.

After the LVPA was implemented, we began hearing concerns from the industry that there is a conflict within our policy. Currently, our policy allows an ESRD facility to remain eligible for the LVPA when they have a change of ownership (CHOW) that does not result in a new Provider Transaction Access Number (PTAN). However, our regulations at 42 CFR 413.232(b) suggest that MACs must verify treatment counts using cost reports for 12-consecutive month cost periods even though CHOWs often result in costs reports that are nonstandard, that is, longer or shorter than 12 months. In particular, the previous owner's final cost report may not coincide with the ESRD facility's cost report fiscal year end under its new ownership, resulting in two costs reports that are not 12-consecutive month cost reports. For example, where a CHOW occurs in the middle of the cost reporting period and the new owner wishes to retain the established cost report fiscal year end, the previous owner submits a final cost report covering their period of ownership and the new owner submits a cost report covering the remainder of the cost reporting period. Alternatively, a new owner could also choose not to retain the previous owner's established cost reporting fiscal year end, in which case the CHOW could result in a cost reports that exceed twelve months when combined. Further details regarding the policies for filing cost reports during a CHOW are available in the Provider Reimbursement Manual—Part 1, chapter 15, ''Change of Ownership.''

We agree with the industry that there is a conflict in the policies governing LVPA that may prevent an otherwise qualified ESRD facility from receiving the adjustment. We have always intended that if an ESRD facility has a CHOW where the new owner accepts the previous owner's assets and liabilities by retaining the facility's PTAN, they should continue to be eligible for the LVPA. However, some MACs used a strict reading of the regulatory language and denied these providers the LVPA. Other MACs added short cost reports together or prorated treatment counts for cost reporting periods spanning greater than 12 months.

In order to ensure consistent verification of LVPA eligibility, we are restating our intention that when there is a CHOW that does not result in a new PTAN 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.

For example, prior to a CHOW, Facility A had a cost reporting period that spanned January 1 through December 31. Facility A had a CHOW mid-year that did not result in a new PTAN but caused a break in the cost reporting period. Consistent with the clarification of our policy, the MAC would add Facility A's cost report that spanned January 1 through May 31 to its cost report that spanned June 1 through December 31 to verify the total treatment count.

The other situation that could occur is when a CHOW results in a change of the original fiscal period. For example, prior to a CHOW, Facility B had a cost reporting period that spanned January 1 through December 31 and, based on its cost reports for 2012 and 2013, it met the LVPA eligibility criteria. Then, Facility B had a CHOW in the beginning of 2014 that did not result in a new PTAN, but changed its cost reporting period to that of its new owner, October

1, 2014 through September 30, 2015. This scenario would create a short and a long cost report that would not total 12 months that the MAC would need to review for verification. That is, Facility B would have a cost report that spanned January 1, 2014 through July 31, 2014 (7 months) and a cost report that spanned August 1, 2014 through September 30, 2015 (14 months).

In this situation, the MAC should combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period. Finally, we propose to amend the regulation text by adding a new paragraph (h)(2) to § 413.232 to clarify the verification process for ESRD facilities that experience a CHOW with no change in the PTAN. We are soliciting comments on the proposed changes at § 413.232(h)(2).

Section 413.232(f) requires ESRD facilities to submit LVPA attestations by November 1 of each year. However, the changes we are proposing to the LVPA regulation text would not be finalized in enough time to give the ESRD facilities the opportunity to learn about the policy clarifications and provide an attestation to their MAC by November 1, 2014. For these reasons, we are proposing to amend § 413.232(f) to extend the deadline for CY 2015 LVPA attestations until December 31, 2014. This timeframe would allow ESRD facilities to reassess their eligibility and apply for the LVPA for CY 2015. It would also give MACs an opportunity to verify any new attestations and reassess LVPA eligibility verifications made since 2011. We will issue guidance with additional detail regarding this policy clarification, which will include details about the process ESRD facilities should follow to seek the LVPA for past years.

G. Continued Use of ICD–9–CM Codes and Corrections to the ICD–10–CM Codes Eligible for the Comorbidity Payment Adjustment

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based upon case mix that may take into account, among other things, patient comorbidities. Comorbidities are specific patient conditions that coexist with the patient's principal diagnosis that necessitates dialysis. The comorbidity payment adjustments recognize the increased costs associated with comorbidities and provide additional payment for certain conditions that occur concurrently with the need for dialysis. For a detailed discussion of our approach to developing the comorbidity payment adjustment, see the CY 2011 ESRD PPS final rule (75 FR 49094 through 49108).

In the CY 2011 ESRD PPS final rule, we finalized six comorbidity categories that are eligible for a comorbidity payment adjustment, each with associated International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) diagnosis codes (75 FR 49100). These categories include three acute, short-term diagnostic categories (pericarditis, bacterial pneumonia, and gastrointestinal tract bleeding with hemorrhage) and three chronic diagnostic categories (hereditary hemolytic sickle cell anemia, myelodysplastic syndrome, and monoclonal gammopathy). The comorbidity categories eligible for an adjustment and their associated ICD–9–CM codes were published in the Appendix of the CY 2011 ESRD PPS final rule as Table E: ICD–9–CM—Codes Recognized for the Comorbidity Payment Adjustment (75 FR 49211).

In the CY 2012 ESRD PPS final rule (76 FR 70252), we clarified that the ICD–9–CM codes eligible for the comorbidity payment adjustment are subject to the annual ICD–9–CM coding updates that occur in the hospital IPPS final rule and are effective October 1st every year. We explained that any updates to the ICD–9–CM codes that affect the categories of comorbidities and the diagnoses within the comorbidity categories that are eligible for a comorbidity payment adjustment would be communicated to ESRD facilities through sub-regulatory guidance.

Together with the rest of the healthcare industry, CMS was scheduled to implement the 10th revision of the ICD coding scheme—ICD–10—on October 1, 2014. Hence, in the CY 2014 ESRD PPS (78 FR 72175 through 72179), we finalized a policy that ICD–10–CM codes will be eligible for a comorbidity payment adjustment where they crosswalk from ICD–9–CM codes that are eligible for a comorbidity payment adjustment with two exceptions.

On April 1, 2014, PAMA was enacted. Section 212 of PAMA, titled ''Delay in Transition from ICD–9 to ICD–10 Code Sets,'' provides that ''[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and section 162.1002 of title 45, Code of Federal Regulations.'' On May 1, 2014, the Secretary announced that HHS expects to issue an interim final rule that will require use of ICD–10 beginning October 1, 2015 and continue to require use of ICD–9–CM through September 30, 2015. This announcement is available on the CMS Web site at *http://cms.gov/Medicare/Coding/ICD10/index.html*. Before the passage of PAMA, our policy required facilities to utilize ICD–10–CM codes to identify comorbidities eligible for the comorbidity payment adjustment beginning October 1, 2014. However, in light of section 212 of PAMA and the Secretary's announcement of the new compliance date for ICD–10, we are proposing to require use of ICD–10–CM to identify comorbidities beginning on October 1, 2015. Until that time, we will continue to require use of the ICD–9–CM codes to identify comorbidities eligible for the comorbidity payment adjustment. The ICD–9–CM codes that are eligible for the comorbidity payment adjustment are listed in the crosswalk tables below.

Because facilities will begin using ICD–10 during the calendar year to which this rule applies, we are correcting several typographical errors and omissions in the Tables that appeared in the CY 2015 ESRD PPS final rule. First, we are correcting one ICD–9–CM diagnosis code that was incorrectly identified due to a typographical error in Table 1—ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE (78 FR 72176). In Table 2—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES (78 FR 72177), we are correcting two ICD–10–CM codes because of typographical errors and proposing two additional ICD–10–CM codes that were inadvertently omitted from the crosswalk. Lastly, in Table 3—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE (78 FR 72178), we are proposing to include 9 additional ICD–10–CM crosswalk codes for eligibility for the comorbidity payment adjustment. These codes were omitted in error from the CY 2014 ESRD PPS final rule, and we have furnished an updated Table 20 below reflecting the additional codes.

We note that the ICD–10–CM codes that facilities will be required to use to identify eligible comorbidities when ICD–10 becomes the required medical data code set on October 1, 2015 are those that were finalized in the CY 2014 ESRD PPS final rule at 78 FR 72175 to 78 FR 72179 with the corrections and proposed additions included below.

Table 18— ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE (78 FR 72175 through 78 FR 72176).

Table 18 lists all the instances in which one ICD–9–CM code crosswalks to one ICD–10–CM code. We finalized a policy in last year's rule that all identified ICD–10–CM codes would receive a comorbidity adjustment with the exception of K52.81 Eosinophilic gastritis or gastroenteritis. We have since discovered that under the section titled Myelodysplastic Syndrome, ICD–9–CM code 238.7 Essential thrombocythemia was inaccurately identified. The table below has been amended to accurately identify ICD–9–CM diagnostic code 238.71 Essential thrombocythemia.

TABLE 18—ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE

ICD–9 Descriptor	ICD–10 Descriptor
Gastrointestinal Bleeding	
530.21 Ulcer of esophagus with bleeding	K22.11 Ulcer of esophagus with bleeding.
535.71 Eosinophilic gastritis, with hemorrhage	K52.81 Eosinophilic gastritis or gastroenteritis.
537.83 Angiodysplasia of stomach and duodenum with hemorrhage	K31.811 Angiodysplasia of stomach and duodenum with bleeding.
569.85 Angiodysplasia of intestine with hemorrhage	K55.21 Angiodysplasia of colon with hemorrhage.
Bacterial Pneumonia	
003.22 Salmonella pneumonia	A02.22 Salmonella pneumonia.
482.0 Pneumonia due to Klebsiella pneumonia	J15.0 Pneumonia due to Klebsiella pneumoniae.
482.1 Pneumonia due to Pseudomonas	J15.1 Pneumonia due to Pseudomonas.
482.2 Pneumonia due to Hemophilus influenzae [H. influenzae]	J14 Pneumonia due to Hemophilus influenzae.
482.32 Pneumonia due to Streptococcus, group B	J15.3 Pneumonia due to streptococcus, group B.
482.40 Pneumonia due to Staphylococcus, unspecified	J15.20 Pneumonia due to staphylococcus, unspecified.
482.41 Methicillin susceptible pneumonia due to Staphylococcus aureus.	J15.211 Pneumonia due to Methicillin susceptible Staphylococcus aureus.
482.42 Methicillin resistant pneumonia due to Staphylococcus aureus	J15.212 Pneumonia due to Methicillin resistant Staphylococcus aureus.
482.49 Other Staphylococcus pneumonia	J15.29 Pneumonia due to other staphylococcus.
482.82 Pneumonia due to escherichia coli [E. coli]	J15.5 Pneumonia due to Escherichia coli.
482.83 Pneumonia due to other gram-negative bacteria	J15.6 Pneumonia due to other aerobic Gram-negative bacteria.
482.84 Pneumonia due to Legionnaires' disease	A48.1 Legionnaires' disease.
507.0 Pneumonitis due to inhalation of food or vomitus	J69.0 Pneumonitis due to inhalation of food and vomit.
507.8 Pneumonitis due to other solids and liquids	J69.8 Pneumonitis due to inhalation of other solids and liquids.
510.0 Empyema with fistula	J86.0 Pyothorax with fistula.
510.9 Empyema without mention of fistula	J86.9 Pyothorax without fistula.
Pericarditis	
420.91 Acute idiopathic pericarditis	I30.0 Acute nonspecific idiopathic pericarditis.
Hereditary Hemolytic and Sickle Cell Anemia	
282.0 Hereditary spherocytosis	D58.0 Hereditary spherocytosis.
282.1 Hereditary elliptocytosis	D58.1 Hereditary elliptocytosis.
282.41 Sickle-cell thalassemia without crisis	D57.40 Sickle-cell thalassemia without crisis.
282.43 Alpha thalassemia	D56.0 Alpha thalassemia.
282.44 Beta thalassemia	D56.1 Beta thalassemia.
282.45 Delta-beta thalassemia	D56.2 Delta-beta thalassemia.
282.46 Thalassemia minor	D56.3 Thalassemia minor.
282.47 Hemoglobin E-beta thalassemia	D56.5 Hemoglobin E-beta thalassemia.
282.49 Other thalassemia	D56.8 Other thalassemias.
282.61 Hb-SS disease without crisis	D57.1 Sickle-cell disease without crisis.
282.63 Sickle-cell/Hb-C disease without crisis	D57.20 Sickle-cell/Hb-C disease without crisis.
282.68 Other sickle-cell disease without crisis	D57.80 Other sickle-cell disorders without crisis.
Myelodysplastic Syndrome	
238.71 Essential thrombocythemia	D47.3 Essential (hemorrhagic) thrombocythemia.
238.73 High grade myelodysplastic syndrome lesions	D46.22 Refractory anemia with excess of blasts 2.
238.74 Myelodysplastic syndrome with 5q deletion	D46.C Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality.
238.76 Myelofibrosis with myeloid metaplasia	D47.1 Chronic myeloproliferative disease.

Table 19—ONE ICD–9–CM CODE CROSSWALKS TO MULIPLE ICD–10–CM CODES (78 FR 72177 through 78 FR 72178).

Table 19 lists all of the instances in which one ICD–9–CM code crosswalks to multiple ICD–10–CM codes. We finalized a policy in last year's rule that all identified ICD–10–CM codes would receive a comorbidity adjustment with the exception of D89.2 Hypergammaglobulinemia, unspecified. Under the section titled Gastrointestinal Bleeding, ICD–9–CM code 562 Diverticulosis of small intestine with hemorrhage was inaccurately identified, as the complete code number is 562.02. The table below has been amended to accurately identify ICD–9–CM diagnostic code 562.02 Diverticulosis of small intestine with hemorrhage.

Also under the section titled Gastrointestinal Bleeding, ICD–9–CM diagnostic code 562.13 Diverticulitis of colon with hemorrhage did not include a complete crosswalk to ICD–10–CM diagnostic codes. Therefore, we propose to include ICD–10–CM diagnostic codes K57.81 Diverticulitis of intestine, part unspecified, with perforation and abscess with bleeding and K57.93 Diverticulitis of intestine, part unspecified, without perforation or abscess with bleeding, in addition to the ICD–10–CM diagnostic codes K57.21, K57.33, K57.41, and K57.53, as eligible for the comorbidity payment adjustment when the use of ICD–10–CM is required, on October 1, 2015.

Under the section titled Pericarditis, ICD–10–CM code 130.1 Infective pericarditis was inaccurately identified. The table below has been amended to accurately identify the ICD–10–CM diagnostic code I30.1 Infective pericarditis as eligible for a comorbidity payment adjustment when the use of ICD–10–CM is required, on October 1, 2015.

TABLE 19—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES

ICD–9 Descriptor	ICD–10 Descriptor
Gastrointestinal Bleeding	
562.02 Diverticulosis of small intestine with hemorrhage	K57.11 Diverticulosis of small intestine without perforation or abscess with bleeding. K57.51 Diverticulosis of both small and large intestine without perforation or abscess with bleeding.
562.03 Diverticulitis of small intestine with hemorrhage	K57.01 Diverticulitis of small intestine with perforation and abscess with bleeding. K57.13 Diverticulitis of small intestine without perforation or abscess with bleeding. K57.41 Diverticulitis of both small and large intestine with perforation and abscess with bleeding. K57.53 Diverticulitis of both small and large intestine without perforation or abscess with bleeding.
562.12 Diverticulosis of colon with hemorrhage	K57.31 Diverticulosis of large intestine without perforation or abscess with bleeding. K57.91 Diverticulosis of intestine, part unspecified, without perforation or abscess with bleeding. K57.51 Diverticulosis of both small and large intestine without perforation or abscess with bleeding.
562.13 Diverticulitis of colon with hemorrhage	K57.21 Diverticulitis of large intestine with perforation and abscess with bleeding. K57.33 Diverticulitis of large intestine without perforation or abscess with bleeding. K57.41 Diverticulitis of both small and large intestine with perforation and abscess with bleeding. K57.53 Diverticulitis of both small and large intestine without perforation or abscess with bleeding. K57.81 Diverticulitis of intestine, part unspecified, with perforation and abscess with bleeding.
K57.93 Diverticulitis of intestine, part unspecified, without perforation or abscess with bleeding.	
Bacterial Pneumonia	
513.0 Abscess of lung	J85.0 Gangrene and necrosis of lung. J85.1 Abscess of lung with pneumonia. J85.2 Abscess of lung without pneumonia.
Pericarditis	
420.0 Acute pericarditis in diseases classified elsewhere	A18.84 Tuberculosis of heart. I32 Pericarditis in diseases classified elsewhere. M32.12 Pericarditis in systemic lupus erythematosus.
420.90 Acute pericarditis, unspecified	I30.1 Infective pericarditis. I30.9 Acute pericarditis, unspecified.
420.99 Other acute pericarditis.	I30.8 Other forms of acute pericarditis. I30.9 Acute pericarditis, unspecified.
Hereditary Hemolytic and sickle cell anemia	
282.2 Anemias due to disorders of glutathione metabolism	D55.0 Anemia due to glucose-6-phosphate dehydrogenase [G6PD] deficiency. D55.1 Anemia due to other disorders of glutathione metabolism.
282.3 Other hemolytic anemias due to enzyme deficiency	D55.2 Anemia due to disorders of glycolytic enzymes. D55.3 Anemia due to disorders of nucleotide metabolism. D55.8 Other anemias due to enzyme disorders. D55.9 Anemia due to enzyme disorder, unspecified.
282.42 Sickle-cell thalassemia with crisis	D57.411 Sickle-cell thalassemia with acute chest syndrome. D57.412 Sickle-cell thalassemia with splenic sequestration.

TABLE 19—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES—Continued

ICD–9 Descriptor	ICD–10 Descriptor
	D57.419 Sickle-cell thalassemia with crisis, unspecified.
282.62 Hb-SS disease with crisis	D57.00 Hb-SS disease with crisis, unspecified. D57.01 Hb-SS disease with acute chest syndrome. D57.02 Hb-SS disease with splenic sequestration.
282.64 Sickle-cell/Hb-C disease with crisis	D57.211 Sickle-cell/Hb-C disease with acute chest syndrome. D57.212 Sickle-cell/Hb-C disease with splenic sequestration. D57.219 Sickle-cell/Hb-C disease with crisis, unspecified.
282.69 Other sickle-cell disease with crisis	D57.811 Other sickle-cell disorders with acute chest syndrome. D57.812 Other sickle-cell disorders with splenic sequestration. D57.819 Other sickle-cell disorders with crisis, unspecified.
Monoclonal Gammopathy	
273.1 Monoclonal paraproteinemia	D47.2 Monoclonal gammopathy. D89.2 Hypergammaglobulinemia, unspecified.
Myelodysplastic Syndrome	
238.72 Low grade myelodysplastic syndrome lesions	D46.0 Refractory anemia without ring sideroblasts, so stated. D46.1 Refractory anemia with ring sideroblasts. D46.20 Refractory anemia with excess of blasts, unspecified. D46.21 Refractory anemia with excess of blasts 1. D46.4 Refractory anemia, unspecified. D46.A Refractory cytopenia with multilineage dysplasia. D46.B Refractory cytopenia with multilineage dysplasia and ring sideroblasts.
238.75 Myelodysplastic syndrome, unspecified	D46.9 Myelodysplastic syndrome, unspecified. D46.Z Other myelodysplastic syndromes.

Table 20—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE (78 FR 72178).

Table 20 displays the crosswalk where multiple ICD–9–CM codes crosswalk to one ICD–10–CM code. We finalized a policy in last year's rule that all of the ICD–10–CM codes listed in Table 3 would be eligible for the comorbidity payment adjustment. Under the section titled Gastrointestinal Bleeding, nine ICD–10–CM codes (K25.0 Acute gastric ulcer with hemorrhage, K25.2 Acute gastric ulcer with both hemorrhage and perforation, K25.4 Chronic or unspecified gastric ulcer with hemorrhage, K25.6 Chronic or unspecified gastric ulcer with both hemorrhage and perforation, K26.0 Acute duodenal ulcer with hemorrhage, K26.2 Acute duodenal ulcer with both hemorrhage and perforation, K26.4 Chronic or unspecified duodenal ulcer with hemorrhage, K26.6 Chronic or unspecified duodenal ulcer with both hemorrhage and perforation, and K27.0 Acute peptic ulcer, site unspecified, with hemorrhage) and the corresponding ICD–9–CM codes were inadvertently omitted from the crosswalk. We propose that these ICD–10–CM diagnostic codes—K25.0, K25.2 K25.4, K25.6, K26.0, K26.2, K26.4, K26.6, K27.0—will be eligible for the comorbidity payment adjustment beginning October 1, 2015. We also propose that the corresponding ICD–9–CM codes will be eligible for the comorbidity adjustment through September 30, 2015.

TABLE 20—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE

Gastrointestinal Bleeding	
531.00 Acute gastric ulcer with hemorrhage, without mention of obstruction. 531.01 Acute gastric ulcer with hemorrhage, with obstruction.	K25.0 Acute gastric ulcer with hemorrhage.
531.20 Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction. 531.21 Acute gastric ulcer with hemorrhage and perforation, with obstruction.	K25.2 Acute gastric ulcer with both hemorrhage and perforation.
531.40 Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction. 531.41 Chronic or unspecified gastric ulcer with hemorrhage, with obstruction.	K25.4 Chronic or unspecified gastric ulcer with hemorrhage.
531.60 Chronic or unspecified gastric ulcer with hemorrhage and perforation, without mention of obstruction. 531.61 Chronic or unspecified gastric ulcer with hemorrhage and perforation, with obstruction.	K25.6 Chronic or unspecified gastric ulcer with both hemorrhage and perforation.
532.00 Acute duodenal ulcer with hemorrhage, without mention of obstruction. 532.01 Acute duodenal ulcer with hemorrhage, with obstruction.	K26.0 Acute duodenal ulcer with hemorrhage.
532.20 Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction.	K26.2 Acute duodenal ulcer with both hemorrhage and perforation.

TABLE 20—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE—Continued

532.21 Acute duodenal ulcer with hemorrhage and perforation, with obstruction.	
532.40 Chronic or unspecified duodenal ulcer with hemorrhage, without mention of obstruction.	K26.4 Chronic or unspecified duodenal ulcer with hemorrhage.
532.41 Chronic or unspecified duodenal ulcer with hemorrhage, with obstruction.	
532.60 Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction.	K26.6 Chronic or unspecified duodenal ulcer with both hemorrhage and perforation.
532.61 Chronic or unspecified duodenal ulcer with hemorrhage and perforation, with obstruction.	
533.00 Acute peptic ulcer of unspecified site with hemorrhage, without mention of obstruction.	K27.0 Acute peptic ulcer, site unspecified, with hemorrhage.
533.01 Acute peptic ulcer of unspecified site with hemorrhage, with obstruction.	
533.20 Acute peptic ulcer of unspecified site with hemorrhage and perforation, without mention of obstruction.	K27.2 Acute peptic ulcer, site unspecified, with both hemorrhage and perforation.
533.21 Acute peptic ulcer of unspecified site with hemorrhage and perforation, with obstruction.	
533.40 Chronic or unspecified peptic ulcer of unspecified site with hemorrhage, without mention of obstruction.	K27.4 Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage.
533.41 Chronic or unspecified peptic ulcer of unspecified site with hemorrhage, with obstruction.	
533.60 Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation, without mention of obstruction.	K27.6 Chronic or unspecified peptic ulcer, site unspecified, with both hemorrhage and perforation.
533.61 Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation, with obstruction.	
534.00 Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction.	K28.0 Acute gastrojejunal ulcer with hemorrhage.
534.01 Acute gastrojejunal ulcer, with hemorrhage, with obstruction.	
534.20 Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction.	K28.2 Acute gastrojejunal ulcer with both hemorrhage and perforation.
534.21 Acute gastrojejunal ulcer with hemorrhage and perforation, with obstruction.	
534.40 Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction.	K28.4 Chronic or unspecified gastrojejunal ulcer with hemorrhage.
534.41 Chronic or unspecified gastrojejunal ulcer, with hemorrhage, with obstruction.	
534.60 Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction.	K28.6 Chronic or unspecified gastrojejunal ulcer with both hemorrhage and perforation.
534.61 Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, with obstruction.	
Bacterial Pneumonia	
482.30 Pneumonia due to Streptococcus, unspecified 482.31 Pneumonia due to Streptococcus, group A. 482.39 Pneumonia due to other Streptococcus.	J15.4 Pneumonia due to other streptococci.
482.81 Pneumonia due to anaerobes 482.89 Pneumonia due to other specified bacteria.	J15.8 Pneumonia due to other specified bacteria.

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

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).

Specifically, section 1881(h) requires the Secretary to establish an ESRD QIP by (i) selecting measures; (ii) establishing the performance standards that apply to the individual measures; (iii) specifying a performance period with respect to a year; (iv) 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 (v) 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 the ESRD QIP, including for PYs 2017 and 2018.

B. Considerations in Updating and Expanding Quality Measures Under the ESRD QIP

Throughout the past decade, Medicare has been transitioning from a program that pays for healthcare based on particular services furnished to a beneficiary to a program that bases payments to providers and suppliers on the quality of services they furnish. By paying for the quality of care rather than simply the quantity of care, and by focusing on better care and lower costs through improvement, prevention and population health, expanded healthcare coverage, and enterprise excellence, we are strengthening the healthcare system

while also advancing the National Strategy for Quality Improvement in Health Care (that is, the National Quality Strategy (NQS)). We are also working to update a set of domains and specific quality measures for our VBP programs, and to link the aims of the NQS with our payment policies on a national scale. We are working in partnership with beneficiaries, providers, advocacy groups, the National Quality Forum (NQF), the Measures Application Partnership, operating divisions within the Department of Health and Human Services (HHS), and other stakeholders to develop new measures where gaps exist, refine measures where necessary, and remove measures when appropriate. We are also collaborating with stakeholders to ensure that the ESRD QIP serves the needs of our beneficiaries and also advances the goals of the NQS to improve the overall quality of care, improve the health of the U.S. population, and reduce the cost of quality healthcare.[2]

We believe that the development of an ESRD QIP that is successful in supporting the delivery of high-quality healthcare services in dialysis facilities is paramount. We seek to adopt measures for the ESRD QIP that promote better, safer, and more coordinated care. Our measure development and selection activities for the ESRD QIP take into account national priorities such as those established by the HHS Strategic Plan (*http://www.hhs.gov/strategic-plan/priorities.html*), the NQS (*http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm*), and the HHS National Action Plan to Prevent Healthcare Associated Infections (HAIs) (*http://www.hhs.gov/ash/initiatives/hai/esrd.html*). To the extent feasible and practicable, we have sought to adopt measures that have been endorsed by a national consensus organization; recommended by multi-stakeholder organizations; and developed with the input of providers, beneficiaries, health advocacy organizations, and other stakeholders.

C. Web Sites for Measure Specifications

In an effort to ensure that facilities and the general public are able to continue accessing the specifications for the measures that are being proposed for and have been adopted in the ESRD QIP, we are now posting these measure specifications on a CMS Web site, instead of posting them on *www.dialysisreports.org* as we have in the past. Measure specifications from previous years, as well as those proposed for the PY 2017 and PY 2018 programs, can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

D. Updating the NHSN Bloodstream Infection in Hemodialysis Outpatients Clinical Measure for the PY 2016 ESRD QIP and Future Payment Years

The NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure (that is, NHSN Bloodstream Infection clinical measure) that we adopted beginning with the PY 2016 ESRD QIP is based on NQF #1460. At the time we adopted it, the measure included a risk adjustment for patients' vascular access type but did not include any reliability adjustments to account for differences in the amount of exposure or opportunity for healthcare associated infections (HAIs) among patients. On April 4, 2014, in response to a measure update proposal submitted by CDC, NQF endorsed a reliability adjustment for volume of exposure and unmeasured variation across facilities to NQF #1460. This reliability adjustment is called the Reliability-Adjusted Standardized Infection Ratio or Adjusted Ranking Metric (ARM). As a result of this change to the NQF-endorsed measure specifications, a facility's performance on NQF #1460 will be adjusted towards the mean (that is, facilities with low exposure volume will be adjusted more than facilities with high exposure volume, and the performance rate will be adjusted up or down depending on the facility estimate and mean) to account for the differences in the reliability of the infection estimates based on the number of patient-months at a facility and any unmeasured variation across facilities. Because the adjustment is based on the volume of exposure, facility scores will be adjusted more if there are fewer patient-months in the denominator, and facility scores will be adjusted less if there are many patient-months in the denominator.

We propose to adopt the same reliability adjustment for purposes of calculating facility performance on the NHSN Bloodstream Infection clinical measure, beginning with the PY 2016 ESRD QIP. We believe that the inclusion of this reliability adjustment, in addition to the risk factor adjustment, will enable us to better differentiate among facility performance on this measure, because it accounts not only for the variation in patient risk by vascular access type, but also for variation in the number of patients a facility treats in a given month. The ARM will be incorporated into the existing risk-adjustment methodology, which will also continue to include a risk adjustment for patient vascular access type. Further information about the reliability adjustment, and the NHSN Bloodstream Infection measure specifications can be found at *http://www.cdc.gov/nhsn/PDFs/dialysis/NHSN–ARM.pdf, http://www.cdc.gov/nhsn/dialysis/dialysis-event.html,* and *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

E. Oral-Only Drugs Measures in the ESRD QIP

Section 217(d) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, amends section 1881(h)(2) of the Act to require the Secretary, for PY 2016 and subsequent years, to adopt measures (outcome-based, to the extent feasible) in the ESRD QIP that are specific to the conditions treated with oral-only drugs. We believe that the Hypercalcemia clinical measure adopted beginning with the PY 2016 program (78 FR 72200 through 72203) meets this new statutory requirement because hypercalcemia is a condition that is treated with oral-only drugs. The Hypercalcemia clinical measure is not an outcome-based measure, and we have considered the possibility of adopting outcomes-based measures that pertain to conditions treated with oral-only drugs. However, we have determined that it is not feasible to propose to adopt an outcome-based measure on this topic at this time because we are not aware of any outcome measures developed on this topic.

F. Proposed Requirements for the PY 2017 ESRD QIP

1. Proposed Revision to the Expanded ICH CAHPS Reporting Measure

For the ICH CAHPS reporting measure, we are proposing one change to the reporting requirements finalized in the CY 2014 ESRD PPS Final Rule for PY 2017. In the CY 2014 ESRD PPS final rule, we finalized that facilities would be eligible to receive a score on the measure if they treated 30 or more survey-eligible patients during the performance period (78 FR 72220 through 72221). Subsequently, we were made aware that facilities may not know whether they will have enough survey-eligible patients during the performance period to be eligible for the ICH CAHPS

[2] 2013 Annual Progress Report to Congress: National Strategy for Quality Improvement in Health Care, *http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm.*

measure when they are making decisions about whether or not they will contract with a vendor to administer the survey. We agree that it would be preferable if facilities knew at the beginning of the performance period if they will be eligible to receive a score on the ICH CAHPS measure, because this would allow facilities to make informed decisions about whether they should contract with a vendor to administer the survey. For this reason, we propose that beginning with the PY 2017 program, facilities will be eligible to receive a score on the ICH CAHPS measure if they treat 30 or more survey-eligible patients during the ''eligibility period,'' which we define as the CY before the performance period. However, even if a facility is eligible to receive a score on the measure because it has treated at least 30 survey-eligible patients according to the ICH CAHPS Survey measure specifications during the calendar year prior to the performance period, we are proposing that the facility will still not receive a score for performance during the performance period if it cannot collect 30 survey completes during the performance period. We believe that facilities should be able to determine quickly the number of survey-eligible patients that they treated during the eligibility period, and that reaching this determination should not impact facilities' ability to contract with a vender in time to meet the semiannual survey administration requirements. Technical specifications for the ICH CAHPS reporting measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We seek comments on this proposal.

2. Proposed Measures for the PY 2017 ESRD QIP

a. PY 2016 Measures Continuing in PY 2017 and Future Payment Years

We previously finalized 11 measures in the CY 2014 ESRD PPS Final Rule for the PY 2016 ESRD QIP, and these measures are summarized in Table 21 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 10 of these 11 measures in the PY 2017 ESRD QIP. As we discuss in more detail below, we are proposing to remove one measure, Hemoglobin Greater than 12 g/dL, beginning with the PY 2017 measure set (see Table 22 below).

TABLE 21—PY 2016 ESRD QIP MEASURES BEING CONTINUED IN PY 2017

NQF #	Measure title and description
0249	Hemodialysis Adequacy: Minimum delivered hemodialysis dose. Percent of hemodialysis patient-months with spKt/V greater than or equal to 1.2.
0318	Peritoneal Dialysis Adequacy: Delivered dose above minimum. Percent of peritoneal dialysis patient-months with spKt/V greater than or equal to 1.7 (dialytic + residual) during the four month study period.
1423	Pediatric Hemodialysis Adequacy: Minimum spKt/V. Percent of pediatric in-center hemodialysis patient-months with spKt/V greater than or equal to 1.2.
0257	Vascular Access Type: AV Fistula. 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. Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A [1]	National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients. Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.[2]
1454	Hypercalcemia. Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
N/A [3]	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration. 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 [4]	Mineral Metabolism Reporting. Number of months for which facility reports serum phosphorus for each Medicare patient.
N/A	Anemia Management Reporting. Number of months for which facility reports ESA dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient.

[1] We note that this measure is based on a current NQF-endorsed bloodstream infection measure (NQF#1460).

[2] We are proposing a new method of calculating performance on this measure using the ARM methodology. If we decide to finalize this proposal based on public comments, the NHSN Bloodstream Infection clinical measure description will be updated to read: ''ARM of Bloodstream Infection will be calculated among inpatients receiving hemodialysis at outpatient hemodialysis centers.''

[3] We note that a related measure utilizing the results of this survey has been NQF-endorsed (#0258). We are proposing to adopt NQF #0258 in the PY 2018 program.

[4] We note that this measure is based upon a current NQF-endorsed serum phosphorus measure (NQF #0255).

TABLE 22—MEASURE PROPOSED FOR REMOVAL BEGINNING WITH THE PY 2017 ESRD QIP

NQF#	Measure title
N/A	Anemia Management: Hgb >12. Percentage of Medicare patients with a mean hemoglobin value greater than 12 g/dL.

b. Proposal To Determine When a Measure is ''Topped-Out'' in the ESRD QIP, and Proposal To Remove a Topped-Out Measure From the ESRD QIP, Beginning With PY 2017

In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized a list of seven criteria we would consider when making determinations about whether to remove or replace a measure: ''(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; (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 unintended consequences.''

In the CY 2014 ESRD PPS final rule (78 FR 72192), we stated that we were in the process of evaluating all of the ESRD QIP measures against the criteria. Subsequent to the publication of the CY 2014 ESRD PPS final rule, we completed our evaluation and determined that none of the measures finalized in the PY 2016 ESRD QIP met criteria 2 through 7, as listed above. With respect to the first criterion, we are proposing to more specifically define when performance on a clinical measure is so high and unvarying that the measure no longer reflects meaningful distinctions in improvements or performance. The statistical definitions that we are proposing to adopt will align our methodology with that used by the Hospital VBP program to determine when a measure is topped out (76 FR 26496 through 26497). Under this methodology, a clinical measure is considered to be topped out if national measure data show (1) statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) a truncated coefficient of variation (CV) of less than or equal to 0.1.

To determine whether a clinical measure is topped out, we initially focused on the top distribution of facility performance on each measure and noted if their 75th and 90th percentiles were statistically indistinguishable. Then, to ensure that we properly accounted for the entire distribution of scores, we analyzed the truncated coefficient of variation (CV) for each of the clinical measures.

The CV is a common statistic that expresses the standard deviation as a percentage of the sample mean in a way that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual facility scores, with large and presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual facility scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual facility performance scores. We used a modified version of the CV, namely a truncated CV, for each clinical measure, in which the 5 percent of facilities with the lowest scores, and the 5 percent of facilities with the highest scores were first truncated (set aside) before calculating the CV. This was done to avoid undue effects of the highest and lowest outlier facilities; if included, they would tend to greatly widen the dispersion of the distribution and make the clinical measure appear to be more reliable or discerning. For example, a clinical measure for which most facility scores are tightly clustered around the mean value (a small CV) might actually reflect a more robust dispersion if there were also a number of facilities with extreme outlier values, which would greatly increase the perceived variance in the measure. Accordingly, the truncated CV of less than or equal to 0.10 was added as a criterion for determining whether a clinical measure is topped out.

We seek comments on this proposal.

We evaluated each of the clinical measures finalized in the PY 2016 ESRD QIP against these proposed statistical conditions. The full analysis is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* The results of that analysis appear below in Table 23.

TABLE 23—PY 2016 CLINICAL MEASURES USING CROWNWEB AND MEDICARE CLAIMS DATA FROM JANUARY 2013–DECEMBER 2013

Measure	N	75th percentile	90th percentile	Std. error	Statistically indistin-guishable	Truncated CV	TCV <0.10
Adult HD Kt/V	5665	96.1	97.4	0.13	No	0.04	Yes.
Adult PD Kt/V	1176	92.9	94.8	0.55	No	0.15	No.
Pediatric HD Kt/V	10	94.5	97.1	2.71	Yes	0.08	Yes.
Hgb > 12	5521	0.0	0.0	0.02	Yes	< 0.01	Yes.
Fistula Use	5561	72.3	77.0	0.16	No	0.14	No.
Catheter Use	5586	5.9	2.8	0.10	No	≤ 0.01	Yes.
Hypercalcemia	5685	0.3	0.0	0.04	No	≤ 0.01	Yes.

As the information presented in Table 23 suggests, the Hemoglobin Greater than 12 g/dL measure meets the proposed criteria for determining when a clinical measure is topped-out in the ESRD QIP. Accordingly, we propose to remove the Hemoglobin Greater than 12 g/dL measure from the ESRD QIP, beginning with the PY 2017 program. We recognize that the Pediatric Hemodialysis Adequacy measure also meets the conditions for being a topped-out clinical measure in the ESRD QIP. However, we are not proposing to remove the Pediatric Hemodialysis Adequacy measure from the ESRD QIP because we have determined that removing the measure will not be useful for dialysis facilities. There are currently very few measures available that focus on the care furnished to

pediatric patients with ESRD, and we are reticent to remove a measure that addresses the unique needs of this population. In addition, although only 10 facilities were eligible to receive a score on the Pediatric Hemodialysis Adequacy measure (based on CY 2013 data), we believe that the publicly reported performance of these facilities can influence the standard of care furnished by other facilities that treat pediatric patients, even if a facility does not treat a sufficient number of pediatric patients to be eligible to be scored on the measure.

For these reasons, we believe that the drawbacks of removing a topped out clinical measure could be outweighed by the other benefits to retaining the measure. Accordingly, we propose that even if we determine that a clinical measure is topped out according to the statistical criteria we apply, we will not remove or replace it if we determine that its continued inclusion in the ESRD QIP measure set will continue to set a high standard of care for dialysis facilities.

We seek comments on these proposals.

c. New Measures Proposed for PY 2017 and Future Payment Years

As the program evolves, we believe it is important to continue to evaluate and expand the measures selected for the ESRD QIP. Therefore, for the PY 2017 ESRD QIP and future payment years, we are proposing to adopt one new clinical measure that addresses care coordination (see Table 24).

TABLE 24—NEW MEASURE PROPOSED FOR THE PY 2017 ESRD QIP

NQF#	Measure title
N/A [1]	Standardized Readmission Ratio, a clinical measure. Risk-adjusted standardized hospital readmissions ratio.

[1] We note that this measure is currently under review at NQF.

i. Proposed Standardized Readmission Ratio (SRR) Clinical Measure

Background

At the end of 2011, 615,899 patients were being dialyzed, 115,643 of whom were new (incident) patients with ESRD.[3] The SRR measure assesses the rate of unplanned readmissions of ESRD patients to an acute care hospital within 30 days of an index discharge from an acute care hospital, thereby identifying potentially poor or incomplete quality of care in the dialysis facility. In addition, the SRR reflects an aspect of ESRD care that is especially resource-intensive. In 2011, the total amount paid by Medicare for the ESRD program was approximately $34.3 billion, a 5.4 percent increase from 2010.[2] In particular, Medicare paid more than $10.5 billion for costs associated with hospitalized ESRD patients in 2011. In 2011, ESRD dialysis patients were admitted to the hospital twice on average, and spent an average of 12 total days in the hospital over the year, accounting for approximately 38 percent of Medicare expenditures for patients with ESRD.[2] Furthermore, a substantial percentage (30 percent) of ESRD patients discharged from the hospital have an unplanned readmission within 30 days.[2] In the non-ESRD population, clinical studies have demonstrated that improved care coordination and discharge planning may reduce readmission rates. The literature also reports a wide range of estimates of the percentage of readmissions that may be preventable. One literature review of more than 30 studies found the median proportion of readmissions that may be preventable was 27%, with a range of 5% to 79%.[4] Preventability varied widely across diagnoses. Readmissions were more likely to be preventable in patients with more severe conditions. Therefore, a systematic measure on unplanned readmissions is essential for controlling escalating medical costs; it can identify where readmission rates are unusually high, and help facilities to provide cost-effective healthcare.

Overview of Measure

The SRR is a one-year risk-standardized measure of a facility's 30-day, all-cause rate of unplanned hospital readmissions among Medicare-covered ESRD dialysis patients. The number of expected readmissions is determined by a risk-adjustment model that accounts for the hospital where the index discharge took place, certain patient characteristics (including age, sex, and comorbidities), and the national median expected performance for all dialysis facilities, given the same patient case mix.

We are proposing to adopt the SRR measure currently under review by NQF (NQF #2496). Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iv) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (that entity currently is NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed, so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We have given due consideration to endorsed measures, as well as those adopted by a consensus organization, and we are proposing this measure under the authority of 1881(h)(2)(B)(ii) of the Act. Although the NQF has endorsed an all-cause hospital readmission measure (NQF #1789), we do not believe it is feasible to adopt this measure in the ESRD QIP because NQF #1789 is specified for use in hospitals, not dialysis facilities. In addition, NQF #1789 is intended to evaluate readmissions across all patient types, whereas the proposed SRR measure is specified for the unique population of ESRD dialysis patients, which have a different risk profile than the general population captured in NQF #1789. Because the proposed SRR measure has been developed specifically for the dialysis-facility setting, and because the measure has the potential to improve clinical practice and decrease healthcare costs, we believe it is appropriate to adopt the SRR in the ESRD QIP at this time.

We have analyzed the measure's reliability, the results of which are provided below and in greater detail in the SRR Measure Methodology report, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* The Inter-Unit Reliability (IUR) was calculated for the proposed SRR using data from 2012 and a ''bootstrap'' approach, which uses a resampling scheme to estimate the within-facility variation that cannot be directly estimated by the analysis of variance (ANOVA). The SRRs that we calculated for purposes of this analysis were for dialysis facilities that had at least 11 patients who had been discharged from a hospital during 2012. A small IUR (near 0) reveals that most of the variation of the measures between

[3] United States Renal Data System, USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2013.

[4] van Walraven C, Bennett C, Jennings A, Austin PC, Forster AJ. Proportion of hospital readmissions deemed avoidable: a systematic review. CMAJ. 2011;183(7):E391–E402.

facilities is driven by ''random noise,'' indicating the measure would not be a reliable characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real differences between facilities. The IUR for the proposed SRR measure was found to be 0.49, indicating that about one-half of the variation in the SRR can be attributed to between-facility differences, and about half to within-facility variation. This value of IUR indicates that an average-size facility would achieve a moderate degree of reliability for this measure. This level of reliability is consistent with the reliability of other outcome measures in CMS quality-reporting and VBP programs, such as the 30-day Risk-Standardized All-Cause Acute Myocardial Infarction, Heart Failure, and Pneumonia Readmission and Mortality measures used in the Hospital IQR and VBP Programs. We therefore believe that facilities can be reliably scored on the proposed SRR measure.

We convened a technical expert panel (TEP) in May 2012 for the purpose of evaluating this measure, but the TEP did not reach a final consensus and declined to support the measure. Some members of the TEP were concerned that we did not risk-adjust for the nephrologist treating the patients, because actions taken by nephrologists can impact readmission rates. After reviewing the TEP's arguments, we determined that the suggested risk adjustment for nephrologist care would constitute a reversal of CMS policy not to risk adjust for factors related to care for which the provider is responsible. We do not think that it is appropriate to risk-adjust the measure for the nephrologist because the nephrologist is part of the facility's multi-disciplinary team, and medical directors, as employees of the dialysis facilities, are responsible for ensuring that appropriate care is provided by a multi-disciplinary team. The Measures Application Partnership reviewed this measure in February 2013 and supported the direction of the measure, advising CMS that the measure would require additional development prior to implementation. Subsequently, we released draft specifications for the measure to the public for a 30-day comment period and, based on comments received, finalized measure specifications in September 2013. We also, on a voluntary basis, provided individual dialysis facilities with a facility-specific report that calculated their SRR measure results and compared those results to SRR measure results at the state and national level, as well as discharge-level data upon request. Facilities also had an opportunity to submit questions to CMS regarding the measure and their reports. We therefore believe that the proposed SRR measure risk-adjusts appropriately for patient condition and comorbidities at the start of care for which the facility is not responsible. We also believe that the measure is ready for adoption because, as explained above, it achieves a moderate degree of reliability.

Data Sources

The data we will use to calculate the proposed SRR measure come from various CMS-maintained data sources for ESRD patients including the CROWNWeb database, the CMS Annual Facility Survey (Form CMS–2744), Medicare claims, the CMS Medical Evidence Form (Form CMS–2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS–2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. These data sources include all Medicare-covered patients with ESRD. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs) and past-year comorbidity is obtained from Medicare Claims SAFs (inpatient, outpatient, physician/supplier, home health, hospice, and skilled nursing facility claims).

Outcome

The outcome for this measure is 30-day all-cause, unplanned readmission defined as a hospital readmission for any cause beginning within 30 days of the discharge date of an index discharge, with the exclusion of planned readmissions. This 30-day readmission period is consistent with other publicly reported readmission measures endorsed by NQF and currently implemented in the Hospital Inpatient Quality Reporting Program and Hospital Readmission Reduction Program, and reflects an industry standard.

Cohort

All discharges of Medicare ESRD dialysis patients from an acute care hospital in a calendar year are considered eligible for this measure, with the exception of the exclusions listed in the next section.

Inclusion and Exclusion Criteria

The proposed SRR measure excludes from the measure cohort hospitalizations: (1) Where the patient died during the index hospitalization; (2) where the patient dies within 30 days of the index discharge with no readmission; (3) where the patient is discharged against medical advice; (4) where the patient was admitted with a primary diagnosis of certain conditions related to cancers, mental health conditions, or rehabilitation procedures (because these patients possess radically different risk profiles, and therefore cannot reasonably be compared to other patients discharged from hospitals); (5) where the patient is discharged from a PPS-exempt cancer hospital (because these hospitals care for a unique population of patients that cannot reasonably be compared to the patients admitted to other hospitals); (6) where the patient is transferred to another acute care hospital; and (7) where the patient has already been discharged 12 times during the same calendar year (to respond to concerns raised by the TEP that patients who are hospitalized this frequently during a calendar year could unduly skew the measure rates for small facilities).

Risk Adjustment

The measure adjusts for differences across facilities with regard to their patient case mix. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race, because risk adjusting for these characteristics would hold facilities with a large proportion of patients who are minorities and/or who have low socioeconomic status to a different standard of care than other facilities. One goal of this measure is to illuminate quality differences that such risk adjustment would obscure. As with the Hospital-Wide Readmission measure employed by the Hospital Readmissions Reduction program, the SRR employs a hierarchical logistic regression model to estimate the expected number of readmissions to an acute care hospital, taking into account the performance of all dialysis facilities, the discharging hospital, and the facility's patient case-mix.

Although the SRR risk-adjustment model is generally aligned with the Hospital-Wide Readmission measure risk-adjustment methodology, we are proposing to modify it to account for comorbidities and patient characteristics relevant to the ESRD population. The proposed SRR measure includes the following patient characteristics as risk adjustors, which are obtained from the following data sources:

Risk adjustor	Data source
Sex	CMS Form 2728.
Age	REMIS database.
Years on ESRD	CMS Form 2728.
Diabetes as cause of ESRD	CMS Form 2728.
BMI at incidence of ESRD	CMS Form 2728.
Days hospitalized during index admission	Part A Medicare Inpatient Claims SAFs.
23 past-year comorbidities (e.g., cardiorespiratory failure/shock; drug and alcohol disorders).	Medicare Claims SAFs: Part A Inpatient, home health, hospice, and skilled nursing facility; and Part B Outpatient.
Discharged with any of 11 high-risk conditions (for example, cystic fibrosis, and hepatitis).	Part A Medicare Inpatient Claims SAFs.

More details on the risk-adjustment calculations, and the rationale for selecting these risk adjustors and not others, can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.* We are proposing to risk adjust the proposed SRR measure based on sex, because we have determined that patients' sex affects the measure in ways that are beyond the control of dialysis facilities. We reached this determination by examining the effects of the risk adjusters, both independently and in combination, on rates of unplanned readmissions. This analysis yielded two conclusions. First, the analysis indicated that females are generally more likely than males to experience an unplanned readmission, even when accounting for the other risk adjustors. Second, the disparate effects of gender were substantially impacted by the effects of age: Females aged 15 to 45 were much more likely to experience an unplanned readmission than males of the same age, but this disparity was significantly reduced for men and women younger than 15 and older than 45. Based on these two conclusions, we believe that women in the 15–45 age range face a greater risk of experiencing an unplanned readmission, as compared to men of the same age with similar risk profiles. This does not appear to be a consequence of facility performance, however, because the disparity is not generally applicable to women, but only to a limited age group. We therefore believe it is essential to risk-adjust for sex to ensure that facilities with larger numbers of women aged 15 to 45 are not inappropriately disadvantaged, because not risk-adjusting for sex would potentially incentivize facilities to deny access to these individuals.

As indicated in the table above, the measure is risk-adjusted, in part, based on 23 comorbidities that develop in the year prior to the index hospitalization, as well as 11 high-risk conditions that are present at the time of the index discharge. These data are taken from Medicare claims submitted by hospitals, dialysis facilities, and other types of long-term and post-acute care facilities.

We believe that this proposed approach to risk-adjusting the SRR measure is consistent with NQF guidelines for measure developers. NQF evaluates measures on the basis of four criteria: Importance, scientific acceptability, feasibility, and usability. The validity and reliability of a measure's risk-adjustment calculations fall under the ''scientific acceptability'' criterion, and Measure Evaluation Criterion 2b4 specifies NQF's preferred approach for risk-adjusting outcome measures (*http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx#scientific*). This criterion states that patient comorbidities should only be included in risk-adjustment calculations if they are (1) present at the start of care and (2) not indicative of disparities or deficiencies in the quality of care provided. As indicated in the ''Inclusion and Exclusion Criteria'' subsection above, as well as the measure specifications that are currently under review at NQF, the start of care is defined as the index hospitalization. Accordingly, we believe that NQF Measure Evaluation Criterion 2b4 supports risk adjusting the proposed SRR measure on the basis of patient comorbidity data collected in the year prior to the index hospitalization, because these comorbidities are likely present at the start of care (that is, the date(s) that the patient spends in the hospital during the index hospitalization). For these reasons, we believe that the risk-adjustment methodology for the proposed SRR measure is consistent with NQF guidelines for measure developers and is appropriate for this measure.

Full documentation of the SRR risk-adjustment methodology is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.*

Calculating the SRR Measure

The SRR measure is calculated as the ratio of the number of observed unplanned readmissions to the number of expected unplanned readmissions. Facilities that have more unplanned readmissions than would be expected for an average facility with a similar case-mix would have a ratio greater than one. Facilities having fewer unplanned readmissions than would be expected for an average facility with a similar case-mix would have a ratio less than one. This ratio calculation is consistent with that employed by one NQF-endorsed outcome measure for ESRD, the Standardized Hospitalization Ratio (NQF #1463).

Hospitalizations are counted as events in the numerator if they meet the definition of unplanned readmission—which is that they (a) occurred within 30 days of the index discharge and (b) are not preceded by a ''planned'' readmission that also occurred within 30 days of the index discharge. Planned readmissions are defined as readmissions that do not bear on the quality of care furnished by the dialysis facility, that occur as a part of ongoing appropriate care of patients, or that involve elective care. Building on the algorithm developed for the Hospital-Wide Readmission measure (NQF #1789), the proposed planned readmission list incorporates minor changes appropriate to the ESRD population as suggested by technical experts. The full planned readmission list and algorithm are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.* In general, a readmission is considered ''planned'' under two scenarios.

1. The patient undergoes a procedure that is always considered planned (example, bone marrow transplant) or has a primary diagnosis that always indicates the hospitalization is planned (for example, maintenance chemotherapy).

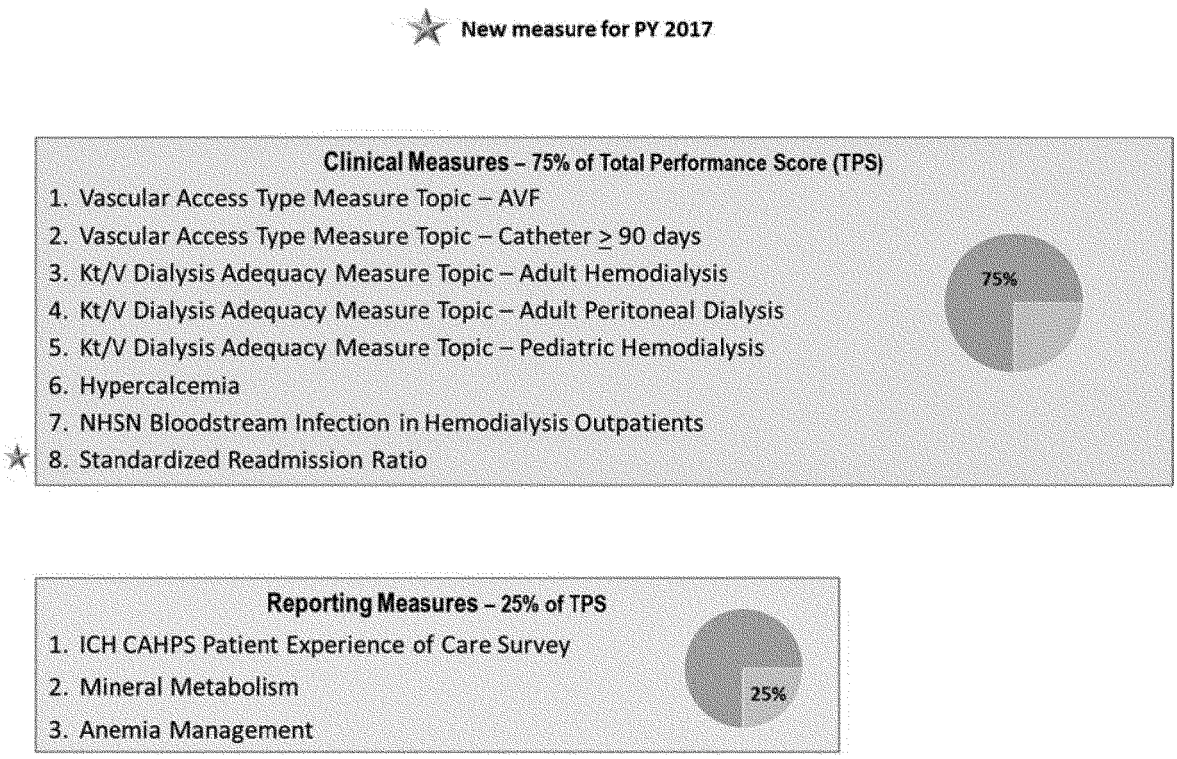
2. The patient undergoes a procedure that *may* be considered planned if it is not accompanied by an acute diagnosis. For example, a hospitalization involving a heart-valve procedure accompanied by

a primary diagnosis of acute myocardial infarction would be considered unplanned, whereas a hospitalization involving a heart-valve procedure accompanied by a primary diagnosis of diabetes would be considered planned (because acute myocardial infarction is a plausible alternative acute indication for hospitalization).

The expected number of readmissions is calculated using hierarchical logistic modeling (HLM). This approach accounts for the hospital from which the patient was discharged and the patient case mix (as defined by factors such as age, sex, and patient comorbidities), as well as the national median performance of all dialysis facilities. The HLM is an appropriate statistical approach to measuring quality based on patient outcomes when patients are clustered within facilities (and therefore the patients' outcomes are not statistically independent), and when the number of qualifying patients for the measure varies from facility to facility. The HLM approach is also currently used to calculate readmission and mortality measures that are used in several quality-reporting and VBP programs by CMS, such as the Heart Failure and Pneumonia Mortality measures in the Hospital IQR and Hospital VBP Programs.

The proposed SRR measure is a point estimate—the best estimate of a facility's readmission rate based on the facility's case mix. For more information on the proposed calculation methodology, please refer to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.*

Figure 1: Summary of Proposed PY 2017 Measure Set



3. Proposed Performance Period for the PY 2017 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. In the CY 2013 ESRD PPS Final Rule (77 FR 67500), we stated our belief that, for most measures, a 12-month performance period is the most appropriate for the program because this period accounts for any potential seasonal variations that might affect a facility's score on some of these measures, and also provides adequate incentive and feedback for facilities and Medicare beneficiaries. CY 2015 is the latest period of time during which we can collect a full 12 months of data and still implement the PY 2017 payment reductions. Therefore, we propose to establish CY 2015 as the performance period for PY 2017 ESRD QIP.

We seek comments on this proposal.

4. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2017 ESRD QIP

We are proposing to adopt performance standards for the PY 2017 ESRD QIP measures similar to those we finalized for PY 2016 (78 FR 72211 through 72213). 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 2017 ESRD QIP

With the exception of the NHSN Bloodstream Infection clinical measure, we propose to set the performance standards, achievement thresholds, and benchmarks for the PY 2017 clinical measures at the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2013, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2017 program prior to the beginning of the performance period. We continue to believe that 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. As stated in the CY 2014 ESRD PPS Final Rule (78 FR 72213 through 72215), CY 2014 is the first year for which we will have data for the NHSN Bloodstream Infection clinical measure. Accordingly, we propose to set the performance standard, achievement threshold, and benchmark for the NHSN Bloodstream Infection clinical measure based on the 50th, 15th, and 90th percentiles, respectively, of national performance in CY 2014.

We seek comments on these proposals.

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Proposed for the PY 2017 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks for the clinical measures, because we do not yet have complete data from CY 2013. Nevertheless, we are able to estimate these numerical values based on the most recent data available. For all of the proposed clinical measures except the proposed SRR measure, this partial data comes from the period of January through December 2013. For the proposed SRR measure, this partial data comes from the period of January through December 2012. In Table 25, we have provided the estimated numerical values for all of the proposed PY 2017 ESRD QIP clinical measures except the NHSN Bloodstream Infection clinical measure. We will publish updated values for the clinical measures, using data from the first part of CY 2014, in the CY 2015 ESRD PPS final rule.

TABLE 25—ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2017 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Performance standard	Achievement threshold	Benchmark
Vascular Access Type:			
%Fistula	64.49%	52.43%	78.64%
%Catheter	9.9%	18.36%	3.21%
Kt/V:			
Adult Hemodialysis	93.65%	86.97%	97.55%
Adult Peritoneal Dialysis	87.50%	70.42%	95.74%
Pediatric Hemodialysis	92.48%	79.55%	97.98%
Hypercalcemia	1.32%	4.78%	0.00%
NHSN Bloodstream Infection	50th percentile of eligible facilities' performance during CY 2014.	15th percentile of eligible facilities' performance during CY 2014.	90th percentile of eligible facilities' performance during CY 2014.
Standardized Readmission Ratio	0.996	1.242	0.658

We believe that the ESRD QIP should not have lower performance standards than in previous years. In accordance with our statements in the CY 2012 ESRD PPS final rule (76 FR 70273), 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 2016 ESRD QIP, then we propose to substitute the PY 2016 performance standard, achievement threshold, and/or benchmark for that measure.

We seek comments on this proposal.

c. Proposed Performance Standards for the PY 2017 Reporting Measures

In the CY 2014 ESRD PPS Final Rule, we finalized performance standards for the Anemia Management, Mineral Metabolism, and ICH CAHPS reporting measures (78 FR 72213). We are proposing to continue to use these performance standards for these measures in the PY 2017 ESRD QIP. We seek comments on this proposal.

5. Proposal for Scoring the PY 2017 ESRD QIP Measures

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). In determining a facility's achievement score for each measure under the PY 2017 ESRD QIP, we propose to continue using this methodology for all clinical measures. Under this methodology, facilities receive points along an achievement range based on their performance during the proposed performance period for each measure, which we define as a scale between the achievement threshold and the benchmark.

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 2017 ESRD QIP, we propose to continue using this methodology for all clinical measures. 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 2014. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2015 (the proposed performance period) to its performance rate on the measure during CY 2014.

6. 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 most recently in the CY 2014 ESRD PPS (78 FR 72217), to weight clinical measures as 75 percent and reporting measures as 25 percent of the 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 2017 ESRD QIP and Proposal for Changing Attestation Process for Patient Minimums

For the same reasons described in the CY 2013 ESRD PPS final rule (77 FR 67510 through 67512), for PY 2017 we propose to only score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period. Our current policy is that a facility must treat at least 11 qualifying patients during the performance period in order to be scored on a clinical measure (77 FR 67510 through 67511). We are not proposing any changes to this policy.

However, with respect to the proposed SRR measure, we propose that facilities with fewer than 11 index discharges will not be eligible to receive a score on that measure. We considered proposing to adopt the 11 qualifying patient minimum that we use for the other clinical measures. We decided, however, to base facility eligibility for the measure on the number of index discharges attributed to a facility, because the measure calculations are determined by the number of index discharges, adjusted for patient case-mix. We decided to set the minimum number of index discharges at 11 because this is consistent with reporting for the proposed SRR measure during the dry run conducted earlier this year, as well as with the implementation of outcome measures in the Hospital Readmission Reduction Program, which base case minimums on the number of index discharges attributable to the facility.

Additionally, for the proposed SRR measure, we propose to apply the small-facility adjuster to facilities that treat 41 or fewer index discharges because we determined that this was the minimum number of index discharges needed to achieve an IUR of 0.4 (that is, moderate reliability) for the proposed SRR measure. Because the small-facility adjuster gives facilities the benefit of the doubt when measure scores can be unduly influenced by a few outlier patients, we believe that setting the threshold at 41 index discharges will not unduly penalize facilities that treat small numbers of patients.

In the CY 2014 ESRD PPS Final Rule, we finalized that the case minimum for the Mineral Metabolism and Anemia Management reporting measures is one, and that facilities that treat one qualifying patient could attest to this in CROWNWeb in order to avoid being scored on the measures (78 FR 72197 through 72199 and 72220 through 72221). In the process of responding to questions from facilities about the attestation requirements for the PY 2015 program, however, we found that facilities were confused by this requirement. For this reason, we propose to remove the option for facilities to attest that they did not meet the case minimum for these measures. Accordingly, facilities that meet the case minimum of one qualifying patient would be scored on these measures, facilities with between 2 and 11 qualifying patients would be required to report data for all but one qualifying patient, and facilities with 11 or more qualifying patients would be required to report data for all patients. Due to facility confusion with the attestation process, we also propose to remove the option for facilities to attest that they did not meet the case minimum for the ICH CAHPS survey reporting measure. As we stated above, we are not proposing any further changes to the 30 survey-eligible case minimum for this measure. We are proposing that the ESRD QIP program will determine facility eligibility for these measures based on available data submitted to CROWNWeb, in Medicare claims, and to other CMS administrative data sources.

We seek comments on this proposal.

We are proposing to continue our policies that govern when a newly opened facility would be eligible to be scored on measures as follows.

- Facilities with a CCN open date on or after July 1 of the performance period (for PY 2017, this would be July 1, 2015) are not eligible to be scored on any reporting measures except the ICH CAHPS reporting measure.
- Facilities with a CCN open date on or after January 1 of the performance period (for PY 2017, this would be January 1, 2015) are not eligible to receive a score on the ICH CAHPS reporting measure in the PY 2017 program, due to the time it takes to contract with a CMS-approved third-party vendor to administer the survey.
- Facilities are eligible to receive a score on all of the clinical measures except the NHSN Bloodstream Infection clinical measure if they have a CCN open date at any time before the end of the performance period.
- Facilities with a CCN open date after January 1 of the performance period (for PY 2017, this would be January 1, 2015) are not eligible to receive a score on the NHSN Bloodstream Infection clinical measure, due to the need to collect 12 months of data to accurately score the measure.

We are also proposing to continue our policy that a facility will not receive a TPS unless it receives a score on at least one clinical measure and at least one reporting measure. We note that as a result, facilities will not be eligible for a payment reduction under the PY 2017 ESRD QIP if they have a CCN open date on or after July 1, 2015.

We seek comments on these proposals.

Table 26 displays the proposed patient minimum requirements for each of the reporting measures, as well as the CCN open dates after which a facility will not be eligible to receive a score on a reporting measure.

TABLE 26—PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2017 ESRD QIP

Measure	Minimum data requirements	CCN Open date	Small facility adjuster
Adult Hemodialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Adult Peritoneal Dialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Pediatric Hemodialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.

TABLE 26—PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2017 ESRD QIP—Continued

Measure	Minimum data requirements	CCN Open date	Small facility adjuster
Vascular Access Type: Catheter (Clinical).	11 qualifying patients	N/A	11–25 patients.
Vascular Access Type: Fistula (Clinical).	11 qualifying patients	N/A	11–25 patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 patients.
NHSN Bloodstream Infection (Clinical).	11 qualifying patients	On or before January 1, 2015.	11–25 patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
ICH CAHPS (Reporting)	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, 2015	N/A.
Anemia Management (Reporting).	Facilities with 11 or more qualifying patients must report data for all patients. Facilities with between 2 and 11 qualifying patients must report data on all but 1 qualifying patient. Facilities with 1 qualifying patient must report for that patient.	Before July 1, 2015	N/A.
Mineral Metabolism (Reporting).	Facilities with 11 or more qualifying patients must report data for all patients. Facilities with between 2 and 11 qualifying patients must report data on all but 1 qualifying patient. Facilities with 1 qualifying patient must report for that patient.	Before July 1, 2015	N/A.

8. Proposed Payment Reductions for the PY 2017 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. For PY 2017, we are proposing that 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;
- It received zero points for each clinical measure that does not have a numerical value for the performance standard established through the rulemaking process before the beginning of the PY 2017 performance period; and
- It received 10 points (which is the 50th percentile of facility performance on the PY 2015 reporting measures) for each reporting measure.

We recognize that these conditions are more stringent than the conditions used to establish the minimum TPS in the PY 2016 ESRD QIP, because this proposal increases the number of points a facility would have to receive on each reporting measure from 5 to 10. The PY 2015 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 2017 (i.e., CY 2015). We note that facility performance on the Anemia Management, Mineral Metabolism, NHSN Dialysis Event, and ICH CAHPS reporting measures in the PY 2015 program is so high that the median score on each of the measures was 10 points. We are proposing to increase the number of points a facility would have to achieve for each reporting measure to the 50th percentile of facility performance on the PY 2015 reporting measures (i.e., the average of the median scores for each reporting measure), because a score of 5 on each of these reporting measures is indicative of a below-average performance, and we want to incentivize facilities to provide above-average care.

We seek comments on this proposal.

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, such that 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, with a maximum reduction of 2.0 percent. We are not proposing any changes to this policy at this time.

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are likewise not able to calculate the minimum TPS at this time. Based on the estimated performance standards listed above, we estimate that a facility must meet or exceed a minimum TPS of 58 for PY 2017. For all of the clinical measures except the NHSN Bloodstream Infection clinical measure, these data come from CY 2013. For the NHSN Bloodstream Infection clinical measure, we set the performance standard to zero for purposes of this estimate, because we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the PY 2017 performance period. We are proposing that facilities failing to meet the minimum TPS, as established in the CY 2015 ESRD PPS Final Rule, will receive payment reductions based on the estimated TPS ranges indicated in Table 27 below.

TABLE 27—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2017 BASED ON THE MOST RECENTLY AVAILABLE DATA FROM CY 2013

Total performance score	Reduction (%)
100—58	0
57—48	0.5
47—38	1.0
37—28	1.5
27—0	2.0

9. Proposal for 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 we have

procured the services of a data-validation contractor that is tasked with validating a national sample of facilities' records as they report CY 2014 data to CROWNWeb. Our first priority was to develop a methodology for validating data submitted to CROWNWeb under the pilot data-validation program, and this continues to be our goal. Once this methodology has been fully developed, we will propose to adopt it 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 will have 60 days to comply once they receive requests for records. We are proposing to continue this pilot for the PY 2017 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 2015. If a facility is randomly selected to participate in the pilot validation study but does not provide CMS 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.

We seek comments on this proposal.

We are also proposing a feasibility study for validating data reported to CDC's NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure. HAIs are relatively rare, and we are proposing 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. The methodology for this proposed feasibility study would resemble the methodology used by 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 535553).

Specifically, we propose to randomly select nine facilities to participate in the feasibility study. A CMS contractor will send these facilities quarterly requests for lists of 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. A CMS contractor will then develop a methodology for determining when a positive blood culture qualifies as a ''candidate dialysis event,'' and is therefore appropriate for further validation. Once the contractor determines a methodology for identifying candidate dialysis events, the contractor will analyze the records of patients who had a positive blood culture in order to determine if 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 propose to deduct 10 points from the facility's TPS.

The goals of the proposed feasibility study will be five-fold: (1) To estimate the burden and associated costs to facilities of validating the NHSN Bloodstream Infection clinical measure; (2) to assess the costs to CMS to validate this measure; (3) to develop a methodology for identifying candidate dialysis events from lists of positive blood cultures; (4) to develop a methodology for determining whether a facility accurately reported dialysis events under the NHSN Bloodstream Infection clinical measure; and (5) to reach some preliminary conclusions about whether facilities are accurately reporting data under the NHSN Bloodstream Infection clinical measure. Based on the results of this study, we will consider the feasibility of proposing in future rulemaking to validate the NHSN Bloodstream Infection clinical measure for all facilities.

We seek comments on this proposal.

10. Proposal To Monitor Access to Dialysis Facilities

Public comments on the proposal to adopt the Standardized Hospitalization Ratio measure in the PY 2014 ESRD QIP (76 FR 70267) expressed concerns that ''the measure may lead to 'cherry-picking' of patients based on their risk of hospitalizations, causing access to care issues for patients with more severe illness.'' We share commenters' concerns about the SHR measure, and we believe that these concerns equally apply to other outcome measures proposed for the ESRD QIP. We recognize that, in general, inadequate risk adjustment in outcome measure calculations can create an incentive for facilities to deny services to sicker patients, because these patients' illnesses would not be properly accounted for in the risk-adjustment calculations. We believe that outcome measures proposed and adopted for the ESRD QIP properly risk adjust for patients with severe illnesses, but we remain concerned that misperceptions to the contrary might negatively impact access to dialysis therapy.

Since we are proposing to adopt the SRR clinical measure for the PY 2017 program, and below we are proposing to adopt the STrR clinical measure for the PY 2018 program, we propose to initiate a monitoring program focused on access to dialysis therapy. This program would compare dialysis data before and after the adoption of an outcome measure, looking for changes in admission and discharge practices, as well as changes in rates and patterns of involuntary discharges. Specifically, this program would assess and analyze the characteristics of beneficiaries admitted to dialysis centers (stratified by location, size, and setting) in order to determine when and if selective admission and discharge practices are coupled with negative patient attributes and trends over time. We believe this program will enable us to identify patterns that are indicative of diminished access to dialysis therapy.

We seek comments on this proposal.

11. Proposed Extraordinary Circumstances Exception

Many comments on the CY 2014 ESRD PPS proposed rule included the recommendation to exempt a facility from all the requirements of the ESRD QIP clinical and reporting measures during the time the facility was forced to close temporarily due to a natural disaster or other extraordinary circumstances. In response to these comments, we agreed that ''there are times when facilities are unable to submit required quality data due to extraordinary circumstances that are not within their control, and we do not wish to penalize facilities for such circumstances or unduly increase their

burden during these times'' (78 FR 72209).

Section 1881(h)(3)(A)(i) of the Act states, ''[T]he Secretary shall develop a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected under paragraph (2) for a performance period established under paragraph (4)(D).'' Given the possibility that facilities could be unfairly penalized for circumstances that are beyond their control, we believe the best way to implement an extraordinary circumstances exception is under the authority of this section. We are therefore proposing to interpret section 1881(h)(3)(A)(i) of the Act to enable us to configure the methodology for assessing facilities' total performance such that we will not require a facility to submit, nor penalize a facility for failing to submit, data on any ESRD QIP quality measure data from any month in which a facility is granted an extraordinary circumstances exception.

Under this policy, we propose that, in the event of extraordinary circumstances not within the control of the facility (such as a natural disaster), for the facility to receive consideration for an exception from all ESRD QIP requirements during the period in which the facility was closed, the facility would need to submit a CMS Disaster Extension/Exception Request Form through *www.qualitynet.org* within 90 calendar days of the date of the disaster or extraordinary circumstance. We are proposing that the facility would need to provide the following information on the form:

- Facility CCN;
- Facility name;
- CEO name and contact information;
- Additional contact name and contact information;
- Reason for requesting an exception;
- Dates affected;
- Date facility will start submitting data again, with justification for this date; and
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

Incomplete forms will be returned to the facility without further review of their content. We will evaluate the request and provide the facility with a response. If we determine that the facility was, in fact, closed for a period of time due to extraordinary circumstances, then we will exempt the facility from the ESRD QIP requirements for any month during which the facility was closed due to the extraordinary circumstances. As such, a facility granted a temporary exception will be scored on each measure only for the months during a performance period not covered by the exception. For example, if a facility is granted an extraordinary circumstances exception for the time period between January 15 and February 15, 2015, then the facility will not be required to report, and will not be penalized for not reporting, data on any ESRD QIP measure data for January and February of CY 2015. The effect of this proposal is that if a facility, because it has been granted an exception, cannot meet the reporting requirements that apply to a measure, the facility will not receive a score on the measure. For example, if a facility is granted an extraordinary circumstances exception for February 2015, then that facility would not be scored on the NHSN Bloodstream Infection clinical measure for the applicable payment year, because this measure requires facilities to submit 12 months of data in order to avoid receiving zero points on the measure.

This policy does not preclude us from granting exceptions to facilities that have not requested them when we determine that an extraordinary circumstance (for example, a hurricane or other act of nature) affects an entire region or locale. If we make the determination to grant an exception to facilities in a region or locale, then we propose to communicate this decision through routine communication channels to facilities, vendors, and Networks, including but not limited to issuing memoranda, emails, and notices on a CMS-approved Web site.

We seek comments on this proposal.

G. Proposed Requirements for the PY 2018 ESRD QIP

1. Proposal To Modify the Mineral Metabolism Reporting Measure Beginning in PY 2018

In the CY 2013 ESRD QIP, we adopted a reporting measure focused on mineral metabolism, which was based in part on NQF #0255 (77 FR 67487 through 67487). In the CY 2014 ESRD PPS, we finalized two revisions to the Mineral Metabolism reporting measure: (1) To include home peritoneal dialysis patients in the measure; and (2) to remove serum calcium reporting from the measure because of its reporting under the Hypercalcemia clinical measure (78 FR 72197 through 72198). Accordingly, in order to meet the requirements for the Mineral Metabolism reporting measure, facilities currently must report serum phosphorus values for each qualifying patient treated at the facility on a monthly basis.

Since the publication of the CY 2014 ESRD PPS final rule, members of the renal community requested an ad hoc NQF review of measure #0255, focusing in particular on whether the measure should be updated to allow for the reporting of plasma phosphorus data. The NQF Consensus Standards Approval Committee (CSAC) reviewed the measure and recommended that the phosphorus reporting measure (NQF #0255) be modified to allow for the reporting of plasma phosphorus data as an alternative to serum phosphorus data. Although our TEP reviewed this issue and concluded that measure #0255 should remain unchanged, we concur with the CSAC's recommendation due to the CSAC's ad hoc review of lab data demonstrating the equivalency of plasma and serum measurements of phosphorus, as well as an additional concurrent internal review of the data by CMS and our measure development contractor. We are in agreement with the CSAC that readings of phosphorus using either plasma or serum are appropriate for the measure. As the measure developer for NQF #255, we are also in the process of revising the specifications for that measure and plan to submit the revised measure specifications to the NQF for endorsement. We believe the change to these specifications is non-substantive because plasma readings are an alternative method of reporting on phosphorus data and, as we state above, are roughly equivalent to serum phosphorus readings.

We considered proposing to allow facilities to report plasma phosphorus data for the Mineral Metabolism reporting measure in the PY 2017 program, but we have determined that it is not operationally feasible to configure the relevant data fields in CROWNWeb to accept plasma phosphorus readings prior to January 1, 2015, the beginning of the performance period for that program year. For this reason, we propose to modify the measure specifications for the Mineral Metabolism reporting measure to allow facilities to report either serum phosphorus data or plasma phosphorus data, beginning with the PY 2018 program. We further clarify that we are not proposing any other changes to the measure specifications for the Mineral Metabolism reporting measure.

2. Proposed New Measures for the PY 2018 ESRD QIP and Future Payment Years

For the PY 2018 ESRD QIP, we are proposing to continue to use all of the

measures proposed for the PY 2017 ESRD QIP, with the exception of the ICH CAHPS reporting measure, which we are proposing to convert to a clinical measure. We are also proposing to adopt five new measures. The proposed new measures include one new outcome measure evaluating transfusions in the ESRD population, one measure on pediatric peritoneal dialysis adequacy, one measure on pain assessment, one measure on clinical depression screening, and one measure on healthcare personnel influenza vaccination (see Table 28).

TABLE 28—NEW MEASURES PROPOSED FOR THE PY 2018 ESRD QIP

NQF#	Measure title
N/A	Pediatric Peritoneal Dialysis Adequacy, a clinical measure. Percentage of pediatric peritoneal dialysis patient-months with spKt/V greater than or equal to 1.8 (dialytic + residual).
0258	In-Center Hemodialysis Consumer Assessment of Providers and Systems Survey,[1] a clinical measure. Proportion of responses to rating items grouped into three composite measures and three global ratings.
N/A	Standardized Transfusion Ratio, a clinical measure. Risk-adjusted standardized transfusion ratio for dialysis facility patients.
N/A[2]	Pain Assessment and Follow-Up, a reporting measure. Percentage of adult patients with documentation of pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit and documentation of a follow-up place when pain is present.
N/A[3]	Depression Screening and Follow-Up, a reporting measure. Percentage of adult patients screened for clinical depression using a standardized tool and follow-up plan is documented.
N/A[4]	NHSN Healthcare Personnel Influenza Vaccination, a reporting measure.

[1] The proposed dimensions of the ICH CAHPS survey for use in the PY 2018 ESRD QIP are: Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations, Providing Information to Patients, Overall Rating of the Nephrologists, Overall Rating of the Dialysis Center Staff, and Overall Rating of the Dialysis Facility.

[2] We note that the NQF has previously endorsed a pain measure (NQF #0420) upon which this measure is based.

[3] We note that the NQF has previously endorsed a depression measure (NQF #0418) upon which this measure is based.

[4] We note that the NQF has previously endorsed a vaccination measure (NQF #0431) upon which this measure is based.

a. Proposed Standardized Transfusion Ratio (STrR) Clinical Measure

Background

We are concerned that the inclusion of erythropoiesis-stimulating agents (ESAs) in the ESRD PPS and the removal of the Hemoglobin Less than 10 g/dL clinical measure from the ESRD QIP measure set could result in the underutilization of ESAs to manage anemia in ESRD patients, with the result that these patients have lower achieved hemoglobin levels and more frequently need red-blood-cell transfusions.

In addition, patients with ESRD who are eligible to receive a kidney transplant and are transfused risk becoming sensitized to the donor pool, thereby making it less likely that a transplant will be successful. Blood transfusions also carry a small risk of transmitting blood-borne infections to the patient, and the patient could additionally develop a transfusion reaction. Furthermore, using infusion centers or hospitals to transfuse patients is expensive, inconvenient, and could compromise future vascular access.

Overview of Measure

The Standardized Transfusion Ratio (STrR) for all adult Medicare ESRD patients is a ratio of the number of observed eligible blood transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected from a predictive model that accounts for patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion in the 12 months immediately prior to the transfusion date.

We plan to submit the STrR measure to NQF for review at the next available call for measures. Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iv) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (which is currently NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed, so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We have given due consideration to endorsed measures, as well as those adopted by a consensus organization, and we are proposing this measure under the authority of 1881(h)(2)(B)(ii) of the Act. NQF has not endorsed and a consensus organization has not adopted a measure on transfusions. Because the proposed STrR measure has the potential to decrease transfusions resulting from underutilization of anemia medications, we believe it is appropriate to adopt the STrR in the PY 2018 ESRD QIP. We considered proposing to adopt the measure for the PY 2017, but we recognized that this is a new measure, and wanted to give facilities more time to familiarize themselves with it. The Measure Application Partnership, in its February 1, 2013 Pre-Rulemaking Report, supported the direction of the measure, stating that it ''addresses an important concept, but the establishment of guidelines for hemoglobin range is needed.'' We have received public comments and input from a TEP that we convened on a prototype STrR measure, and finalized development of the proposed STrR measure in September 2013. The resulting measure specifications did not include hemoglobin thresholds, as no input from the TEP or public comments supported moving forward with thresholds included in the measure. We therefore believe these efforts meet the requirements for further development of the STrR prior to implementation in the ESRD QIP.

In the process of preparing to submit the measure for NQF review, we conducted analyses on the reliability of the STrR measure. The full analysis is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* The $\overline{\text{STrR}}$ is not a simple average; instead, we estimate the IUR using a bootstrap approach, which uses a resampling

scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by ''random noise,'' indicating the measure would not be a reliable characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities. We have determined that the average IUR for the STrR measure is 0.54, meaning that about half of the variation in the measure can be attributed to between-facility differences, and about half to within-facility variation. This value of IUR indicates a moderate degree of reliability and is consistent with the reliability of other outcome measures in CMS quality reporting and VBP programs. We therefore believe that facilities can be reliably scored on the proposed STrR measure.

Data Sources

Data for the measure come from various CMS-maintained data sources for ESRD patients including Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the CROWNWeb database, the CMS Annual Facility Survey (Form CMS–2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS–2728), transplant data from the OPTN, the Death Notification Form (Form CMS–2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. These data sources include all Medicare patients. Information on transfusions is obtained from Medicare Inpatient and Outpatient Claims SAFs.

Outcome

The outcome of interest for the STrR is blood transfusion events (defined as the transfer of one or more units of blood or blood products into the recipient's blood stream) among Medicare ESRD patients dialyzing at the facility during the inclusion time periods.

Cohort

The cohort for the STrR includes all adult Medicare ESRD dialysis patients who have been documented as having had ESRD for at least 90 days.

Inclusion and Exclusion Criteria

Patients will not be included in the STrR during the first 90 days of ESRD dialysis treatment. Starting with day 91 after onset of ESRD, a patient is attributed to a facility once he or she has been receiving dialysis there for 60 days. When a patient transfers from one facility to another, we are proposing that the patient would continue to be attributed to the original facility for 60 days from the date of the transfer. Starting on day 61, the patient would be attributed to the transferee facility. Patients would be excluded from the measure for three days prior to the date they receive a transplant to avoid including transfusions associated with the transplant hospitalization.

We are also proposing to require that patients reach a certain level of Medicare-paid dialysis bills to be included in the STrR, or that patients have Medicare-paid inpatient claims during the period. This requirement is intended to assure completeness of transfusion information for all patients included in the measure calculation by excluding non-Medicare patients and patients for whom Medicare is a secondary payer, because they are not expected to have complete information on transfusion available in the claims data. For each patient, a month is included as a month at risk for transfusion if that month in the period is considered ''eligible.'' A month is considered eligible if it is within two months of a month in which a patient has $900 of Medicare-paid claims or at least one Medicare-paid inpatient claim. The $900 amount represents approximately the tenth percentile of monthly dialysis claims per patient.

In addition, a transfusion event is eligible for inclusion in the STrR measure if the patient did not present with certain comorbid conditions during the 12 month period immediately prior to the date of the transfusion event. We are proposing to exclude these transfusion events because the identified comorbid conditions are associated with a higher risk of transfusion and require different anemia management practices that the measure is not intended to address. Specifically, we are proposing that a transfusion event will be excluded from the measure if the patient, during the 12 month look back period, had a Medicare claim for: hemolytic and aplastic anemia; solid organ cancer (breast, prostate, lung, digestive tract and others); lymphoma; carcinoma in situ; coagulation disorders; multiple myeloma; myelodysplastic syndrome and myelofibrosis; leukemia; head and neck cancer; other cancers (connective tissue, skin, and others); metastatic cancer; or sickle cell anemia. The specific diagnoses used to identify each of these conditions are listed in the proposed measure specifications, which are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

Risk Adjustment

The denominator of the STrR uses expected transfusions calculated from a Cox model that is extended to handle repeated events. For computational purposes, the proposed STrR measure adopts a model with piecewise-constant baseline rates. A stage 1 model is fitted to the national data with piecewise-constant baseline rates across facilities. Transfusion rates are adjusted for: patient age; diabetes as a cause of ESRD; duration of ESRD; nursing home status; BMI at incidence; comorbidity index at incidence; and calendar year. This model allows baseline transfusion rates to vary between facilities, and applies the regression coefficients for the risk-adjustment model to each facility identically. This approach is robust to possible differences between facilities in the patient mix being treated. The second stage uses the risk-adjustment factor from the first stage as an offset. The stage 2 model then calculates the national baseline transfusion rate.

The STrR measure includes the following risk adjustors, which are obtained from the following data sources:

Risk adjustor	Data source
Age	REMIS database.
Diabetes as cause of ESRD	CMS Form 2728.
BMI at incidence of ESRD	CMS Form 2728.
Comorbidity index	CMS Form 2728.
Nursing home status	Nursing Home Minimum Dataset.
Duration of ESRD	CMS Form 2728.

More details on the risk-adjustment calculations, and the rationale for selecting these risk adjustors and not others, can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

As indicated in the table above, the proposed STrR measure risk adjusts predominantly on the basis of patient characteristics collected on CMS Form 2728, and we believe that this risk-adjustment methodology is reliable and valid.

NQF evaluates measures on the basis of four criteria: importance, scientific acceptability, feasibility, and usability. The validity and reliability of a measure's risk-adjustment calculations fall under the ''scientific acceptability'' criterion, and Measure Evaluation Criterion 2b4 specifies NQF's preferred approach for risk adjusting outcome measures (*http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx#scientific*). This criterion states that patient comorbidities should only be included in risk-adjustment calculations if they are (1) present at the start of care and (2) not indicative of disparities or deficiencies in the quality of care provided. As indicated in the ''Inclusion and Exclusion Criteria'' subsection above, the proposed STrR clinical measure includes Medicare patients who have been documented as having had ESRD for at least 90 days and are not excluded for other reasons. Accordingly, we believe that NQF Measure Evaluation Criterion 2b4 supports risk-adjusting the proposed STrR measure on the basis of incident patient comorbidity data collected on CMS Form 2728, because these comorbidities are likely present at the start of care. Moreover, comorbidities that develop after the 90th day of chronic dialysis treatment, and are statistically associated with transfusions, can be reflective of the quality of care provided by the facility. Therefore, we do not believe that NQF Measure Evaluation Criterion 2b4 supports risk adjusting the proposed STrR measure on the basis of updated comorbidity data, because doing so may mask disparities or deficiencies in the quality of care provided, thereby obscuring assessments of facility performance. For these reasons, we believe that the risk-adjustment methodology for the proposed STrR measure is consistent with NQF guidelines for measure developers. Testing that we have undertaken has confirmed the validity and reliability of the proposed STrR measure using these data. We anticipate submitting the measure to the NQF for endorsement in CY 2015.

Full documentation of the STrR risk-adjustment methodology is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

Calculating the STrR Measure

The STrR measure is calculated as the ratio of the number of observed transfusions to the number of expected transfusions. The ratio is greater than one for facilities that have more transfusions than would be expected for an average facility with similar cases, and less than one if the facility has fewer transfusions than would be expected for an average facility with similar cases. This ratio is calculated in terms of patient-years at risk. ''Patient-year at risk'' means that the denominator of the rate calculation is obtained by adding exposure times of all patients until a censoring event (that is, death, transplant, or end of the time period) because each patient's time at risk varies based on these censoring events. Time at risk is the time period in which each patient is eligible to have the transfusion event occur for the purposes of the measure calculation, exclusive of all days that have claims pertaining to the exclusionary comorbidities identified within the previous 12 months.

The predicted value from stage 1 of the model and the baseline rate from stage 2 of the model, as described above, are then used to calculate the expected number of transfusion events for each patient over the period during which the patient is seen to be at risk for a transfusion event.

The STrR is a point estimate—the best estimate of a facility's transfusion rate based on the facility's case mix. For more detailed information on the calculation methodology, please refer to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We seek comments on this proposal to adopt the proposed STrR clinical measure.

b. Proposal To Adopt the Pediatric Peritoneal Dialysis Adequacy Clinical Measure and Add the Proposed Measure to the Dialysis Adequacy Measure Topic

Section 1881(h)(2)(A)(i) states that the ESRD QIP must evaluate facilities based on measures of dialysis adequacy. Beginning with the PY 2018 ESRD QIP, we propose to add a new measure of pediatric peritoneal dialysis adequacy to the Dialysis Adequacy measure topic. If this proposal is finalized, then the modified Dialysis Adequacy measure topic would include four clinical measures on dialysis adequacy—(1) Adult Hemodialysis Adequacy; (2) Adult Peritoneal Dialysis Adequacy; and (3) Pediatric Hemodialysis Adequacy; and (4) Pediatric Peritoneal Dialysis Adequacy.

Approximately 900 pediatric patients in the United States receive peritoneal dialysis.[5] Although recent studies suggest improvement in mortality rates among pediatric patients receiving maintenance dialysis over time, mortality in this patient population remains high.[6] Despite a lack of long-term outcome studies on pediatric peritoneal dialysis patients, outcome studies performed in the adult ESRD population have shown an association between the dose of peritoneal dialysis and clinical outcomes,[7] which could suggest that improved quality of dialysis care in the fragile pediatric patient population may further improve survival in those patients.

Section 1881(h)(2)(A)(iv) gives the Secretary authority to adopt 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 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

[5] U.S. Renal Data System, USRDS 2012 Annual Data report: Atlas of Chronic Kidney Disease and End-stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012.

[6] U.S. Renal Data System, USRDS 2012 Annual Data report: Atlas of Chronic Kidney Disease and End-stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012.

[7] Paniagua R, Amato D, Vonesh E, et al. ''Effects of increased peritoneal clearance on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial.'' *Journal of the American Society of Nephrology: JASN* (2002) 13:1307–1320. PMID: 11961019; *See also* Lo WK, Lui SL, Chan TM, et al. ''Minimal and optimal peritoneal Kt/V targets: Results of anuric peritoneal dialysis patient's survival analysis.'' *Kidney international* (2005) 67:2032–2038. PMID: 15840054.

pediatric peritoneal dialysis adequacy currently exist, we are proposing to adopt the Pediatric Peritoneal Dialysis Adequacy clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

The Measure Application Partnership expressed conditional support for measure XCBMM, ''Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V'' in its January 2014 Pre-Rulemaking Report, noting it would ''consider this measure for inclusion in the program once it has been reviewed for endorsement.'' However, we believe the measure is ready for adoption in the ESRD QIP because it has been fully tested for reliability and has received consensus support from the TEP that was tasked with developing it. We intend to submit this measure to the NQF for endorsement in late 2014 or early 2015.

For PY 2018 and future payment years, we propose to adopt the Pediatric Peritoneal Dialysis Adequacy clinical measure, which assesses the percentage of eligible pediatric peritoneal dialysis patient-months in which a Kt/V of greater than or equal to 1.8 was achieved during the performance period. Qualifying patient-months are defined as months in which a peritoneal dialysis patient is under the age of 18 and has been receiving peritoneal dialysis treatment for 90 days or longer. Performance on this measure will be expressed as a proportion of patient-months meeting the measure threshold of 1.8, and the measure will be scored based on Kt/V data entered on Medicare 72x claims. The measure is a complement to the existing Kt/V dialysis adequacy measures previously adopted in the ESRD QIP. Technical specifications for the proposed pediatric peritoneal dialysis adequacy clinical measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.*

We seek comments on this proposal to adopt the Pediatric Peritoneal Dialysis Adequacy measure.

c. Proposed ICH CAHPS Clinical Measure

Section 1881(h)(2)(A)(ii) of the Act states that the Secretary shall specify, to the extent feasible, measures of patient satisfaction. Patients with ESRD are an extremely vulnerable population: They are completely reliant on ESRD providers for life-saving care, and they are often reluctant to express concerns about the care they receive from an array of staff, both professional and non-professional. Patient-centered experience is an important measure of the quality of patient care, and it is a component of the 2013 NQS, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.

Following a rigorous process, the ICH CAHPS Survey was developed to capture the experience of in-center hemodialysis patients. The NQF endorsed and the Measures Application Partnership supported this quality measure (NQF #0258: CAHPS In-Center Hemodialysis Survey). The ICH CAHPS Survey captures the experience of in-center hemodialysis patients on three dimensions: ''nephrologists' communication and caring;'' ''quality of dialysis center care and operations;'' and ''providing information to patients.'' Three global ratings are also part of the standardized ICH CAHPS Survey: Rating of the nephrologist; rating of the staff; and rating of the facility.

We believe that this measure enables patients to rate their experience of in-center dialysis treatment without fear of retribution. Public reporting of results from the ICH CAHPS survey, once enough data are available, will satisfy requests to provide consumers (patients and family members alike) with desired information on viewpoints from patients. In addition, collecting and reporting ICH CAHPS survey results assists facilities with their internal quality improvement efforts and external benchmarking with other facilities, and it provides CMS with information that can be used to monitor the experience of patients with ESRD.

Starting with the PY 2014 program, we have taken steps to develop the baseline data necessary to propose and implement NQF #0258 as a clinical measure in PY 2018. In the PY 2014 and PY 2015 programs, we adopted a reporting measure related to the ICH CAHPS survey, which required that facilities attest they had administered the survey according to the specifications set by the Agency for Healthcare Research and Quality (AHRQ). In the CY 2014 ESRD PPS final rule, we: (1) Expanded the ICH CAHPS reporting measure to require facilities to submit (via CMS-approved vendors) their survey results to CMS; (2) increased the patient minimum for the measure from 11 to 30 survey-eligible patients; (3) required that facilities (via CMS-approved vendors) administer the survey according to specifications set by CMS; and (4) required facilities (via CMS-approved vendors) to administer the survey twice during each performance period, and to report both sets of survey results by the date specified on *http://ichcahps.org,* starting in PY 2017 (78 FR 72193 through 72196).

By CY 2016 (the proposed performance period for the PY 2018 ESRD QIP), we will have worked with dialysis facilities for four years to help them become familiar with the ICH CAHPS survey. By that time, we believe that facilities will be sufficiently versed in the survey administration process to be reliably evaluated on the NQF-endorsed ICH CAHPS measure (NQF #0258). Because facilities (and CMS-approved vendors) will be familiar enough with the ICH CAHPS survey instrument to be reliably scored on the basis of their survey results, we believe it is reasonable to expand the ICH CAHPS reporting measure into a clinical measure for the PY 2018 ESRD QIP.

For these reasons, and because a clinical measure would have a greater impact on clinical practice by holding facilities accountable for their actual performance, we propose to replace the ICH CAHPS reporting measure that we adopted in the CY 2014 ESRD PPS Final Rule with a new clinical measure for PY 2018 and future payment years. This proposed ICH CAHPS clinical measure is NQF #0258: CAHPS In-Center Hemodialysis Survey. We are not proposing to change the semiannual survey administration and reporting requirements. The proposed scoring methodology for the ICH CAHPS clinical measure is discussed below in section III.G.4.c. Technical specifications for the ICH CAHPS clinical measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.*

We seek comments on this proposal.

d. Proposed Screening for Clinical Depression and Follow-Up Reporting Measure

Depression is the most common psychological disorder in patients with ESRD. Depression causes suffering, a decrease in quality of life, and impairment in social and occupational functions; it is also associated with increased health care costs. Current estimates put the depression prevalence rate as high as 20 percent to 25 percent in patients with ESRD.[8] Studies have also shown that depression and anxiety are the most common comorbid

[8] Kimmel PL, Cuckor D, Cohen SD, Peterson RA. Depression in end-stage renal disease patients: a critical review. Advances in Chronic Kidney Disease. 2007:14(4):328–34.

illnesses in patients with ESRD.[9] Moreover, depressive affect and decreased perception of social support have been associated with higher rates of mortality in the ESRD population, and some studies suggest that this association is as strong as that between medical risk factors and mortality.[10] Nevertheless, depression and anxiety remain under-recognized and under-treated, despite the availability of reliable screening instruments.[11] Therefore, a measure that assesses whether facilities screen patients for depression, and develop follow-up plans when appropriate, offers an opportunity to improve the health of patients with ESRD.

We are proposing to adopt a depression measure that is based on an NQF-endorsed measure (NQF #0418: Screening for Clinical Depression). NQF #0418 assesses the percentage of patients screened for clinical depression using an age-appropriate standardized tool and documentation of a follow-up plan where necessary. The Measures Application Partnership supported the use of NQF #0418 in the ESRD QIP in its January 2014 Pre-Rulemaking Report, because the measure ''addresses a National Quality Strategy [NQS] aim not adequately addressed in the program measure set'' and promotes person- and family-centered care. We are proposing to adopt a reporting measure based on this NQF-endorsed 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 the clinical version of this measure in future rulemaking. Although we recognize that we recently adopted the NHSN Bloodstream Infection clinical measure despite a lack of baseline data to calculate achievement and improvement scores, we believe that measure warranted special treatment in light of the fact that it addresses patient safety. Because the proposed screening for clinical depression measure addresses quality of life and patient well-being, and not patient safety, we think it is appropriate to adopt it as a reporting measure until such time that we can collect the baseline data needed to score it as a clinical measure.

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) [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 NQF #0418 as a clinical measure in the ESRD QIP at this time, we are proposing to adopt the Screening for Clinical Depression and Follow-Up Plan reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

For PY 2018 and future payment years, we propose that facilities must report one of the following conditions in CROWNWeb, at least once per performance period, for each qualifying patient (defined below):

1. Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
2. Screening for clinical depression documented as positive, and a follow-up plan not documented, and the facility possess documentation stating the patient is not eligible.
3. Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given.
4. Screening for clinical depression is documented as negative, and a follow-up plan is not required.
5. Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible.
6. Clinical depression screening not documented, and no reason is given.

For this proposed measure, qualifying patients are defined as patients 12 years or older who have been treated at the facility for 90 days or longer. This proposed measure will collect the same data described in NQF #0418, but we are proposing to score facilities based on whether they successfully report the data, and not the measure results. More specifically, facilities will be scored on whether they report one of the above conditions for each qualifying patient once before February 1 of the year directly following the performance period. Technical specifications for the Screening for Clinical Depression and Follow-Up reporting measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.*

We seek comments on these proposals.

e. Proposed Pain Assessment and Follow-Up Reporting Measure

Pain is one of the most common symptoms in patients with ESRD.[12] Studies have shown that pain is a significant problem for more than 50 percent of patients with ESRD, and up to 82 percent of those patients report moderate to severe chronic pain.[13] Pain is commonly associated with quality of life in early- and late-stage chronic kidney disease patients, but it is not effectively managed in the ESRD patient population and chronic pain often goes untreated.[14] Observational studies suggest that under-managed pain has the potential to induce or exacerbate comorbid conditions in ESRD, which may in turn adversely affect dialysis treatment.[15] Patients with ESRD frequently experience pain that has a debilitating impact on their daily lives, and research has shown a lack of effective pain management strategies currently in place in dialysis facilities.[16] Therefore, a measure that assesses whether facilities regularly assess their patients' pain, and develop follow-up plans as necessary, offers the possibility

[9] Feroze, U., Martin, D., Reina-Patton, A., Kalantar-Zadeh, K., & Kopple, J. D. (2010). Mental health, depression, and anxiety in patients on maintenance dialysis. *Iranian Journal of Kidney Diseases,* 4(3), 173–80.

[10] Cukor, D., Cohen, S. D., Peterson, R. A., & Kimmel, P. L. (2007). Psychosocial aspects of chronic disease: ESRD as a paradigmatic illness. *Journal of the American Society of Nephrology,* 18(12), 3042–3055; and Kimmel, P. L., Peterson, R. A., Weihs, K. L., Simmens, S. J., Alleyne, S., Cruz, I., & Veis, J. H. (2000). Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. *Kidney International,* 57(5), 2093–2098.

[11] Preljevic, V. T., Østhus, T. B. H., Sandvik, L., Opjordsmoen, S., Nordhus, I. H., Os, I., & Dammen, T. (2012). Screening for anxiety and depression in dialysis patients: Comparison of the Hospital Anxiety and Depression Scale and the Beck Depression Inventory. *Journal of Psychosomatic Research,* 73(2), 139–144.

[12] Cohen, S. D., Patel, S. S., Khetpal, P., Peterson, R. A., & Kimmel, P. L. (2007). Pain, sleep disturbance, and quality of life in patients with chronic kidney disease. *Clinical Journal of the American Society of Nephrology,* 2(5), 919–925.

[13] Davison SN. Pain in hemodialysis patients: prevalence, cause, severity, and management. *American Journal of Kidney Disease.* 2003; 42:1239–1247

[14] Davison, S. N. (2007). The prevalence and management of chronic pain in end-stage renal disease. *Journal of Palliative Medicine,* 10(6), 1277–1287.

[15] De Castro C. (2013). Pain assessment and management in hemodialysis patients. *CANNT Journal;* 23(3):29–32; Weisbord SD, Fried LF, Arnold RM, Fine MJ, Levenson DJ, et al. Prevalence, severity, and importance of physical and emotional symptoms in chronic hemodialysis patients. (2005) *Journal of the American Society of Nephrology;* 16(8):2487–2494.

[16] De Castro C. (2013). Pain assessment and management in hemodialysis patients. *CANNT Journal;* 23(3):29–32; Wyne A, Rai R, Cuerden M, Clark WF, Suri RS. (2011). Opioid and benzodiazepine use in end-stage renal disease: a systematic review. *Clinical Journal of the American Society of Nephrology.* 6(2):326–333.

of improving the health and well-being of patients with ESRD.

We are proposing to adopt a pain measure that is based on an NQF-endorsed measure (NQF #0420: Pain Assessment and Follow-Up). NQF #0420 assesses the percentage of patients with documentation of a pain assessment using a standardized tool, and documentation of a follow-up plan when pain is present. The Measures Application Partnership supported the use of NQF #0420 in the ESRD QIP in its January 2014 Pre-Rulemaking Report, because the measure ''addresses a National Quality Strategy [NQS] aim not adequately addressed in the program measure set'' and promotes person- and family-centered care. We are proposing to adopt a reporting measure based on this NQF-endorsed 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 the clinical version of this measure in future rulemaking. Although we recognize that we recently adopted the NHSN Bloodstream Infection clinical measure despite a lack of baseline data to calculate achievement and improvement scores, we believe that measure warranted special treatment in light of the fact that it addresses patient safety. Because the proposed screening for pain measure addresses quality of life and patient well-being, and not patient safety, we think it is appropriate to adopt it as a reporting measure until such time that we can collect the baseline data needed to score it as a clinical measure.

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 so 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 Pain Assessment and Follow-Up reporting measure under the authority of section1881(h)(2)(B)(ii) of the Act.

For PY 2018 and future payment years, we propose that facilities must report one of the following conditions in CROWNWeb, once every six months per performance period, for each qualifying patient (defined below):

1. Pain assessment using a standardized tool is documented as positive, and a follow-up plan is documented.
2. Pain assessment documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible.
3. Pain assessment documented as positive using a standardized tool, a follow-up plan is not documented, and no reason is given.
4. Pain assessment using a standardized tool is documented as negative, and no follow-up plan required.
5. No documentation of pain assessment, and the facility possesses documentation the patient is not eligible for a pain assessment using a standardized tool.
6. No documentation of pain assessment, and no reason is given.

For this measure, a qualifying patient is defined as a patient aged 18 years or older who has been treated at the facility for 90 days or longer. This proposed measure will collect the same data described in NQF #0420, but we are proposing a few modifications to the NQF-endorsed version. First, we are proposing that facilities must report data for each patient once every six months, whereas NQF #0420 requires facilities to report the data based on each visit. We are proposing this modification because we agree with public comments reflected on the Measures Application Partnership's January 2014 Pre-Rulemaking Report, which stated that conducting a pain assessment every time a patient receives dialysis would be unduly burdensome for facilities. Second, we are proposing that conditions covering the first six months of the performance period must be reported in CROWNWeb before August 1 of the performance period, and that conditions covering the second six months of the performance period must be reported in CROWNWeb before February 1 of the year directly following the performance period. We believe this reporting schedule will ensure regular monitoring and follow-up of patients' pain without imposing an undue burden on facilities. Third, 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 Pain Assessment and Follow-Up reporting measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We seek comments on this proposal.

f. Proposed NHSN Healthcare Personnel Influenza Vaccination Reporting Measure

Infection is the second most common cause of death in patients with ESRD, following cardiovascular causes,[17] and influenza accounts for significant morbidity and mortality in patients receiving hemodialysis.[18] Healthcare personnel (HCP) can acquire influenza from patients and transmit influenza to patients and other HCP; decreasing transmission of influenza from HCP to persons at high risk likely reduces influenza-related deaths among persons at high risk for complications from influenza, including patients with ESRD.[19] Vaccination is an effective preventive measure against influenza that can prevent many illnesses, deaths, and losses in productivity.[20] In addition, HCP are considered high priorities for vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients, and to reduce disease burden and healthcare costs. Results of studies in post-acute care settings similar to the ESRD facility setting indicate that higher vaccination coverage among HCP is associated with lower all-cause mortality.[21] We therefore propose to adopt an NHSN HCP Influenza Vaccination reporting measure for PY 2018 and future payment years.

We are proposing to use a measure that is based on an NQF-endorsed measure (NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel) of the percentage of qualifying HCP who (a) received an influenza vaccination; (b) were determined to have a medical

[17] Soni R, Horowitz B, Unruh M. Immunization in end-stage renal disease: Opportunity to improve outcomes. Semin, Dial. 2013 Jul–Aug;26(4):416–26.

[18] Fiore AE, Shay DK, Haber P, et al. Prevention and control of influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2007;56:1–54.

[19] Pearson ML, Bridges CM, Harper SA. Influenza vaccination of health-care personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). MMWR. 2006:55:1–16.

[20] Talbot TR, Bradley SE., Cosgrove SE., et al. Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infect Control Hosp Epidemiol. 2005;26(11):882–90.

[21] Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomized controlled trial. Lancet. 2000;355(9198):93–7; *see also* Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. J infect Dis. 1997;175(1):1–6.

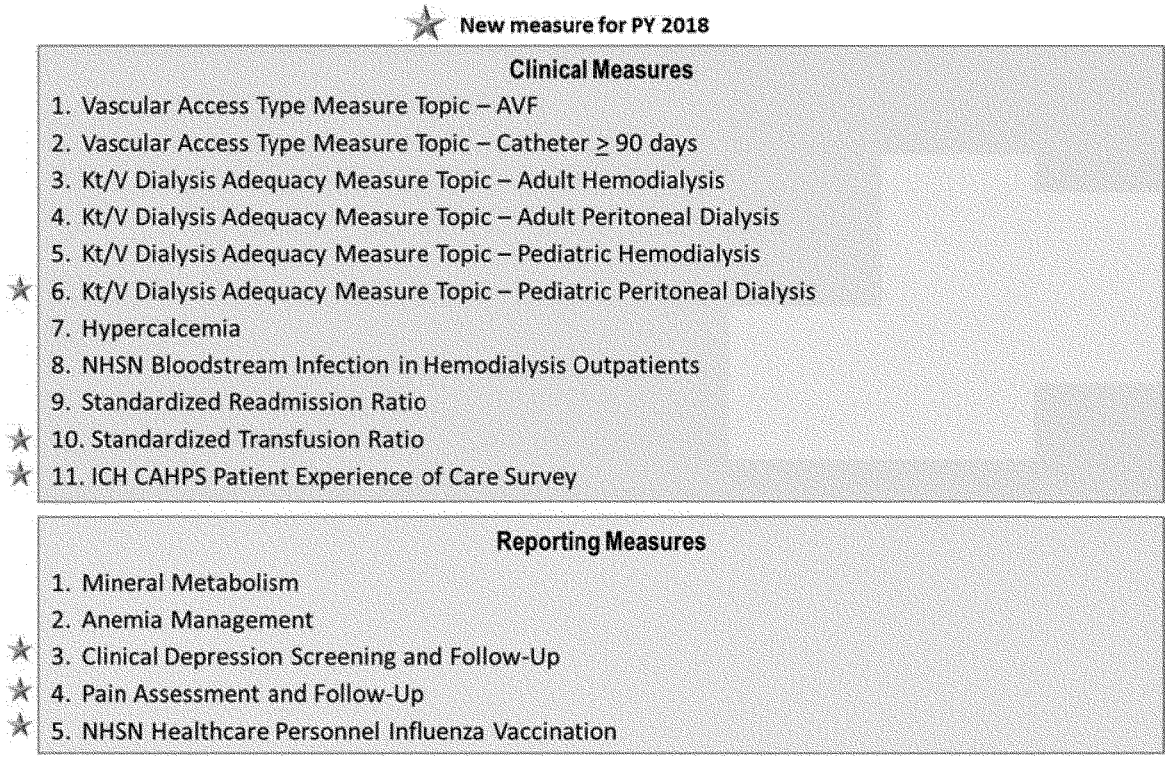
contraindication; (c) declined influenza vaccination; or (d) were of an unknown vaccination status. A ''qualifying HCP'' is defined as an employee, licensed independent practitioner, or adult student/trainee/volunteer who works in a facility for at least one day between October 1 and March 31. The Measures Application Partnership supported the use of NQF #0431 in the ESRD QIP in its January 2014 Pre-Rulemaking Report because the measure is NQF-endorsed for use in the dialysis facility care setting. We are proposing to adopt a reporting measure based on this NQF-endorsed 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 the clinical version of this measure in future rulemaking. Although we recognize that we recently adopted the NHSN Bloodstream Infection clinical measure despite a lack of baseline data to calculate achievement and improvement scores, we believe that measure warranted special treatment in light of the fact that it addresses patient safety. Because the proposed NHSN HCP Influenza Vaccination reporting measure addresses population health, and not patient safety, we think it is appropriate to adopt it as a reporting measure until such time that we can collect the baseline data needed to score it as a clinical measure.

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) [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 this measure in the ESRD QIP, we are proposing to adopt the NHSN Healthcare Personnel Influenza Vaccination reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

For PY 2018 and future payment years, we propose that facilities must submit, on an annual basis, an HCP Influenza Vaccination Summary Form to CDC's NHSN system, according to the specifications available in the NHSN Healthcare Personnel Safety Component Protocol (*http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf*). This proposed measure differs from NQF #0431 in that we are proposing to collect the same data but will score facilities on the basis of whether they submit this data, rather than on the percentage of HCP vaccinated. We propose that the deadline for reporting this information to NHSN be May 15th of each year. This date is consistent with the reporting deadline established by CMS for other provider types reporting HCP vaccination data to NHSN. Because the flu season typically spans from October to April, NHSN protocols submitted by May 15 would document vaccinations received during the preceding flu season. For example, NHSN HCP Influenza Vaccination Summary Forms submitted by May 15, 2016, would contain data from October 1, 2015 to March 31, 2016, and would be used for the PY 2018 ESRD QIP; NHSN protocols submitted by May 15, 2017, would contain data from October 1, 2016 to March 31, 2017, and would be used for the PY 2019 ESRD QIP, and so on. Technical specifications for this measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html*.

We request comments on this proposal.

Figure 2: Summary of Proposed PY 2018 Measures



2. Proposed Performance Period for the PY 2018 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish the performance period with respect to a year, and that the performance period occur prior to the beginning of such year. In accordance with our proposal to adopt CY 2015 as the performance period for the PY 2017 ESRD QIP, as well as our policy goal to collect 12 months of data on each measure when feasible, we are proposing to adopt CY 2016 as the performance period for the PY 2018 ESRD QIP. With respect to the NHSN Healthcare Personnel Influenza Vaccination Reporting measure, we are proposing that the performance period will be from October 1, 2015 through March 31, 2016, which is consistent with the length of the 2015–2016 influenza season.

We seek comments on these proposals.

3. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2018 ESRD QIP

a. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2018 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 2018 to set the performance standards, achievement thresholds, and benchmarks based on the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2014 for all the clinical measures except for the proposed ICH CAHPS clinical measure. As finalized in the CY 2014 ESRD PPS Final Rule (78 FR 72213), facilities are not required to administer the ICH CAHPS survey (via a CMS-approved third-party vendor) on a semiannual basis until CY 2015, the proposed performance period for the PY 2017 ESRD QIP. We believe that ICH CAHPS data collected during CY 2014 will not be reliable enough to use for the purposes of establishing performance standards, achievement thresholds, and benchmarks, because facilities are only required to administer the survey once in CY 2014. Therefore, we propose to set the performance standards, achievement thresholds, and benchmarks based on the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2015 for the proposed ICH CAHPS clinical measure.

We seek comments on these proposals.

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Proposed for the PY 2018 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 2014 or the first portion of CY 2015. We will publish values for the clinical measures, using data from CY 2014 and the first portion of CY 2015, in the CY 2016 ESRD PPS Final Rule.

c. Proposed Performance Standards for the PY 2018 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). We are not proposing any changes to this policy beyond the proposal to modify the reporting requirements for the Mineral Metabolism reporting measure, which appears above in Section III.G.1.

For the Screening for Clinical Depression and Follow-Up reporting measure, we propose to set the performance standard as successfully reporting one of the above-listed clinical depression and follow-up screening conditions for each qualifying patient in CROWNWeb before the February 1st

directly following the performance period.

For the Pain Assessment and Follow-Up reporting measure, we propose to set the performance standard as successfully reporting one of the above-listed pain assessment and follow-up conditions for each qualifying patient in CROWNWeb twice annually: once before August 1st for the first 6 months of the performance period, and once before the February 1st directly following the performance period for the last six months of the performance period.

For the NHSN Healthcare Provider Influenza Vaccination reporting measure, we propose to set the performance standard as successfully submitting the HCP Influenza Vaccination Summary Form to CDC's NHSN system by May 15, 2017.

We seek comments on these proposals.

4. Proposal for Scoring the PY 2018 ESRD QIP Measures

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). In determining a facility's achievement score for each measure under the PY 2018 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 achievement range based on their performance during the proposed performance period for each measure, which we define as a scale between the achievement threshold and the benchmark.

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 2018 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 2015. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2016 (the proposed performance period) to its performance rate on the measure during CY 2015.

c. Proposal for Scoring the ICH CAHPS Clinical Measure

For PY 2018 and future payment years, we propose the following scoring methodology for the ICH CAHPS clinical measure. We propose to score the measure on the basis of three composite measures and three global ratings.

Composite Measures:

- Nephrologists' Communication and Caring;
- Quality of Dialysis Center Care and Operations; and
- Providing Information to Patients.

Global Ratings:

- Overall rating of the nephrologists (Question 8)
- Overall rating of the dialysis center staff (Question 32)
- Overall rating of the dialysis facility (Question 35)

The composite measures are groupings of questions that measure the same dimension of healthcare. (Groupings of questions and composite measures can be found at *https://ichcahps.org/Portals/0/ICH_Composites_English.pdf.*) Global ratings questions employ a scale of 0 to 10, worst to best; each of the questions within a composite measure use either ''Yes'' or ''No'' responses, or response categories ranging from ''Never'' to ''Always,'' to assess the patient's experience of care at a facility. Facility performance on each composite measure will be determined by the percent of patients who choose ''top-box'' responses (i.e., most positive or ''Always'') to the ICH CAHPS survey questions in each domain. Examples of questions and top-box responses are displayed below:

Q11: In the last 3 months, how often did the dialysis center staff explain things in a way that was easy for you to understand?

Top-box response: ''Always''

Q19: The dialysis center staff can connect you to the dialysis machine through a graft, fistula, or catheter. Do you know how to take care of your graft, fistula or catheter?

Top-box response: ''Yes''

We propose that a facility will receive an achievement score and an improvement score for each of the composite measures and global ratings in the ICH CAHPS survey instrument. For purposes of calculating achievement scores for the ICH CAHPS clinical measure, we propose to base the score on where a facility's performance rate falls relative to the achievement threshold and the benchmark for that measure. We propose that facilities will earn between 0 to 10 points for achievement based on where its performance for the measure falls relative to the achievement threshold. If a facility's performance rate during the performance period is:

- Equal to or greater than the benchmark, then the facility would receive 10 points for achievement;
- Less than the achievement threshold, then the facility would receive 0 points for achievement; or
- Equal to or greater than the achievement threshold, but below the benchmark, then the following formula would be used to derive the achievement score: [9 * ((Facility's performance period rate − achievement threshold)/(benchmark − achievement threshold))] + .5, with all scores rounded to the nearest integer, with half rounded up.

For the purposes of calculating improvement scores for the ICH CAHPS clinical measure, we propose that the improvement threshold will be defined as facility performance in CY 2015, and further propose to base the score on where a facility's performance rate falls relative to the improvement threshold and the benchmark for that measure. We propose that a facility can earn between 0 to 9 points based on how much its performance on the measure during the performance period improves from its performance on the measure during the baseline period. If a facility's performance rate during the performance period is:

- Less than the improvement threshold, then the facility would receive 0 points for improvement; or
- Equal to or greater than the improvement threshold, but below the benchmark, then the following formula would be used to derive the improvement score: [10 * ((Facility performance period rate − Improvement threshold)/(Benchmark − Improvement threshold))] − .5, with all scores rounded to the nearest integer, with half rounded up.

We further propose that 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. Additionally, we propose that achievement and/or improvement scores on the three composite measures and the three global ratings will be averaged together to yield an overall score on the ICH CAHPS clinical measure.

The timing and frequency of administering the ICH CAHPS survey is critical to obtaining reliable results. For

example, if a facility did not conduct two semiannual surveys during a given performance period, then patient experiences during the 6-month period(s) covered by the missed survey(s) would not be captured. Additionally, if facilities (via CMS-approved vendors) do not report their ICH CAHPS survey results to CMS, then these results cannot be taken into account when establishing national performance standards for the measure, thereby diminishing the measure's reliability. Because timely survey administration and data reporting is critical to reliably scoring ICH CAHPS as a clinical measure in the ESRD QIP, we propose that a facility will receive a score of 0 on the measure if it does not meet the survey administration and reporting requirements finalized in the CY 2014 ESRD PPS Final Rule (78 FR 72193 through 72196).

We seek comments on these proposals to score the ICH CAHPS clinical measure.

d. Proposals for Calculating Facility Performance on Reporting Measures

In the CY 2014 ESRD PPS Final Rule, we finalized policies for scoring performance on the Anemia Management and Mineral Metabolism reporting measures in the ESRD QIP (78 FR 72216). We are not proposing any changes to these policies beyond the proposals that were made beginning with the PY 2017 program, which appear in section III.F.7 above.

With respect to the Screening for Clinical Depression and Follow-up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures, we propose that facilities will receive a score of 10 on the measures if they meet the proposed performance standards for the measures, and a score of 0 on the measure if they do not. We are proposing to score these reporting measures differently than the Anemia Management and Mineral Metabolism reporting measures because they require annual or semiannual reporting, and therefore scoring based on monthly reporting rates is not feasible.

We seek comments on these proposals.

5. Proposed Minimum Data for Scoring Measures for the PY 2018 ESRD QIP

With the following exceptions discussed below, we are not proposing to change the minimum data policies for the PY 2018 ESRD QIP from that proposed above for the PY 2017 ESRD QIP. We are also proposing that the 30 survey-eligible patient minimum during the eligibility period and 30 survey complete minimum during the performance period that we proposed to adopt for the ICH CAHPS reporting measure will also apply to the ICH CAHPS clinical measure. We have determined that the ICH CAHPS survey is satisfactorily reliable when a facility obtains a total of at least 30 completed surveys during the performance period. Therefore, even if a facility meets the 30 survey-eligible patient minimum during the eligibility period and the survey administration and reporting requirements, if the facility is only able to obtain 29 or fewer survey completes during the performance period, the facility will not be eligible to receive a score on the ICH CAHPS clinical measure.

We further propose the facilities with fewer than 10 patient-years at risk will not be eligible to receive a score on the proposed STrR clinical measure. We considered adopting the 11-patient minimum requirement that we use for the other clinical measures. We decided, however, to base facilities' eligibility for the measure in terms of the number of patient-years at risk, because facility performance rates are based on the number of patient-years at risk, not the number of patients. Additionally, we decided to set the minimum data requirements at 10 patient-years at risk because, based on national average event rates, this is the time required to achieve an average of 5 transfusion events. The 5 expected transfusion events requirement translates to a standard deviation of approximately 0.45 if the facility has rates exactly corresponding to the national average. In addition, 10 patient-years at risk is the threshold used in the Dialysis Facility Compare program, and we believe that public-reporting and VBP programs for ESRD should adopt consistent measure specifications where feasible.

For the proposed STrR measure, we propose to apply the small-facility adjuster to facilities with 21 or fewer patient-years at risk. We decided to base the threshold for applying the small-facility adjuster on the number of patient-years at risk, because facility performance rates are based on the number of patient-years at risk, not the number of patients. We are proposing to set the threshold at 21 patient-years at risk, because we determined that this was the minimum number of patient-years at risk needed to achieve an IUR of 0.4 (that is, moderate reliability) for the proposed STrR measure. Because the small-facility adjuster gives facilities the benefit of the doubt when measure scores can be unduly influenced by a few outlier patients, we believe that setting the threshold at 21 qualifying patient-years at risk will not unduly penalize facilities that treat small numbers of patients on the proposed STrR clinical measure.

With these exceptions, we are not proposing to change the policy, finalized most recently in the CY 2014 ESRD PPS Final Rule (78 FR 72220 through 72221), that facilities must have at least 11 qualifying patients for the entire performance period in order to be scored on a clinical measure.

We currently have a policy, most recently finalized in the CY 2014 ESRD PPS final rule (78 FR 72197 through 72198 and 72220 through 72221), to score facilities on reporting measures only if they have a minimum number of qualifying patients during the performance period. As discussed in Section III.F.7 above, we are proposing to modify the case minimum requirements for the Anemia Management and Mineral Metabolism reporting measures beginning with the PY 2017 ESRD QIP. We are not proposing any additional changes in the patient minimum requirements for the Anemia Management and Mineral Metabolism reporting measures in the PY 2018 program.

For the Screening for Clinical Depression and Follow-Up and the Pain Assessment and Follow-Up reporting measures, we propose a case minimum of one qualifying patient. We believe this patient minimum requirement will enable us to gather a sufficient amount of data to calculate future performance standards, benchmarks, and achievement thresholds, should we propose to adopt clinical versions of these measures in the future.

As discussed in Section III.G.2.f, we are not proposing that a facility will have to meet a patient minimum in order to receive a score on the NHSN Healthcare Provider Influenza Vaccination reporting measure. We believe it is standard practice for all HCP to receive influenza vaccinations and, as discussed above, HCP vaccination is likely to reduce influenza-related deaths and complications among the ESRD population. Accordingly, we are proposing that all facilities, regardless of patient population size, will be scored on the influenza vaccination measure.

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, 2016, are eligible to be scored on the Anemia Management and Mineral Metabolism reporting measures in the PY 2018

program. We are proposing to apply this finalized policy to the proposed Screening for Depression and Follow-Up and the Pain Assessment and Follow-Up reporting measures. We further propose that facilities with a CCN open date after January 1, 2016, will not be eligible to receive a score on the NHSN Healthcare Personnel Influenza Vaccination reporting measure in the PY 2018 program. Due to the time it takes for facilities to register with NHSN and become familiar with the NHSN Healthcare Personnel Safety Component Protocol, we do not believe it is reasonable to expect facilities with CCN open dates after January 1, 2016, to submit an HCP Influenza Vaccination Summary Form to CDC's NHSN system before the May 15, 2016, deadline.

As finalized in the CY 2014 ESRD PPS Final Rule (78 FR 72220), facilities are generally eligible to receive a score on the clinical measures if their CCN open date occurs before the end of the performance period. However, facilities with a CCN open date after January 1 of the performance period are not eligible to receive a score on the NHSN Bloodstream Infection clinical measure, due to the need to collect 12 months of data to accurately score the measure. We are now proposing that facilities with a CCN open date after January 1, 2016, will also not be eligible to receive a score on the ICH CAHPS clinical measure in the PY 2018 program. Due to the additional time needed to arrange to contract with CMS-approved third-party vendors, and for vendors to administer the survey twice and report the results to CMS, we do not believe facilities with CCN open dates after January 1, 2016, can reasonably be expected to meet the requirements associated with the proposed ICH CAHPS clinical measure for that performance period.

As discussed in the Section III.G.7 below, we are continuing our policy that a facility will not receive a TPS unless it receives a score on at least one clinical measure and at least one reporting measure. We note that finalizing the above proposals would result in facilities not being eligible for a payment reduction for the PY 2018 ESRD QIP if they have a CCN open date on or after July 1, 2016.

We seek comments on these proposals.

Table 29 displays the proposed patient minimum requirements for each of the measures, as well as the proposed CCN open dates after which a facility will not be eligible to receive a score on a reporting measure.

TABLE 29—PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2018 ESRD QIP

Measure	Minimum data requirements	CCN Open date	Small facility adjuster
Adult Hemodialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Adult Peritoneal Dialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Pediatric Hemodialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Pediatric Peritoneal Dialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Vascular Access Type: Catheter (Clinical).	11 qualifying patients	N/A	11–25 patients.
Vascular Access Type: Fistula (Clinical).	11 qualifying patients	N/A	11–25 patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 patients.
NHSN Bloodstream Infection (Clinical).	11 qualifying patients	Before January 1, 2016	11–25 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, 2016	N/A.
Anemia Management (Reporting).	Facilities with 11 or more qualifying patients must report data for all patients. Facilities with between 2 and 11 qualifying patients must report data on all but 1 qualifying patient. Facilities with 1 qualifying patient must report for that patient.	Before July 1, 2016	N/A.
Mineral Metabolism (Reporting).	Facilities with 11 or more qualifying patients must report data for all patients. Facilities with between 2 and 11 qualifying patients must report data on all but 1 qualifying patient. Facilities with 1 qualifying patient must report for that patient.	Before July 1, 2016	N/A.
Depression Screening and Follow-Up (Reporting).	One qualifying patient	Before July 1, 2016	N/A.
Pain Assessment and Follow-Up (Reporting).	One qualifying patient.	Before July 1, 2016	N/A.
NHSN HCP Influenza Vaccination (Reporting).	N/A	Before January 1, 2016	N/A.

6. Proposal for Calculating the Clinical Measure Domain Score

As the ESRD QIP evolves and we continue to adopt new clinical measures that track the goals of the NQS, we do not believe that the current scoring methodology provides the program with enough flexibility to strengthen incentives for quality improvement in areas where quality gaps continue to exist. Therefore, under the authority of Section 1881(h)(3)(A)(i) of the Act, we are proposing to revise the scoring methodology beginning with the PY 2018 ESRD QIP so that we assign measure scores on the basis of two domains: a Clinical Measure Domain and a Reporting Measure Domain.

First, we propose to establish a Clinical Measure Domain, which we define as an aggregated metric of facility performance on the clinical measures and measure topics in the ESRD QIP. Under this proposed approach, we would score individual clinical measures and measure topics using the methodology we finalize for that measure or measure topic. Clinical measures and measure topics would then be grouped into subdomains within the Clinical Measure Domain, according to quality categories. Within these subdomains, measure scores would be multiplied by a weighting coefficient, weighted measure scores would be summed together to determine subdomain scores, and then subdomain scores would be summed together to determine a facility's Clinical Measure Domain score. This scoring methodology provides more flexibility to focus on quality improvement efforts, because it makes it possible to group measures according to quality categories and to weight each category according to opportunities for quality improvement.

We further propose to divide the clinical measure domain into three subdomains for the purposes of calculating the Clinical Measure Domain score:

- Safety
- Patient and Family Engagement/Care Coordination
- Clinical Care

We took several considerations into account when selecting these particular subdomains. First, safety, patient engagement, care coordination, and clinical care are all NQS goals for which the ESRD QIP has proposed and/or finalized measures. We are attempting to align all CMS quality improvement efforts with the NQS because its patient-centered approach prioritizes measures across our quality reporting and pay-for-performance programs to ensure that the measurement approaches in these programs, as a whole, can make meaningful improvements in the quality of care furnished in a variety of settings. We also believe that adopting an NQS-based subdomain structure for the clinical measures in the ESRD QIP is responsive to stakeholder requests that we align our measurement approaches across HHS programs.

Second, we are proposing to combine the NQS goals of Care Coordination and Patient- and Caregiver-Centered Experience of Care into one subdomain because we believe the two goals complement each other. ''Care Coordination'' refers to the NQS goal of promoting effective communication and coordination of care. ''Patient- and Caregiver-Centered Experience of Care'' refers to the NQS goal of ensuring that each patient and family is engaged as a partner in care. In order to engage patients and families as partners, we believe that effective communication and coordination of care must coexist, and that patient and family engagement cannot occur independently of effective communication and care coordination. We therefore believe that it is appropriate to combine measures of care coordination with those of patient and family engagement for the purposes of calculating a facility's clinical measure domain score.

For PY 2018 and future payment years, we propose to include the following measures in the following subdomains of the proposed clinical measure domain (see Table 30):

TABLE 30—PROPOSED SUBDOMAINS IN THE CLINICAL MEASURE DOMAIN

Subdomain	Measures and measure topics
Safety Subdomain	NHSN Bloodstream Infection measure.
Patient and Family Engagement/Care Coordination Subdomain	ICH CAHPS measure. SRR measure.
Clinical Care Subdomain	STrR measure. Dialysis Adequacy measure topic. Vascular Access Type measure topic. Hypercalcemia measure.

We seek comments on these proposals to adopt a Clinical Measure Domain that includes three subdomains (safety, patient and family engagement/care coordination, and clinical care) for the purpose of calculating a facility's clinical measure domain score for PY 2018.

In deciding how to weight the proposed subdomains that comprise the clinical measure domain score, we took the following considerations into account: (1) the number of measures and measure topics in a proposed subdomain; (2) how much experience facilities have had with the measures and measure topics in a proposed subdomain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD. Because the proposed Clinical Care subdomain contains the largest number of measures, and facilities have the most experience with the measures in this subdomain, we are proposing to weight the Clinical Care subdomain significantly higher than the other subdomains. Facilities have more experience with the NHSN Bloodstream Infection measure in the proposed Safety subdomain than they do with the SRR measure in the proposed Patient and Family Engagement/Care Coordination subdomain, but we are proposing to include a larger number of measures in the Patient and Family Engagement/Care Coordination subdomain. We are proposing to give the Patient and Family Engagement/Care Coordination subdomain slightly more weight than the Safety subdomain, because it includes two measures, whereas only one measure appears in the proposed Safety subdomain. In future rulemaking, we will consider revising these weights based on facility experience with the measures contained within these proposed subdomains.

For these reasons, we propose the following weights for the three subdomains in the clinical measure domain score for PY 2018:

Subdomain	Weight in the clinical measure domain score (%)
Safety	20
Patient and Family Engagement/Care Coordination	30
Clinical Care	50

We seek comments on this proposal.

In deciding how to weight measures and measure topics within a proposed subdomain, we took into account the same considerations we considered when deciding how to weight the proposed subdomains. Because the NHSN Bloodstream Infection clinical measure is the only measure in the proposed Safety subdomain, we are proposing to assign the entire subdomain weight to that measure. We additionally note that improving patient safety and reducing bloodstream infections in patients with ESRD is one of our highest priorities for quality improvement, so we believe it is appropriate to weight the NHSN Bloodstream Infection clinical measure at 20 percent of a facility's Clinical Measure Domain Score. Because facilities have substantially more experience with the ICH CAHPS clinical measure, as compared with the SRR clinical measure, we are proposing to give the proposed ICH CAHPS measure twice as much weight as the proposed SRR measure. Additionally, we note that improving patients' experience of care is as high a priority for CMS quality improvement efforts as improving patient safety, so we believe it is appropriate to assign the ICH CAHPS clinical measure the same weight as the NHSN Bloodstream Infection clinical measure. We are proposing to give the Dialysis Adequacy and Vascular Access Type measure topics the most weight in the Clinical Care subdomain because facilities have substantially more experience with these measure topics, as compared to the other measures in the Clinical Care subdomain. We are proposing to assign equal weights to the STrR and Hypercalcemia measures because PY 2018 would be the first program year in which facilities are measured on the STrR measure, and because the clinical significance of the Hypercalcemia measure is diminished in the absence of other information about mineral metabolism (for example, a patient's phosphorus and plasma parathyroid hormone levels), which would provide a more comprehensive assessment of mineral metabolism (78 FR 72217). For these reasons, we propose to use the following weighting system for calculating a facility's Clinical Measure domain score:

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 topic	18
Vascular Access Type measure topic	18
Hypercalcemia measure	7

We seek comments on this proposal for weighting individual measures within the Clinical Measure Domain.

7. Proposal for Calculating the Reporting Measure Domain Score, the Reporting Measure Adjuster, and the TPS for the PY 2018 ESRD QIP

Starting with the PY 2014 program, the ESRD QIP has used a scoring methodology in which the clinical measures receive substantially more weight than the reporting measures in the TPS, and the weighting coefficients for the two types of measures total 100 percent of the TPS. We continue to believe it is appropriate to incorporate reporting measure scores in the TPS calculations because ''reporting is an important component in quality improvement'' (76 FR 70274); we also continue to believe that clinical measures should carry substantially more weight than reporting measures because clinical measures ''score providers/facilities based upon actual outcomes'' (76 FR 70275). These statements reflect the fact that clinical and reporting measures serve different functions in the ESRD QIP. Clinical measures provide a direct assessment of the quality of care a facility provides, relative to either the facility's past performance or standards of care nationwide. Reporting measures create an incentive for facilities to monitor significant indicators of health and illness, and they help facilities become familiar with CMS data systems. In addition, they allow the ESRD QIP to collect the robust clinical data needed to establish performance standards for clinical measures.

As we continue to add reporting measures to the ESRD QIP measure set, it becomes increasingly challenging to not weight them so heavily that they dilute the significance of the clinical measures, while still ensuring that we do not weight the reporting measures so lightly that facilities are not incentivized to meet the reporting measure requirements.

Although we considered the possibility of abandoning the use of reporting measures, we determined that this is not feasible because doing so would make it impossible to calculate performance standards for many clinical measures that promise to promote high-quality care. We also considered the possibility of weighting the reporting measures such that each reporting measure comprised a smaller percentage of the TPS. We believe, however, that doing so would result in the reporting measures not carrying enough weight to provide facilities with an incentive to meet the reporting requirements, particularly if additional reporting measures were added to the program. For example, if 5 reporting measures were adopted in the ESRD QIP, and the reporting measures collectively were weighted at 5 percent of a facility's TPS (in order to preserve the significance of the clinical measures), then each reporting measure would only comprise 1 percent of a facility's TPS. Under such conditions, we believe that facilities

may choose not to meet the reporting measure requirements, because not doing so would have a negligible impact on their overall TPS. If enough facilities reached this determination, then we would not be able to establish reliable baselines, should we propose to adopt clinical measure versions of the reporting measures. For these reasons, we are proposing the following scoring methodology for determining the impact of reporting measure scores on a facility's payment reductions.

For PY 2018 and future payment years, we propose to establish a new Reporting Measure Domain. We further propose that a facility's reporting measure domain score will be the sum of all the reporting measure scores that the facility receives. We strive to expand reporting measures into clinical measures in the ESRD QIP as quickly as measure development and administrative processes permit. Therefore, unlike the case with clinical measures in the Clinical Domain Score, we do not intend to continue to use any particular reporting measure in the ESRD QIP for an indefinite period of time. For this reason, we believe that it would be unnecessarily opaque and confusing to group reporting measures into subdomains, as we are proposing for the clinical measures in the Clinical Measure Domain.

Additionally, we propose to establish a Reporting Measure Adjuster (RMA), which will provide the ESRD QIP with an index of facility performance on reporting measures within the Reporting Measure Domain. We propose to use the following general formula to determine a facility's RMA, based on its reporting measure domain score:

$$\left[\begin{array}{c}(\text{available Reporting Measure points}) - \\ (\text{Reporting Measure Domain score})\end{array}\right] \times (\text{coefficient } C)$$

This formula is constructed such that a high RMA is indicative of low performance on the reporting measures, and a low RMA is indicative of high performance. A facility's Reporting Measure Domain score (that is, the sum of its scores on the reporting measures) is subtracted from the total number of points a facility could earn on the reporting measures for which it was eligible. This result is then multiplied by ''C,'' which is a coefficient used to translate reporting measure points into TPS points. As C increases, so too does the TPS ''value'' of a reporting measure point. For example, if C is set to 2, then 1 reporting measure point is worth 2 TPS points. If C is set to 0.5, then 1 reporting measure point is worth one-half of a TPS point. The value of C is in not tied to the number of reporting measures in the ESRD QIP; rather, it represents how much value we place on the reporting measures' contribution to the quality goals of the ESRD QIP. We will use the rulemaking process to set the value for C for each program year.

For the PY 2018 ESRD QIP, we propose to use the following formula to determine a facility's RMA:

$$\left[(\text{eligible Reporting Measure points}) - (\text{Reporting Measure Domain score})\right] \times 5/6$$

We set coefficient C at five-sixths for the PY 2018 program because each reporting measure point in the PY 2016 program, and the proposed PY 2017 program, is equivalent to five-sixths of a TPS point (that is, 30 points for three reporting measures comprised 25 TPS points). We believe it is important to maintain as much consistency as possible in the transition to the proposed scoring methodology. Therefore, we are proposing that the ''value'' of a reporting measure point in the TPS, as finalized in the PY 2016 program and proposed for the PY 2017 program, will remain constant in PY 2018.

For the reasons described above, we continue to believe that the clinical measures are considerably more important than the reporting measures in the ESRD QIP. We therefore believe that a facility's TPS should be predominantly determined by its Clinical Measure Domain score, and that a facility's TPS should be downwardly adjusted in the case of noncompliance with the reporting measure requirements. The RMA, as described above, is constructed such that a high RMA value indicates low reporting measure scores and a low RMA value indicate high reporting measure scores. As a result, a facility's TPS would be entirely determined by its Clinical Measure Domain score if it receives full credit on the reporting measures; the TPS would be slightly decreased if the facility received high (but not perfect) scores on the reporting measures; and the TPS would be significantly decreased if it performed poorly on the reporting measures. For these reasons, we propose to calculate a facility's TPS by subtracting the facility's RMA from its Clinical Measure Domain score. Additionally, we propose to continue our policy to require a facility to be eligible for a score on at least one reporting and one clinical measure in order to receive a TPS (78 FR 72217).

In an effort to estimate the impact of this proposed change for the ESRD QIP's scoring methodology, we conducted an analysis of how the proposed scoring methodology affected payment reduction distributions, based on data from CY 2012 and CY 2013. This analysis compared the scoring methodology proposed in this section and the previous section to the scoring methodology finalized for the PY 2016 program. In order to ensure that the analysis reliably estimated the impact on facilities' payment reductions, the proposed scoring methodology and the methodology finalized for the PY 2016 program were each applied to the PY 2016 measure set. The full analysis is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*. The results of this analysis are presented below in Table 31.

TABLE 31—EXPECTED IMPACT OF PROPOSED SCORING METHODOLOGY ON THE DISTRIBUTION OF PAYMENT REDUCTIONS, USING MEASURES AND MEASURE WEIGHTS FINALIZED FOR THE PY 2016 ESRD QIP AND DATA FROM CY 2012 AND CY 2013

Payment reduction (%)	Finalized scoring methodology for PY 2016, applied to measures and measure weights finalized in the PY 2016 program		Proposed scoring methodology for PY 2018, applied to measures and measure weights finalized in the PY 2016 program	
	Number of facilities	Percent	Number of facilities	Percent
0	4,828	79.4	4,606	75.7
0.5	884	14.5	739	12.2
1.0	242	4.0	306	5.0
1.5	69	1.1	108	1.8
2.0	59	1.0	323	5.3

As illustrated in Table 31, we expect that 4.3 percent more facilities (222 overall) would receive a payment reduction under the proposed methodology for PY 2018, as compared with the scoring methodology that we will use for the PY 2016 program. We therefore believe that adopting the scoring methodology proposed in this section and the previous section will not appreciably change the distribution of facility payment reductions, as is our intention.

We seek comments on these proposals for calculating a facility's reporting measure domain score, to calculate the RMA, and to determine the TPS.

Although we believe advantages are afforded by adopting the scoring methodology proposed in this section and the previous section, we also recognize that there may be advantages associated with maintaining consistency with previous years' scoring methodology. Accordingly, as an alternative to the scoring methodology proposed in this section and the previous section, we are also seeking public comments on whether we should continue to use the same methodology we currently use to weight measures in the ESRD QIP and calculate a facility's TPS, with the exception that the clinical and reporting measures would be weighted at 90 percent and 10 percent, respectively, of a facility's TPS.

8. Example of the Proposed PY 2018 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the proposed scoring methodology for PY 2018 and future payment years. Figures 3–7 illustrate how to calculate the clinical measure domain score, the reporting measure domain score, the RMA, and the TPS. Note that for this example, Facility A, a hypothetical facility, has performed very well. Figure 1 illustrates the general methodology used to calculate domain scores for the clinical measure domain, as well as the example calculations for Facility A.

Figure 3

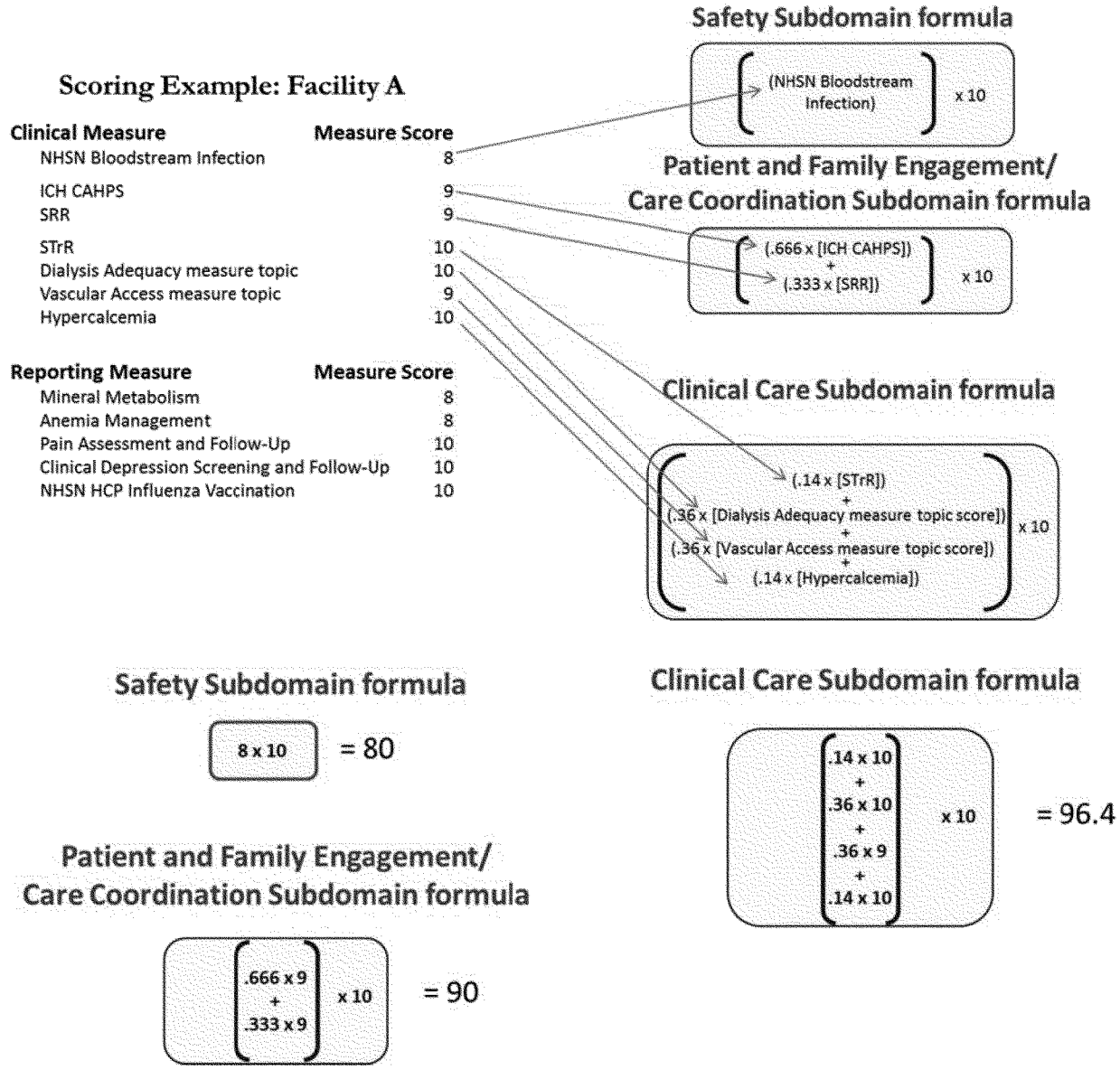


Figure 2 illustrates the general methodology for weighting subdomains in the clinical measure domain, as well as the example calculations for Facility A's clinical measure domain score.

Figure 4

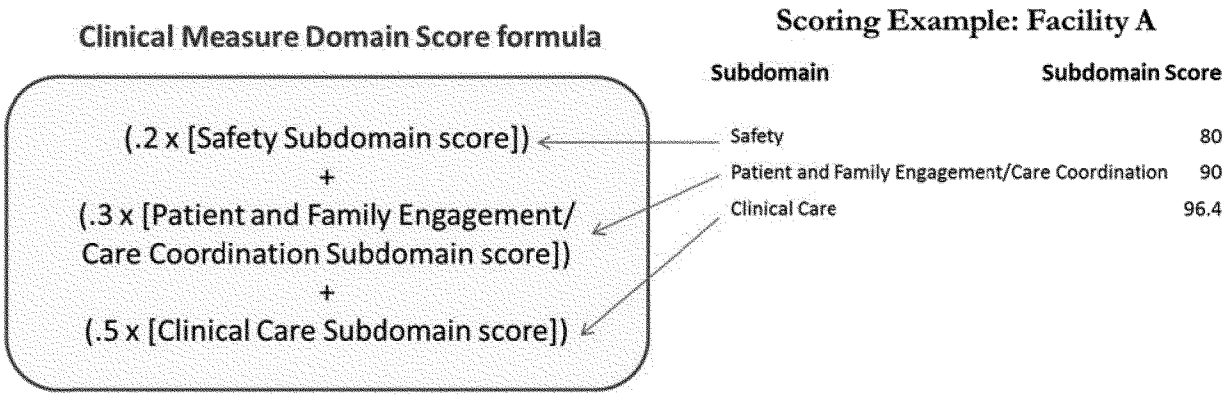


Figure 3 illustrates the general methodology for calculating a facility's reporting measure domain score, as well as the example calculations for Facility A.

Figure 5

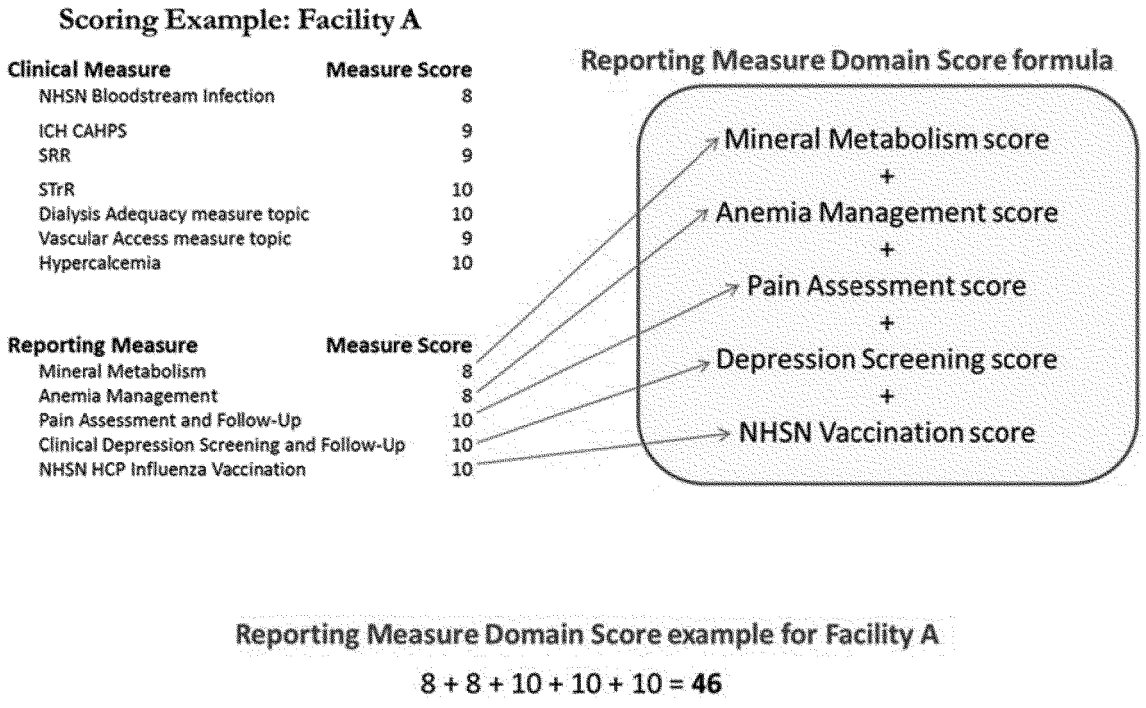


Figure 4 illustrates the general methodology for calculating a facility's RMA, as well as the example calculations for Facility A.

Figure 6

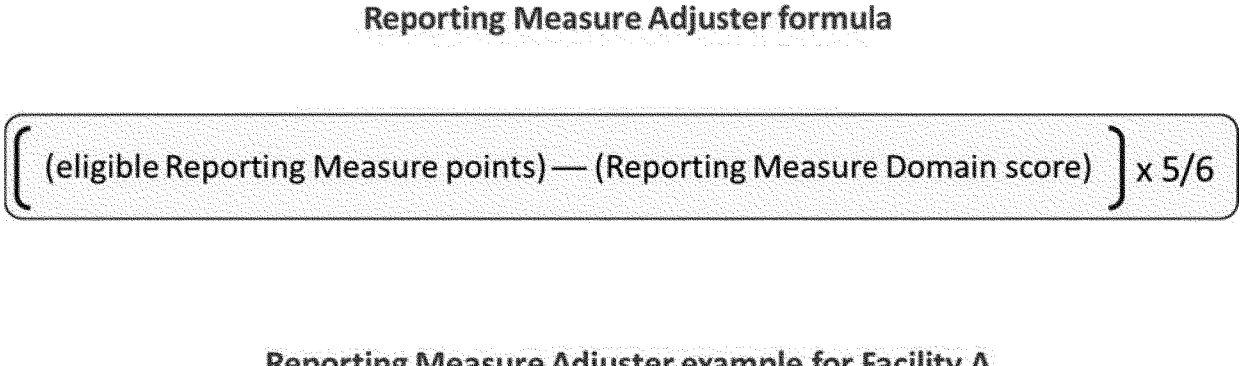
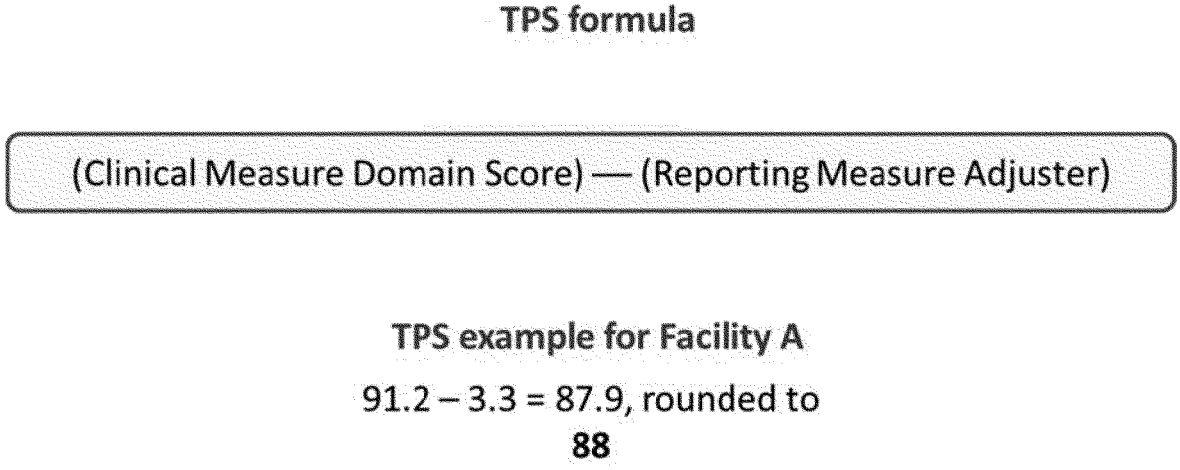


Figure 5 illustrates the general methodology for calculating a facility's TPS, as well as the example calculations for Facility A.

Figure 7



9. 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 scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. For the same reasons described in Section III.F.8 above, we propose that a facility would not receive a payment reduction for PY 2018 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;
- It received 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.

The PY 2016 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 2018 (i.e., CY 2016). Because we have not yet calculated final measure scores, we are unable to determine the 50th percentile of facility performance on the PY 2016 reporting measures. We will publish that value in the CY 2016 ESRD PPS final rule once we have calculated final measure scores for the PY 2016 program.

We seek comments on this proposal.

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 at this point.

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 2014 and the first part of

CY 2015, in the CY 2016 ESRD PPS Final Rule.

We seek comments on this proposal.

H. Future Considerations for Stratifying ESRD QIP Measures for Dual-Eligible Beneficiaries

CMS recognizes that individuals with both Medicare and Medicaid (also known as ''dual-eligible beneficiaries''), comprise a relatively large proportion of Medicare enrollees with ESRD. Because ESRD programs have a long history of performance measurement linked with public reporting, and because there are a large number of dual-eligible beneficiaries receiving ESRD care, we are considering stratifying ESRD QIP measures for Medicare-Medicaid enrollees.

Measure reporting under the ESRD QIP does not currently allow us to separately review results for dual-eligible beneficiaries or compare those results with results achieved by other patients with ESRD, so it is not currently known if their experiences are better, worse, or the same as other patients. Even the basic demographics of dual-eligible beneficiaries receiving ESRD care are not well understood. After discussion of the pros and cons that included input from the ESRD provider community, the Measures Application Partnership's dual-eligible workgroup recommended that CMS take the first step in exploring the feasibility of requiring facilities to separately report ESRD QIP measures for Medicare-Medicaid enrollees by analyzing the composition of the dual-eligible beneficiary population receiving ESRD care and determining potential ways in which stratified reporting may further quality improvement efforts. Furthermore, the Measures Application Partnership recommended, in the context of measure development, that CMS explore whether other risk factors unique to the dual-eligible population receiving ESRD care would present significant hurdles to measure stratification along these lines. We are therefore seeking comments on whether it would be feasible to stratify ESRD QIP measures based on whether the beneficiary is a dual eligible. We are interested in whether stakeholders recommend stratification and, if so, for what specific measures stakeholders would find stratification most compelling.

We are particularly interested in public comments on whether Medicare-Medicaid stratified quality measures under the ESRD QIP should be reported publicly, and how we should factor those measures into our scoring methodology. We seek comments on the meaningfulness of stratifying measures, and the feasibility and burden associated with reporting stratified measures.

IV. Technical Corrections for 42 Part 405

In the April 15, 2008, final rule ''Conditions for Coverage for End-Stage Renal Disease Facilities,'' (73 FR 20370) we revised the health and safety standards for Medicare-participating End-Stage Renal Disease (ESRD) facilities. This rule made the first comprehensive revisions to the ESRD Conditions for Coverage (CfCs) since they were adopted in 1976. The original ESRD CfCs at 42 CFR Part 405 Subpart U were deleted and new conditions were issued at 42 CFR Part 494. Subpart U now only addresses certain requirements for ESRD networks.

As a part of these revisions, we intended to delete most of the terms and definitions set out in Part 405 Subpart U, and create new definitions in Part 494. This is discussed in the 2008 final rule and in the corresponding proposed rule (70 FR 6184), and is laid out in the final rule crosswalk (comparing the old CfCs with the new ones) at 73 FR 20451.

While we intended to delete most of the definitions at Part 405 Subpart U, we inadvertently omitted the regulations text that would have made those changes. Subpart U, at § 405.2102, still has 32 definitions, most of them unnecessary and several of them obsolete. This creates confusion for ESRD stakeholders, patients, and suppliers.

We propose to make a technical correction that deletes the outdated terms and definitions at § 405.2102. Specifically, we propose to delete these terms and definitions: agreement, arrangement, dialysis, end-stage renal disease (ESRD), ESRD facility, renal dialysis center, renal dialysis facility, self-dialysis unit, special purpose renal dialysis facility, ESRD service, dialysis service, inpatient dialysis, outpatient dialysis, staff-assisted dialysis, self-dialysis, home dialysis, self-dialysis and home dialysis training, furnishes directly, furnishes on the premises, medical care criteria, medical care norms, medical care standards, medical care evaluation study (MCE), qualified personnel, chief executive officer, dietitian, medical record practitioner, nurse responsible for nursing service, physician-director, and social worker. We also propose to delete the term and definition for ''ESRD network organization,'' as it is duplicated within § 405.2102 as ''network organization.'' We would retain the terms and definitions for ''network, ESRD,'' and ''network organization.'' These changes are also outlined in Table 32 below.''

TABLE 32—TECHNICAL CORRECTIONS TO § 405.2102

Term	Proposed action	Other FR location
Agreement	Delete	
Arrangement	Delete	
Dialysis	Delete	
End-Stage Renal Disease (ESRD)	Delete	406.13(b).
ESRD facility introductory text	Delete	
Renal dialysis center	Delete	
Renal dialysis facility	Delete	494.10.
Self-dialysis unit	Delete	
Special purpose renal dialysis facility	Delete	494.120.
ESRD Network organization	Delete	
ESRD service introductory text	Delete	
Dialysis service	Delete	
Inpatient dialysis	Delete	
Outpatient dialysis	Delete	
Staff-assisted dialysis	Delete	
Self-dialysis	Delete	494.10.
Home dialysis	Delete	494.10.
Self-dialysis and home dialysis training	Delete	

TABLE 32—TECHNICAL CORRECTIONS TO § 405.2102—Continued

Term	Proposed action	Other FR location
Furnishes directly	Delete	494.10.
Furnishes on the premises	Delete	494.180(d)
Medical care criteria	Delete	
Medical care norms	Delete	
Medical care standards	Delete	
Medical care evaluation study (MCE)	Delete	
Network, ESRD	Retain	N/A.
Network organization	Retain	N/A.
Qualified personnel	Delete	
Chief executive officer	Delete	
Dietitian	Delete	494.140(c).
Medical record practitioner	Delete	
Nurse responsible for nursing service	Delete	494.140(b).
Physician-director	Delete	494.140(a).
Social worker	Delete	494.140(d).

V. Methodology for Adjusting DMEPOS Payment Amounts Using Information From Competitive Bidding Programs

A. Background

1. Payment Basis for Certain DMEPOS

Section 1834(a) of the Act governs payment for durable medical equipment (DME) covered under Part B and under Part A for a home health agency and provides for the implementation of a fee schedule payment methodology for DME furnished on or after January 1, 1989. Sections 1834(a)(2) through (a)(7) of the Act set forth separate payment categories of DME and describe how the fee schedule for each of the following categories is established:

- Inexpensive or other routinely purchased items,
- Items requiring frequent and substantial servicing,
- Customized items,
- Oxygen and oxygen equipment,
- Other covered items (other than DME), and
- Other items of DME (capped rental items).

Section 1834(h) of the Act governs payment for prosthetic devices, prosthetics, and orthotics (P&O) and sets forth fee schedule payment rules for P&O. Effective for items furnished on or after January 1, 2002, payment is also made on a national fee schedule basis for parenteral and enteral nutrition (PEN) in accordance with the authority under section 1842(s) of the Act. The term ''enteral nutrition'' will be used throughout this document to describe enteral nutrients supplies and equipment covered as prosthetic devices in accordance with section 1861(s)(8) of the Act and paid for on a fee schedule basis and enteral nutrients under DMEPOS Competitive Bidding Program (CBP), as authorized under section 1847(a)(2)(B) of the Act. Section 1842(o)(1)(D) of the Act mandates that payment for infusion drugs furnished through a covered item of DME on or after January 1, 2004, is equal to 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

For DMEPOS items subject to payment under 1834 of the Act (not subject to the CBP), the Medicare's allowed payment amount is equal to the lesser of the actual charge for the item or the fee schedule amount for the item. The fee schedule amounts are based on average payments made under the previous payment methodology of reasonable charges, which utilized supplier charges for furnishing items and services in local areas throughout the nation to establish the Medicare allowed payment amounts for the items and services. The reasonable charge data used is from a specific period of time that varies slightly by payment class (for example, July 1986 through June 1987 for inexpensive DME). The fee schedule amounts for most items are updated on an annual basis by covered item update factors provided in the statute for DME under section 1834(a)(14) of the Act, for P&O under section 1834(h)(4)(A) of the Act, and for enteral nutrition under section 1842(s)(1)(B) of the Act.

The rules pertaining to the calculation of reasonable charges are located at 42 CFR Part 405, Subpart E of our regulations. Under this general methodology, several factors were taken into consideration in determining the reasonable charge for an item. Each supplier's ''customary charge'' for an item, or the 50th percentile of charges for an item over a 12-month period, was one factor used in determining the reasonable charge. The ''prevailing charge'' in a local area, or the 75th percentile of suppliers' customary charges for the item in the locality, was also used in determining the reasonable charge. For PEN items and services only, the ''lowest charge level (LCL)'' was also taken into consideration and was based on the 25th percentile of all charges for an item. For the purpose of calculating prevailing charges, a ''locality'' is defined at 42 CFR 405.505 and ''may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a state, or a group of states.'' The regulation further specifies that the locality ''should include a cross section of the population with respect to economic and other characteristics.'' For PEN items and services only, the entire nation was used as the locality for the purpose of calculating the LCL and prevailing charges.

Effective for items furnished on or after October 1, 1985, an additional factor, the inflation-indexed charge (IIC) as cited at 42 CFR 405.509, was added to the factors taken into consideration in determining the reasonable charge for an item. The IIC is equal to the lowest of the customary charge, prevailing charge, LCL (if applicable), and IIC from the previous year updated by an inflation adjustment factor. To summarize, the reasonable charges for each item that were used to calculate the fee schedule amounts are equal to the lower of:

- the supplier's actual charge on the claim;
- the supplier's customary charge for the item;
- the prevailing charge in the locality for the item;
- the LCL in the locality for the item, if applicable; or
- the IIC.

Under the reasonable charge payment methodology, it is assumed that suppliers took all of their costs of

furnishing various items and services in various localities throughout the nation into account in setting the prices they charge for covered items and services.

We implemented the fee schedule payment methodologies for PENs at 42 CFR Part 414, Subparts C, and for DME prosthetic devices, prosthetics, orthotics, and surgical dressings at 42 CFR Part 414, Subpart D of our regulations. In accordance with section 1834(a)(10) of the Act, the Secretary may adjust DMEPOS fee schedule amounts in situations where it is determined that the amounts are not inherently reasonable. This ''inherent reasonableness'' authority for adjusting fee schedule payment amounts is governed by paragraphs (8) and (9) of section 1842(b) of the Act and implemented at 42 CFR Part 405, Subpart E of our regulations. Finally, in the case of DMEPOS furnished on or after January 1, 2011, under section 1834(a)(1)(F)(ii) of the Act, the Secretary may (in beginning January 1, 2016, must) use information on the payment determined under the CBP in accordance with section 1847 of the Act to adjust the fee schedule payment amounts for DME that are not in a competitive bidding area (CBA), and the inherent reasonableness authority does not apply. Adjustment of fee schedule amounts based on CBP payment information (and the limitation on using inherent reasonableness) is also authorized under section 1834(h)(1)(H)(ii) of the Act for certain orthotics and section 1842(s)(3)(B) of the Act for enteral nutrition in non-competitive bid areas.

2. Fee Schedule Payment Methodologies

Section 4062(b) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100–203, added section 1834(a) of the Act and mandated the implementation of local fee schedule amounts in 1989 for DME and P&O based on the average of reasonable charges for items and services furnished in carrier service areas throughout the United States. The carriers were (now Medicare administrative contractors) responsible for processing claims for Part B items and services in accordance with section 1842(a) of the Act. The carrier service areas used in establishing the fee schedule amounts could not exceed an entire state. A few states were made up of two carrier service areas and the State of New York had three carrier service areas. A carrier service area is not to be confused with a locality established for the purpose of calculating reasonable charges as described above. For example, although claims for items furnished in the State of Texas were processed by a single carrier, for reasonable charge calculation purposes, Texas was divided into more than 50 different localities. In 1993, the local fee schedule amounts for states with more than one carrier service areas were transitioned to statewide fee schedule amounts. The reasonable charge data used to calculate the statewide fee schedule amounts therefore reflected the average payment made under the supplier charge based reasonable charge payment methodology for items and services furnished throughout the state, including both rural and urban areas of the state.

Section 4062(b) of OBRA 87 mandated that local fee schedule amounts for both DME and P&O be transitioned to regional fee schedule amounts as part of a multi-year phase in ending in 1993. Section 4152(b) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), Public Law 101–508, eliminated the regional fee schedule transition for DME and amended section 1834(a) of the Act to mandate that the local (statewide) fee schedule amounts be limited by a national ceiling (upper) limit, based on the median of the statewide fee schedule amounts, and a national floor (lower limit), based on 85 percent of the median of the statewide fee schedule amounts. The fee schedule ceiling and floor limits for DME were phased in from 1991 through 1993. The conversion to regional fee schedule amounts therefore never took place for DME and instead the statewide fee schedule amounts were limited so that they could not vary by more than 15 percent from the national ceiling to the national floor. The fee schedule amounts for areas outside the contiguous United States are not subject to the national ceiling and floor limits. The transition to regional fee schedule amounts was retained for P&O, although OBRA 90 changed the phase in schedule so that the regional fee schedule amounts were not fully phased in until January 1, 1994, rather than January 1, 1993. As explained in more detail below, the regional fee schedule methodology allows for regional geographic variation in fee schedule payment amounts and a wider range in fees across the nation than the fee schedule methodology used for DME which caps the local, statewide fee schedule amounts at the national median. That being said, we have not seen any problems associated with access to either P&O or DME in rural areas or any areas of the country since payments have been made based on these fee schedule methodologies. This has been the case even though the average reasonable charges used to compute the statewide fee schedule amounts include a comingling of reasonable charge data for items and services furnished in both urban and rural areas. In addition, we have not seen any problems with access to PEN in rural areas or any areas of the country since payments have been made based on national fee schedule amounts.

3. Regional Fee Schedule Payment Methodology for P&O

The regional fee schedules for P&O are mandated by section 1834(h)(2)(B) of the Act. The regional fee schedule amounts only apply to areas within the contiguous United States. The regional fee schedule amounts are calculated based on the weighted average (weighted by total Part B claims volume) of statewide fee schedule amounts for states in each of the ten CMS Regional Office boundaries identified below. The statewide fee schedule amounts are based on average reasonable charges (statewide fees) for items furnished from July 1, 1986 through June 30, 1987.

The ten CMS Regional Office boundaries are:

- Boston (Region One), including the six states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont;
- New York (Region Two), including the two states of New Jersey and New York;
- Philadelphia (Region Three), including the five states of Delaware, Maryland, Pennsylvania, Virginia, West Virginia and the District of Columbia;
- Atlanta (Region Four), including the eight states of Alabama, North Carolina, South Carolina, Florida, Georgia, Kentucky, Mississippi, and Tennessee;
- Chicago (Region Five), including the six states of Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin;
- Dallas (Region Six), including the five states of Arkansas, Louisiana, New Mexico, Oklahoma and Texas;
- Kansas City (Region Seven), including the four states of Iowa, Kansas, Missouri and Nebraska;
- Denver (Region Eight), including the six states of Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming;
- San Francisco (Region Nine), including the three states of Arizona, California and Nevada; and
- Seattle (Region Ten), including the three states of Idaho, Oregon and Washington.

As an example, the regional fee schedule amounts for Region Nine are based on the weighted average of the

statewide fees for Arizona, California, and Nevada. Since California accounts for the largest volume of Part B claims in the region, the California statewide fees are weighted more heavily in determining the regional fee schedule amounts than the statewide fees for Arizona or Nevada. Once all of the regional fee schedule amounts are established, the regional fee schedule amounts are further limited by a national ceiling equal to 120 percent of the average of the regional fee schedule amounts for all the states and a national floor equal to 90 percent of the average of the regional fee schedule amounts for all the states.

The national ceiling and floor limits for DME and P&O set national parameters on how much the statewide or regional fee schedule amounts can vary. For DME, the upper payment limit or ceiling is based on the national median of the statewide fees, essentially bringing half of the state fees down to the national median. The lower limit or floor is based on 85 percent of the national median and brings those state fees below the floor amount up to the floor amount. In contrast, the national ceiling and floor parameters for P&O are based on 120 percent and 90 percent, respectively, of the average of the various regional fee schedule amounts. Differences in reasonable charge based fees in various geographic regions of the country are maintained within the parameters of the national ceilings and floors for P&O.

4. DMEPOS Competitive Bidding Programs Payment Rules

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary to establish and implement CBPs in CBAs throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs mandated by section 1847(a) of the Act are collectively referred to as the ''Medicare DMEPOS Competitive Bidding Program.'' Section 1847(a)(2) of the Act provides that the items and services to which competitive bidding applies are:

- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

The DME and medical supplies category includes items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME, but excludes class III devices under the Federal Food, Drug, and Cosmetics Act and Group 3 or higher complex rehabilitative power wheelchairs and related accessories when furnished with such wheelchairs. Sections 1847(a) and (b) of the Act specify certain requirements and conditions for implementation of the Medicare DMEPOS CBP.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) was enacted. Section 154 of the MIPPA amended section 1847 of the Act to make certain limited changes to the Medicare DMEPOS CBP, including a revised timeframe for phasing in the programs.

On March 23, 2010, the Affordable Care Act was enacted. Section 6410(a) of the Affordable Care Act amended section 1847(a)(1) of the Act, mandating the phase in of 21 additional Metropolitan Statistical Areas (MSAs).

Section 1847(a) of the Act requires that the DMEPOS CBP be phased in so that competition under the programs occurs in 9 of the largest Metropolitan Statistical Areas (MSAs) in 2009, 91 additional large MSAs in 2011, and additional areas after 2011 (or, in the case of national mail order for items and services, after 2010). Section 1847(a)(1)(D)(ii) of the Act provides discretion to subdivide MSAs and through notice and comment rulemaking we subdivided the New York-Northern New Jersey-Long Island, NY-NJ-PA; Los Angeles-Long Beach-Santa Ana, CA; and Chicago-Naperville-Joliet, IL-IN-WI MSAs. The final rule was published in the **Federal Register** on November 29, 2010 (75 FR 73454) and divided the New York-Northern New Jersey-Long Island, NY-NJ-PA MSA into six CBAs. In addition, the Los Angeles-Long Beach-Santa Ana, CA MSA was divided into two CBAs and the Chicago-Naperville-Joliet, IL-IN-WI MSA was divided into four CBAs (75 FR 73460). Altogether this created a total of 100 CBAs for the competitions occurring in the 91 MSAs in 2011, or a total of 109 CBAs for the competitions occurring in 100 MSAs in 2009 and 2011.

Finally, section 1847(a)(1)(D)(iii) of the Act specifies that competitions occurring before 2015 for items and services other than national mail order, may not include rural areas or MSAs with a population of less than 250,000.

In addition to the national mail order program for diabetic supplies, the product categories (PCs) that have been phased in thus far in 100 Round 2 CBAs and 9 Round 1 CBAs include the following:

Round 2 CBAs (Contract Period July 1, 2013, Thru June 30, 2016)

- Oxygen, oxygen equipment, and supplies
- Standard (Power and Manual) wheelchairs, scooters, and related accessories
- Enteral nutrients, equipment, and supplies
- Continuous Positive Airway Pressure (CPAP) devices and Respiratory Assist Devices (RADs) and related supplies and accessories
- Hospital beds and related accessories
- Walkers and related accessories
- Negative Pressure Wound Therapy pumps and related supplies and accessories
- Support surfaces (Group 2 mattresses and overlays)

Round 1 CBAs (Contract Period January 1, 2014, Thru December 31, 2016)

- Respiratory Equipment and Related Supplies and Accessories
  - includes oxygen, oxygen equipment, and supplies; CPAP devices and RADs and related supplies and accessories; and standard nebulizers
- Standard Mobility Equipment and Related Accessories
  - includes walkers, standard power and manual wheelchairs, scooters, and related accessories
- General Home Equipment and Related Supplies and Accessories
  - includes hospital beds and related accessories, group 1 and 2 support surfaces, transcutaneous electrical nerve stimulation (TENS) devices, commode chairs, patient lifts, and seat lifts
- Enteral Nutrients, Equipment and Supplies
- Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories
- External Infusion Pumps and Supplies

In addition, contracts and SPAs were in effect in the 9 Round 1 CBAs from January, 1 2011 thru December 31, 2013, for the items listed below which are not included in current Round 1 or 2 PCs:

- Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2)
- Adjustable Wheelchair Seat Cushions

5. Adjusting Payment Amounts Using Information From the DMEPOS Competitive Bidding Program

Section 1834(a)(1)(F)(ii) of the Act provides authority for using information from the DMEPOS CBPs to adjust the DME payment amounts for covered items furnished on or after January 1, 2011, in areas where competitive bidding is not implemented for the items. Similar authority exists at section 1834(h)(1)(H)(ii) of the Act for OTS orthotics, and at section 1842(s)(3)(B) of the Act for enteral nutrition. Section 1834(a)(1)(F) also requires adjustments to the payment amounts for all DME items subject to competitive bidding furnished in areas where CBPs have not been implemented on or after January 1, 2016.

For items furnished on or after January 1, 2016, section 1834(a)(1)(F)(iii) requires us to continue to make such adjustments to DME payment amounts where CBPs have not been implemented, as additional covered items are phased in or information is updated as contracts are recompeted.

Section 1834(a)(1)(G) of the Act requires that the methodology used to adjust payment amounts for DME and OTS orthotics using information from the CBPs be promulgated through notice and comment rulemaking, which is the purpose of this proposed rule. Section 1834(a)(1)(G) of the Act also requires that we consider the ''costs of items and services in areas in which such provisions [sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii)] would be applied compared to the payment rates for such items and services in competitive acquisition [competitive bidding] areas.'' We are proposing to apply the same methodology for making adjustments to the payment amounts for enteral nutrition as authorized by section 1842(s)(3)(B) of the Act.

6. Diversity of Costs

As mentioned above, under section 1834(a)(1)(G) of the Act we must consider the costs of furnishing items and services in areas where prices will be adjusted compared to the payment rates for the items and services furnished in CBAs. We believe that the methodology for using the single payment amounts (SPAs) as a basis for adjusting payment rates in other areas needs to ensure that adjusted payment amounts in an area are adequate to cover the unique costs of furnishing the items and services in those areas.

The SPAs are based on the median of successful bids for furnishing items and services in MSAs, which are mainly urban areas, from suppliers with costs and characteristics that may or may not be similar to suppliers in other areas. In addition, under the DMEPOS CBP, many low population density areas within MSAs were excluded from the CBAs as authorized by statute, making the geographic bidding areas smaller and more densely populated than they would have been if the initial MSA boundaries had been retained for bidding purposes.

Regarding the size of suppliers submitting the bids used to generate the SPAs compared to the size of suppliers in areas where price adjustments based on the SPAs would occur, it is important to note that small suppliers are given special considerations under the CBP and that a majority of contracts are offered to small suppliers. Section 1847(b)(6)(D) of the Act requires that, in developing procedures relating to bidding and the awarding of contracts, CMS ''take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program.'' We have established a number of provisions to ensure that small suppliers are given an opportunity to participate in the DMEPOS CBP. For example, under 42 CFR 414.414(g)(1)(i), we have established a 30 percent target for small supplier participation; thereby, ensuring efforts are made to award at least 30 percent of contracts to small suppliers. Also, CMS worked in coordination with the Small Business Administration (SBA) to develop an appropriate definition of a ''small supplier'' for this program. Under 42 CFR 414.402, a small supplier is one that generates gross revenues of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue. Under 42 CFR 414.418, small suppliers may join together in ''networks'' in order to submit bids that meet the various program requirements. For contracts taking effect on July 1, 2013 in Round 2, in 100 CBAs throughout the country, 63 percent of all contract suppliers are small suppliers, with only 10 percent of contract suppliers being new to the areas. In addition, for contracts taking effect on January 1, 2014 in the Round 1 Recompete, in the 9 initial CBAs, 58 percent of all contract suppliers are small suppliers, with only 3 percent of contract suppliers being new to the areas. Therefore, the majority of bids used in establishing the SPAs come from small suppliers with a history of furnishing the items in the CBAs.

Prior to awarding contracts, each supplier is carefully screened to ensure that it is accredited under applicable Medicare quality standards and meets rigid financial standards, specific Medicare supplier enrollment requirements, and applicable state licensing standards. Each bid is screened to ensure that it is a bona fide bid, and those that fail are excluded from the competition. Approximately 94 percent of bids screened as part of the Round 2 and Round 1 Recompete competitions were determined to be bona fide. The invoices and purchase orders submitted by bidding suppliers to support their bids reflected prices already paid by the supplier (that is, prior to becoming a contract supplier) and for the most part did not reflect large volume purchasing discounts. Once non-bona fide bids are excluded, suppliers are ranked in order based on bid amounts, and the median of bids from the number of suppliers determined to be necessary to meet projected demand are used to establish the SPAs. The projected demand for items and services in a CBA is intentionally overstated for the purpose of ensuring that contracts are awarded to more than a sufficient number of suppliers to serve the beneficiaries in the area. The establishment of the demand level is explained in detail in the competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other issue) published April 10, 2007 (72 FR 18039). Thus, the SPAs are higher than they would otherwise be if demand was not overstated because the high demand generally results in an increase in the number of contract suppliers which in most cases increases the median bid amount. CMS also conducts its review of supplier capacity and expansion plans during the bid evaluation process. If a supplier is new to an area, new to a PC, or submits estimated capacity that represents substantial growth over current levels, CMS may conduct a more detailed evaluation of that supplier's expansion plan to verify the supplier's ability to provide items and services in the CBA on day one of the contract period. If a bidder's financial data and expansion plan do not support the supplier's estimated capacity, CMS will adjust the capacity to the supplier's historic level, which would be zero for a new supplier. CMS uses the estimated capacity information and the bid amounts to determine the array of winning suppliers in a CBA.

Under Round 2 and the Round 1 Recompete competitions, 92 percent of suppliers accepted contract offers at the SPAs set through the competitions. In addition, CMS reviewed all contract

suppliers based on financial standards when evaluating their bids. This process includes review of tax records, credit reports, and other financial data, which leads to the calculation of a score, similar to processes used by lenders when evaluating the viability of a company. All contract suppliers met the financial standards established for the program.

From January 1, 2011, when the initial Round 1 contracts and SPAs took effect, to present, we have seen no indication that beneficiaries have been denied access to necessary items and services subject to the programs in CBAs as a result of the SPAs. In addition, we have been closely monitoring inquiries as well as real time claims and health outcomes data and have seen no negative impacts on access to items and services under the program. Therefore, the SPAs appear to be sufficient to cover the costs of the suppliers furnishing items in the 109 CBAs.

In previous legislation, which we will discuss below, the Congress mandated that the costs of furnishing DME in different geographic regions of the country be studied. Section 135 of the Social Security Act Amendments of 1994, Public Law 103–432, required an examination of the geographic variations in DME supplier costs in order to determine whether the fee schedules are reasonably adjusted to account for any geographic differences. Jing Xing Health and Safety Resources, Inc. provided assistance to the Health Care Financing Administration, now CMS, in conducting this study. The project entitled ''Durable Medical Equipment Supplier Product and Service Cost Study'', was completed under Contract Number HCFA 500–95–0044 and submitted to the agency in June 1996. As part of the study, a Federal Advisory Panel was convened, a formal meeting with representatives of the DME industry was held, and a literature review was conducted. The general consensus among industry representatives and government agencies that participated in the study was that there is no conclusive evidence that urban and rural costs differed significantly or that the costs of furnishing DME items and services were higher in urban areas versus rural areas or vice versa.

The 109 CBAs where competitive bidding has been phased in include a wide range of different size urban areas with surrounding counties, and suppliers take the costs of furnishing items and services in these different areas into account when submitting bids under the programs. They include one CBA (Honolulu, HI) that is not within the contiguous Unites States and CBAs that range in population size from approximately 300 thousand to 10 million (See Table 33). There are 7 CBAs with a population of less than 500,000, 42 CBAs with a population of more than 500,000, but less than 1 million, 27 CBAs with a population of more than 1 million, but less than 2 million, 19 CBAs with a population of 2 to 4 million, and 14 CBAs with a population of over 4 million.

TABLE 33—CBA POPULATION SIZE

CBA	Population
Los Angeles County CBA	9,453,357
Nassau-Brooklyn-Queens-Richmond County Metro CBA	6,630,278
Dallas-Fort Worth-Arlington, TX	6,554,334
Central-Chicago Metro CBA	6,179,455
Houston-Sugar Land-Baytown, TX	6,152,650
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	5,995,992
Washington-Arlington-Alexandria, DC-VA-MD-WV	5,662,358
Miami-Fort Lauderdale-Pompano Beach, FL	5,604,979
Atlanta-Sandy Springs-Marietta, GA	5,293,136
Boston-Cambridge-Quincy, MA-NH	4,595,431
San Francisco-Oakland-Fremont, CA	4,407,286
Detroit-Warren-Livonia, MI	4,256,579
Phoenix-Mesa-Glendale, AZ	4,251,146
Riverside-San Bernardino-Ontario, CA	4,157,332
Seattle-Tacoma-Bellevue, WA	3,522,509
Northern NJ Metro CBA	3,473,815
Minneapolis-St. Paul-Bloomington, MN-WI	3,326,864
San Diego-Carlsbad-San Marcos, CA	3,118,844
Orange County CBA	3,067,829
Southern NY Metro CBA	3,015,460
Bronx-Manhattan NY CBA	2,983,009
St. Louis, MO-IL	2,844,160
Tampa-St. Petersburg-Clearwater, FL	2,810,479
Baltimore-Towson, MD	2,751,529
Denver-Aurora-Broomfield, CO	2,568,221
Pittsburgh, PA	2,361,317
Portland-Vancouver-Hillsboro, OR-WA	2,259,089
San Antonio-New Braunfels, TX	2,223,779
Orlando-Kissimmee-Sanford, FL	2,176,846
Sacramento-Arden-Arcade-Roseville, CA	2,174,556
Cincinnati-Middletown, OH-KY-IN	2,121,660
Cleveland-Elyria-Mentor, OH	2,074,790
Kansas City, MO-KS	2,050,306
Las Vegas-Paradise, NV	1,967,341
San Jose-Sunnyvale-Santa Clara, CA	1,898,173
Columbus, OH	1,844,571
Charlotte-Gastonia-Rock Hill, NC-SC	1,832,391
Austin-Round Rock-San Marcos, TX	1,813,495
Indianapolis-Carmel, IN	1,764,136
Virginia Beach-Norfolk-Newport News, VA-NC	1,673,547
Nashville-Davidson-Murfreesboro-Franklin, TN	1,607,708

TABLE 33—CBA POPULATION SIZE—Continued

CBA	Population
Providence-New Bedford-Fall River, RI-MA	1,603,029
Milwaukee-Waukesha-West Allis, WI	1,570,548
Suffolk County CBA	1,488,017
South-West-Chicago-Metro CBA	1,464,818
Jacksonville, FL	1,371,407
North East NY CBA Metro	1,363,882
Memphis, TN-MS-AR	1,309,806
Louisville/Jefferson County, KY-IN	1,277,282
Oklahoma City, OK	1,276,642
Richmond, VA	1,262,088
Hartford-West Hartford-East Hartford, CT	1,214,313
Raleigh-Cary, NC	1,190,534
Northern-Chicago Metro CBA	1,187,661
New Orleans-Metairie-Kenner, LA	1,182,382
Salt Lake City, UT	1,158,617
Buffalo-Niagara Falls, NY	1,133,325
Birmingham-Hoover, AL	1,121,219
Rochester, NY	1,062,561
Tucson, AZ	1,004,374
Honolulu, HI	962,112
Fresno, CA	949,093
Tulsa, OK	945,366
Bridgeport-Stamford-Norwalk, CT	922,063
Albuquerque, NM	896,202
Omaha-Council Bluffs, NE-IA	883,233
Albany-Schenectady-Troy, NY	866,077
New Haven-Milford, CT	862,551
Dayton, OH	839,984
Oxnard-Thousand Oaks-Ventura, CA	830,680
Allentown-Bethlehem-Easton, PA-NJ	826,740
El Paso, TX	826,163
Baton Rouge, LA	811,243
Bakersfield-Delano, CA	810,348
Worcester, MA	800,404
McAllen-Edinburg-Mission, TX	799,023
Grand Rapids-Wyoming, MI	783,733
Columbia, SC	767,793
Greensboro-High Point, NC	746,685
Little Rock-North Little Rock-Conway, AR	710,371
North Port-Bradenton-Sarasota, FL	708,687
Indiana-Chicago Metro CBA	706,110
Knoxville, TN	705,446
Springfield, MA	698,926
Akron, OH	687,788
Stockton, CA	685,542
Greenville-Mauldin-Easley, SC	683,793
Charleston-North Charleston-Summerville, SC	682,539
Syracuse, NY	671,076
Poughkeepsie-Newburgh-Middletown, NY	665,524
Colorado Springs, CO	665,484
Toledo, OH	649,956
Wichita, KS	634,116
Boise City-Nampa, ID	634,037
Cape Coral-Fort Myers, FL	631,611
Lakeland-Winter Haven, FL	602,671
Augusta-Richmond County, GA-SC	570,656
Scranton-Wilkes-Barre, PA	556,282
Youngstown-Warren-Boardman, OH-PA	553,382
Palm Bay-Melbourne-Titusville, FL	550,416
Jackson, MS	544,285
Chattanooga, TN-GA	533,309
Deltona-Daytona Beach-Ormond Beach, FL	501,906
Visalia-Porterville, CA	439,968
Flint, MI	435,877
Asheville, NC	434,665
Beaumont-Port Arthur, TX	397,872
Ocala, FL	323,229
Huntington-Ashland, WV-KY-OH	289,474

Source: U.S. Census Bureau, Population Division, 2012 Population Estimates. Population estimates for MSAs and counties were adjusted to reflect CBA boundaries.

7. Advanced Notice of Proposed Rulemaking

CMS issued an Advance Notice of Proposed Rulemaking (ANPRM): Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) using Information From Competitive Bidding Programs. The ANPRM was published in the **Federal Register** on February 26, 2014 (79 FR 10754) and solicited comments on several aspects to consider in developing the proposed methodology to adjust DMEPOS fee schedule amounts or other payment amounts in non-competitive areas based on DMEPOS competitive bidding payment information. Specific questions related to this topic were presented in the notice, including:

- Do the costs of furnishing various DMEPOS items and services vary based on the geographic area in which they are furnished?
- Do the costs of furnishing various DMEPOS items and services vary based on the size of the market served in terms of population and/or distance covered or other logistical or demographic reasons?
- Should an interim or different methodology be used to adjust payment amounts for items that have not yet been included in all CBPs (for example, items such as TENS devices that have only been phased into the nine Round 1 areas thus far)?

The comment period for the ANPRM ended on March 28, 2014, and CMS received approximately 185 comments from suppliers, manufacturers, professional, state and national trade associations, physicians, physical therapists, beneficiaries and their caregivers, and one state government office.

Commenters generally agreed that costs do vary by geographic region and that costs in rural and non-contiguous areas are higher than costs in urban areas. However, few commenters offered specific proposals or suggestions for addressing these costs differences and the suggestions that were provided were vague (for example, use the 75th percentile of SPAs rather than the national median SPA). Several commenters stated that the costs of furnishing DMEPOS items and services in different regions of the country do vary. One commenter representing many suppliers said that there exists no reliable cost data. Another commenter representing many manufacturers and suppliers listed several key variables or factors that influence the cost of furnishing items and services in different areas that should be considered, but the commenter did not provide information on how valid and reliable information related to these factors could be obtained. This commenter stated that information of all bids submitted under the programs should also be considered and not just the bids of winning suppliers. Some commenters expressed concern that the SPAs assume a significant increase in volume to offset lower payment amounts. Some commenters suggested that the price adjustments be phased in rather than making full, one-time adjustments.

B. Proposed Provisions

We propose establishing three methodologies for adjusting DMEPOS fee schedule amounts in areas where CBPs have not been established for these items and services based on SPAs established in accordance with the payment rules at § 414.408. Use of SPAs that may be established in accordance with the special payment rules proposed in section V to adjust DMEPOS fee schedule amounts in areas where CBPs have not been established for these items and services would be addressed in future notice and comment rulemaking. One proposed methodology is described in subsection 1 below and would utilize regional adjustments limited by national parameters for items bid in more than 10 CBAs throughout the country. A second proposed methodology is described in subsection 2 below and would be used for lower volume items or other items that were bid in no more than 10 CBAs for various reasons. A third proposed methodology is described in subsection 5 and would be used for mail order items furnished in the Northern Mariana Islands. We are also proposing rules that would apply to all of these proposed methodologies.

1. Proposed Regional Adjustments Limited by National Parameters

CBPs are currently in place in 100 of the largest MSAs in the country for items and services that make up over 80 percent of the total allowed charges for items subject to the DMEPOS CBP. SPAs are currently used in 109 CBAs that include areas in every state throughout the country except for Alaska, Maine, Montana, North Dakota, South Dakota, Vermont, and Wyoming. The number of CBAs, as listed in Table 33 that are fully or partially located within a given state range from one to twelve. The Honolulu CBA was phased in under Round 2 of the program. Suppliers submitting bids for furnishing items and services in these areas have received extensive education that they should factor all costs of furnishing items and services in an area as well as overhead and profit into their bids.

For items and services that are subject to competitive bidding and have been included in more than 10 CBAs throughout the country, we propose to adjust the fee schedule payment amounts for these items and services using a methodology that is modeled closely after the regional fee schedule payment methodology in effect for P&O to allow for variations in payment based on bids for furnishing items and services in different parts of the country. Under the proposed methodology, adjusted fee schedule amounts for areas within the contiguous United States would be determined based on regional SPAs or RSPAs limited by a national floor and ceiling. The RSPA would be established using the average of the SPAs for an item from all CBAs that are fully or partially located in the region. The adjusted payment amount for the item would be equal to its RSPA but not less than 90 percent and not more than 110 percent of the national average, which is the average of the RSPAs weighted by the number of states in the region.

We believe modeling the proposed methodology on the regional fee schedule payment methodology for P&O is appropriate because the regional fee schedule payment methodology for P&O allows for variations in Medicare fee schedule amounts based on supplier charges for furnishing items and services in different regions of the country. The regional fee schedule payment methodology for P&O adjusts the Medicare allowed payments for entire regions of the country, including low population density or rural areas, based primarily on supplier information for furnishing items and services in urban areas. The regional fee schedule payment methodology for P&O has been fully phased in since 1994 in the contiguous United States and has not resulted in any barriers to access since then in any specific region of the country in which it has been applied. The DME and P&O fee schedule amounts are based in a part on statewide average reasonable charges calculated using supplier charges for furnishing items and services in localities throughout each state. Supplier charges for furnishing items in rural areas of the state are combined with charges for furnishing items in urban areas of the state, which represents the bulk of the charges since the vast majority of beneficiaries in each state reside in urban areas rather than rural areas. Although the fee schedule

payments are based heavily on charges for furnishing items and services in urban areas, this has not affected access to items and services in rural areas that are paid based on these fee schedule amounts.

We considered modeling the proposed methodology on the fee schedule payment methodology for DME which establishes an upper limit on all fee schedule amounts based on the median of the state fee schedule amounts; however, this methodology does not allow for regional variations in fee schedule amounts, allows for 0 percent variations in state fee schedule amounts above the national median amount, and only allows for up to 15 percent variation in state fee schedule amounts below the national median amount. The statewide average reasonable charges for DME are updated by an annual covered item update factor and are then limited by a national ceiling and floor based on the median of the statewide amounts and 85 percent of the median of the statewide amounts. The DME fee schedule methodology allows for no variation in payment whatsoever above the national median statewide amount. The maximum variation in fee schedule amounts that is allowed is 15 percent below the national median statewide amount. By contrast, the regional fee schedule methodology for P&O allows for regional variation in fee schedule payment amounts by as much as 10 percent below the national average amount and 20 percent above the national average amount. Similarly, the fee schedules for enteral nutrition are based on national average reasonable charges, and therefore, do not allow for any regional variation in fee schedule amounts. We believe that the model whereby regional fee schedule amounts for P&O are based on supplier charges for furnishing items and services within each region should be adopted when using SPAs to adjust fee schedule payment amounts in a way that reflects bidding in different regions of the country. The regional adjusted amounts are based on supplier bids for furnishing items and services within each region, as explained below.

a. Regional Payment Adjustments

Rather than adjusting state, regional, or national fee schedule amounts or infusion drug payment amounts based on all bids for an item in all CBAs across the country or based on all bids for an item in all CBAs within each state, we propose to adjust the payment amounts based on the average of bids for an item in CBAs that are fully or partially located in different regions of the country. In the first step of the proposed methodology we propose to calculate RSPAs or the average of the SPAs for an item and service in different regions of the country. In keeping with the example established by the P&O regional fee schedule payment methodology, this would allow variation in payment amounts for different regions of the country. For the purpose of establishing the boundaries for the regions, we propose using 8 regions developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce. These regions are proposed based on research and analysis conducted by the BEA indicating that the states in each region share economic ties. Further information can be obtained at *https://www.bea.gov/regional/definitions/nextpage.cfm?key=Regions*.

The information provided at this link states that:

> BEA Regions are a set of Geographic Areas that are aggregations of the states. The following eight regions are defined: Far West, Great Lakes, Mideast, New England, Plains, Rocky Mountain, Southeast, and Southwest. The regional classifications, which were developed in the mid-1950s, are based on the homogeneity of the states in terms of economic characteristics, such as the industrial composition of the labor force, and in terms of demographic, social, and cultural characteristics. For a brief description of the regional classification of states used by BEA, see U.S. Department of Commerce, Census Bureau, Geographic Areas Reference Manual, Washington, DC, U.S. Government Printing Office, November 1994, pp. 6–18;6–19.

Therefore, we propose to revise the definition of *region* in § 414.202 to mean a region developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce for the purpose of calculating regional single payment amounts (RSPAs); the definition of region for the purposes of the P&O regional fee schedule would also continue to apply for those items and services not adjusted based on prices in competitively bid areas. According to the BEA, the regional classifications are based on the homogeneity of the states in terms of economic characteristics, such as the industrial composition of the labor force, and in terms of demographic, social, and cultural characteristics. The contiguous areas of the United States that fall under the 8 BEA regions under our proposal are listed in Table 34 below. Further information can be obtained at *http://www.bea.gov/*.

TABLE 34—BUREAU OF ECONOMIC ANALYSIS REGIONS

Region	Name	States/Areas (count)
1	New England	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont (6).
2	Mideast	Delaware, District of Columbia, Maryland, New Jersey, New York, and Pennsylvania (6).
3	Great Lakes	Illinois, Indiana, Michigan, Ohio, and Wisconsin (5).
4	Plains	Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota (7).
5	Southeast	Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia (12).
6	Southwest	Arizona, New Mexico, Oklahoma, and Texas (4).
7	Rocky Mountain	Colorado, Idaho, Montana, Utah, and Wyoming (5).
8	Far West	California, Nevada, Oregon, and Washington (4).

We are soliciting public comments on whether different regional boundaries (e.g. CMS regions or Census Divisions) should be considered that would better reflect potential regional differences in the costs of furnishing items and services subject to the DMEPOS CBP. In addition to the CMS regions listed in section A.3 above, other established regional boundaries include those defined by the United States Census Bureau in the Department of Commerce for the purpose of reporting and analyzing census data. The Census Bureau uses 4 regions that are further divided into 9 divisions. The Census divisions are as follows:

- New England (Division 1); including the 6 states Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont.

• Middle Atlantic (Division 2); including the 3 states New Jersey, New York and Pennsylvania.

• East North Central (Division 3); including the 5 states Illinois, Indiana, Michigan, Ohio and Wisconsin.

• West North Central (Division 4); including the 7 states Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota and South Dakota.

• South Atlantic (Division 5); including the 9 states Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia and West Virginia.

• East South Central (Division 6); including the 4 states Alabama, Kentucky, Mississippi and Tennessee.

• West South Central (Division 7); including the 4 states Arkansas, Louisiana, Oklahoma, and Texas.

• Mountain (Division 8); including the 8 states Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah and Wyoming.

• Pacific (Division 9); including the 5 states Alaska, California, Hawaii, Oregon and Washington.

Table 35 below lists the states and number of CBAs located in each of the CMS regions, BEA regions, and census divisions.

TABLE 35—STATES AND NUMBER OF CURRENT CBAS PER CMS REGION, BEA REGION, AND CENSUS DIVISION

10 CMS Regions			9 Census Divisions			8 BEA Regions		
Region	States	CBAs	Division	States	CBAs	Region	States	CBAs
Boston	CT, ME, MA, NH, RI, VT.	7	New England	CT, ME, MA, NH, RI, VT.	7	New England	CT, ME, MA, NH, RI, VT.	7
New York	NJ, NY	13	Middle Atlantic	NJ, NY, PA	15	Mideast	DE, DC, MD, NJ, NY, PA.	17
Phila	DE, DC, MD, PA, VA, WV.	9						
Atlanta	AL, FL, GA, KY, MS, NC, SC, TN.	28	South Atlantic	DE, DC, FL, GA, MD, NC, SC, VA, WV.	30	Southeast	AL, AR, FL, GA, KY, LA, MS, NC, SC, TN, VA, WV.	34
			East South Central.	AL, KY, MS, TN	7			
Chicago	IL, IN, MI, MN, OH, WI.	19	East North Central.	IN, IL, MI, OH, WI.	19	Great Lakes	IL, IN, MI, OH, WI.	19
Dallas	AR, LA, NM, OK, TX.	14	West South Central.	AR, LA, OK, TX	13	Southwest	AZ, NM, OK, TX	11
Kansas City	IA, KS, MO, NE	4	West North Central.	IA, KS, MN, MO, NE, ND, SD.	5	Plains	IA, KS, MN, MO, NE, ND, SD.	5
Denver	CO, MT, ND, SD, UT, WY.	3	Mountain	AZ, CO, ID, NM, MT, UT, NV, WY.	8	Rocky Mountain	CO, ID, MT, UT, WY.	4
San Fran	AZ, CA, NV	16	Pacific	CA, OR, WA	15	Far West	CA, NV, OR, WA	16
Seattle	ID, OR, WA	3						

The regional fee schedule amounts for P&O are based on the average of the statewide fees for P&O, weighted by total Part B claims for paid claims with dates of service from July 1, 1991, thru June 30, 1992, which results in fees for states with a greater volume of Part B claims having more influence on the regional fee schedule amounts than states with a smaller volume of Part B claims. We believe this aspect of the regional fee schedule payment methodology for P&O tends to favor more heavily populated states. The statewide fees for larger, more urban states where the most Medicare claims are processed, for example, Massachusetts for Region 1, play a larger role in determining the regional price than the statewide fees for smaller, more rural states in the region, for example, Vermont. Table 36 below shows the relative weighs applied to the statewide fees used in calculating the regional P&O fees for the CMS Boston Region or Region 1.

TABLE 36—P&O REGIONAL FEE WEIGHTS—CMS REGION 1 (BOSTON) (WEIGHTED BY TOTAL PAID CLAIMS FOR DATES OF SERVICE FROM JULY 1, 1991, THRU JUNE 30, 1992)

State	Total part B claims	Percent of total for Region
MA	11,710,121	48%
CT	6,288,638	26%
RI	2,251,892	9%
ME	2,012,385	8%
NH	1,571,936	6%
VT	759,242	3%
Region	24,594,214	

As can be seen in this table, the regional P&O fees for the Boston Region are weighted heavily in favor of the statewide fees and average reasonable charges from 1986/87 for the more heavily populated urban states of Massachusetts and Connecticut with a greater utilization of Part B items and services, whereas the fees for more rural States like Vermont and Maine have a very minor impact in determining the regional fees. In contrast, we are proposing that the RSPAs be calculated based on a simple average of the SPAs for CBAs in each region, without weighting in favor of larger, more heavily populated CBAs. Using the New England BEA Region that is comprised of the same 6 states that make up the CMS Boston Region as an example, the proposed RSPA for this region would be based on the average of the SPAs for the following 7 CBAs, with estimated 2012 population in parentheses:

• Boston-Cambridge-Quincy, MA–NH (4,640,802)

• Providence-New Bedford-Fall River, RI–MA (1,601,374)

• Hartford-West Hartford-East Hartford, CT (1,214,400)

• Bridgeport-Stamford-Norwalk, CT (933,835)

• Worcester, MA (923,762)

• New Haven-Milford, CT (862,813)

• Springfield, MA (625,718)

Therefore, rather than weighting the average of the SPAs in favor of more

heavily populated CBAs, we propose that the RSPA be based on the simple average of the SPAs for the CBAs in the region, with the SPA for the much smaller Springfield, MA CBA and the SPA for the much larger Boston-Cambridge-Quincy, MA–NH Springfield, MA CBA contributing equally toward calculation of the RSPA. We believe this approach would result in adjustments that factor in the regional costs associated with furnishing items and services in the New England region of the country, while not giving undue weight to the costs of furnishing items and services in larger markets.

b. National Parameters

As explained above, the regional fee schedule amounts for P&O are limited by a national ceiling equal to 120 percent of the average of the regional fee schedule amounts for all the states and a national floor equal to 90 percent of the average of the regional fee schedule amounts for all the states. This limits the range in the regional fee schedule amounts from highest to lowest to no more than 30 percent, 20 percent above the national average and 10 percent below the national average. By contrast, the fee schedule payment methodology for DME only allows for a variation in statewide fees of 15 percent below the median of statewide fees for all the states. The national limits to the fee schedule amounts for P&O and DME have not resulted in a barrier to access to items and services in any part of the country. We believe this reflects the fact that the costs of furnishing DMEPOS items and services do not vary significantly from one part of the country to another and that national limits on regional prices is warranted. We therefore propose to limit the variation in the RSPAs using a national ceiling and floor in order to prevent unnecessarily high or low regional amounts that vary significantly from the national average prices for the items and services. The national ceiling and floor limits would be based on 110 percent and 90 percent, respectively, of the average of the RSPAs applicable to each of the 48 contiguous states and the District of Columbia (that is, the average of RSPAs is weighted by the number of contiguous states including the District of Columbia per region). We propose that any RSPA above the national ceiling would be brought down to the ceiling and any RSPA below the national floor would be brought up to the floor. We propose that the national ceiling would exceed the average of the RSPAs by the same percentage that the national floor would be under the average of the RSPAs. This allows for a maximum variation of 20 percent from the lowest RSPA to the highest RSPA. We believe that a variation in payment amounts both above and below the national average price should be allowed, and we believe that allowing for the same degree of variation (10 percent) above and below the national average price is more equitable and less arbitrary than allowing a higher degree of variation (20 percent) above the national average price than below (10 percent), as in the case of the national ceiling and floor for the P&O fee schedule, or allowing for only 15 percent variation below the national average price, as in the case of the national ceiling and floor for the DME fee schedule.

c. Rural and Frontier State Adjustments

Under the DMEPOS CBP, the statute prohibits competitions before 2015 in new CBAs that are rural areas or MSAs with a population of less than 250,000. Even if competitions were to begin in these areas in 2015, it is very unlikely that the SPAs from these areas would be computed and finalized by January 1, 2016. Therefore, we propose that the proposed RSPAs initially be based solely on information from existing programs implemented in 100 MSAs, which are generally comprised of more densely populated, urban areas than areas outside MSAs. We therefore believe that the initial RSPAs would not directly account for unique costs that may be associated with furnishing DMEPOS in states that have few MSAs and are predominantly rural or cover large geographic areas and are sparsely populated. However, in keeping with the discussion above, we do not believe that the cost of furnishing DMEPOS in these areas should deviate significantly from the national average price established based on supplier bids for furnishing items and services in different areas throughout the country.

As explained above, the DMEPOS fee schedule amounts are based primarily on supplier charges for furnishing items and services in urban areas and this has not resulted in problems associated with access to these items and services in rural areas or large, sparsely populated areas. Nonetheless, for the purpose of ensuring access to necessary items and services in states that are more rural or sparsely populated than others, we propose that the adjusted fee schedule amounts for states that are more rural than urban and defined as ''rural states'' or states where a majority of the counties are sparsely populated and defined as ''frontier states'' would be no lower than the national ceiling amount discussed in section b above.

We propose in § 414.202 that a *rural state* be defined as a state where more than 50 percent of the population lives in rural areas within the state as determined through census data, since a majority of the general population of the state lives in rural areas, it is likely that a majority of DMEPOS items and services are furnished in rural settings in the state. This is in contrast to other states where the majority of the general population of the state lives in urban areas, making it more likely that a majority of DMEPOS items and services are furnished in urban settings or in MSAs. We believe that for states where a majority of the general population lives in rural areas, adjustments to the fee schedule amounts should be based on the national ceiling amount if the RSPA is lower than the national ceiling amount. This higher level of payment would provide more assurance that access to items and services in states within a region that are more rural than urban is preserved in the event that costs of furnishing DMEPOS items and services in rural areas is higher than the costs of furnishing DMEPOS items and services in urban areas.

We propose in § 414.202 that a *frontier state,* would be defined as a state where at least 50 percent of counties in the state have a population density of 6 people or less per square mile. In such states, the majority of counties where DMEPOS items and services may be needed are very sparsely populated and suppliers may therefore have to drive considerably longer distances in furnishing these items and services as opposed to other states where the beneficiaries live closer to one another. The designation of states as frontier states or frontier areas is currently used under Medicare Part A to make adjustments to the wage index for hospitals in these remote areas in order to ensure access to services in these areas. The definition of frontier state that is proposed above for the purpose of implementing section 1834(a)(1)(F) and (G) of the Act is consistent with the current definition in section 1886(d)(3)(E)(iii)(II) and (III) of the Act and 42 CFR 412.64(m) of the regulations related to implementation of the hospital wage index adjustments and prospective payment system for hospitals under Part A. We believe that states designated as frontier states have a significant amount of area that is sparsely populated and are more likely to be geographically removed from (that is, a considerable driving distance from) areas where population is more concentrated. However, we solicit

comments on alternative definitions of frontier states.

Based on the 2010 Census data, states designated as rural would include Vermont, Maine, West Virginia, and Mississippi. Other than one CBA that is fully located in Mississippi, one CBA that is partially located in Mississippi, and two CBAs that are partially located in West Virginia, the RSPAs would not include SPAs that reflect the costs of furnishing items and services in these states based on where the CBAs are currently located. Current frontier states include North Dakota, South Dakota, Montana, and Wyoming, and the RSPAs would not include SPAs that reflect the costs of furnishing items and services in any of these states based on where the CBAs are currently located. We propose that the designation of rural and frontier states could change as the U.S. Census information changes. We propose that when a state that is not designated as a rural state or frontier becomes a rural state or frontier state based on new, updated information from the U.S. Census Bureau, that adjustments to the fee schedule amounts in accordance with the proposed provision of this section would take effect as soon as such changes can be implemented. Likewise, we propose that at any time a state that is designated as a rural state or frontier no longer meets the proposed definition in this section for rural state or frontier state based on new, updated information from the U.S. Census Bureau, that adjustments to the fee schedule amounts in accordance with the proposed provision of this section would take effect as soon as such changes can be implemented. We propose that the changes to the state designation would occur based on the decennial Census. The decennial Census uses total population of the state to determine whether the state is predominately rural or frontier. The U.S. Census Bureau also uses current population estimates every 1, 3, and 5 years through the American Community Survey but only samples a small percentage of the population every year, not the total population. Therefore, we propose that the designation of a rural or frontier state occur approximately every 10 years when the total population data is available. For the current proposed fee schedule adjustments, we propose to use the 2010 Census Data. The next update would reflect the 2020 Census Data and any changes in the designation of a rural or frontier state and corresponding fee schedule changes would be implemented after the 2020 Census Data becomes available. For this and subsequent updates, we propose to include a listing of the qualifying rural and frontier States in program guidance that is issued quarterly and to provide at least 6 months advance notice of any adjustments.

Some of the comments received on the ANPRM indicated that the costs of furnishing DMEPOS items and services in rural areas is significantly higher than the costs of furnishing DMEPOS items and services in urban areas. Other commenters suggested that the adjustments to the payment amounts based on information from CBPs be phased in to give suppliers time to adjust to the new payment levels. Although we believe that the costs of furnishing items and services in rural areas are different than the costs of furnishing items and services in urban areas, there is no evidence to support a statement that the difference in costs is significant. However, in order to proceed cautiously on this matter in the interest of ensuring access to covered DMEPOS items and services, we are proposing to phase in the price adjustments, as explained below, so that we can monitor the impact of the adjustments as they are gradually phased in.

In summary, we propose that adjustments to payment amounts for areas within different regions of the contiguous United States would be based on the un-weighted average of SPAs from CBAs that are fully or partially located within these regions. The regional amounts would be limited by a national ceiling and floor and the adjusted payment amounts for all states designated as rural or frontier states would be equal to the national ceiling. In addition, we are soliciting public comments on whether payment in rural areas of states that are not designated as rural or frontier states should be set differently.

d. Areas Outside the Contiguous United States

Given the unique costs of furnishing DMEPOS items and services in remote, isolated areas outside the contiguous United States such as Alaska, Guam, Hawaii, Puerto Rico, the United States Virgin Islands and other areas, we propose that any SPAs from programs in these areas be excluded from the calculation of the RSPAs in section a. In addition, we propose that the adjustments to the fee schedule amounts for areas outside the contiguous United States would not be based on the RSPAs. Rather, we propose that the adjustments to the fee schedule amounts for these areas be based on the higher of the average of SPAs for CBAs in areas outside the contiguous United States (for example, Honolulu) or the national ceiling limit applied to the payment adjustments for areas within the contiguous United States. We believe that, to the extent that SPAs from non-contiguous areas are available, these amounts should be used in making adjustments to the payment amounts for other areas outside the contiguous United States since the challenges and costs of furnishing DMEPOS items and services in all remote, isolated areas is similar. We also believe that the payment adjustments for these areas, like those for the proposed rural and frontier states, should not be lower than the national ceiling established for items and services furnished in the contiguous United States. Areas outside the contiguous United States generally have higher shipping fees and other costs. We believe the SPAs in Honolulu and other areas outside the contiguous United States reflect these costs and could be used to adjust the fee schedule amounts for these areas without limiting access to DMEPOS items and services. However, in the event that the national ceiling limit described in section b above is greater than the average of the SPAs for CBPs in areas outside the contiguous United States, we propose that the higher national ceiling amount be used in adjusting the fee schedule amounts for areas outside the contiguous United States in order to better ensure access to DMEPOS items and services.

We are soliciting comments on these proposals.

2. Methodology for Items and Services Included in Limited Number of Competitive Bidding Programs

In some cases, there may not be a sufficient number of CBAs and SPAs available for use in computing RSPAs, and therefore, a different methodology for implementing section 1834(a)(1)(F)(ii) of the Act would be necessary. For items and services that are subject to competitive bidding and have been included in CBP in no more than 10 CBAs, we propose that payment amounts for these items in all non-competitive bidding areas be adjusted based on 110 percent of the average of the SPAs for the areas where CBPs are implemented. Using a straight average of the SPAs rather than a weighted average of the SPAs gives SPAs for the various CBAs equal weight regardless of the size of the CBA. We believe this avoids giving undo weight to SPAs for more heavily populated areas. We are proposing the additional 10 percent adjustment to the average of the SPAs to account for unique costs such as

delivering items in remote, isolated locations, but would make this a uniform adjustment for program simplification purposes. This issue is discussed in more detail below.

Under the DMEPOS CBP, there may be items and services for which implementation of CBPs could generate significant savings for the beneficiary and/or program, but which are furnished infrequently in most MSAs. In some cases, such items and services could be combined with other items and services under larger PCs or included in mail order competitions, to the extent that these are feasible options. For example, combining infrequently used traction equipment and frequently used hospital beds in the same product for bidding purposes would ensure that any beneficiary that needs traction equipment in the CBA would have access to the item from the suppliers also contracted to furnish hospital beds in the area. This would make it feasible to include traction equipment in numerous MSAs throughout the country and would allow use of the RSPA methodology described above. However, if a PC was established just for traction equipment for bidding purposes, the volume of items furnished in certain MSAs may not be sufficient to generate viable competitions under the program because there may be a limited number of suppliers interested in competing to furnish the items in local areas. Nonetheless, if significant savings for the beneficiary and/or program are possible for the equipment, we are mandated to phase the items in under the DMEPOS CBP.

In addition, for lower volume items within large PCs, such as wheelchair accessories, we propose to include these items in a limited number of local competitions rather than in all CBAs to reduce the burden for suppliers submitting bids under the programs as a whole. In these cases, for the purposes of implementing section 1834(a)(1)(G) of the Act, we propose that payment amounts for these items in all areas where CBPs are not implemented be adjusted based on 110 percent of the average of the SPAs for the areas where CBPs are implemented. We are proposing the additional 10 percent adjustment to the national average price to account for unique costs in certain areas of the country such as delivering items in remote, isolated locations. For example, the PC for standard mobility in the 9Round 1 CBAs includes 25 HCPCS codes for low volume wheelchair accessories that are not included in the PC for standard wheelchairs, scooters, and related accessories in the 100 Round 2 CBAs. We propose that payment amounts for these items in areas where CBPs are not implemented be adjusted based on 110 percent of the average of the SPAs for the 9Round 1 areas where CBPs are implemented. Alternatively, we could include these low volume items in all PCs in all 109 CBAs and suppliers would need to develop bid amounts and enter bids for these 25 codes for low volume items such as toe loop holders, shock absorbers and IV hangers. Including these 25 Healthcare Common Procedure Coding System (HCPCS) codes for low volume wheelchair accessories in the PCs under the 9 Round 1CBAs means that suppliers submitting bids for wheelchairs have 25 bid amounts to develop and enter per CBA for these items, or a total of 225 bid amounts to develop and enter for these low volume items if bidding for wheelchairs in all 9 Round 1 CBAs. In contrast, including these codes in the PCs under all 109CBAs means that suppliers submitting bids for wheelchairs have 2,725 bid amounts to develop and enter for these low volume items, if bidding for wheelchairs in all 109 CBAs. We believe that adjusting fee schedule amounts based on SPAs from 10 or fewer CBAs achieve the savings mandated by the statute for these items while greatly reducing the burden on suppliers and the program in holding competitions for these items in all 109 CBAs across the country.

Finally, if contracts and SPAs for low volume items included in a limited number of CBAs expire and the items are not included in future CBPs, we propose to use the information from the past competitions to adjust the payment amounts for these items nationally based on 110 percent of the average of the SPAs for the areas where CBPs were implemented. Even though the SPAs may no longer be in effect, we believe it is reasonable to use the information to reduce excessive payment amounts for items and services as long as the SPAs did not result in a negative impact on access to quality items and services while they were in effect and as long as the amounts are adjusted to account for increases in costs over time. For example, 4 codes for adjustable wheelchair seat cushions were included in the Round 1 Rebid, with SPAs that were approximately 25 percent below the fee schedule amounts being in effect in 9 CBAs from January 2011 thru December 2013. These items were not bid in future rounds due to the low volume of use relative to other wheelchair seat cushions. During the course of the 3-year contract period when the SPAs were in effect in the 9 areas, there were no reports of access problems and there were no negative health outcomes as a result of including these items under CBPs. For the future, savings for these items could be achieved by including them in future competitions or by using the previous SPAs, updated by an economic update factor to account for increases in costs. If the decision is made not to include these items in future competitions, we believe savings can and should still be obtained based on information from the previous competitions.

We are soliciting comments on these proposals.

3. Adjusted Payment Amounts for Accessories Used With Different Types of Base Equipment

There may be situations where the same accessory or supply identified by a HCPCS code is used with different types of base equipment, and the item (HCPCS code) is included in one or more PCs under competitive bidding for use with some, but not all of the different types of base equipment it is used with. For these situations, we propose to use the weighted average of the SPAs from CBPs and PCs where the item is included for use in adjusting the payment amounts for the item (HCPCS code). We believe that it would be unnecessarily burdensome to have different fee schedule amounts for the same item (HCPCS code) when it is used with similar, but different types of base equipment. We believe that the costs of furnishing the accessory or supply should not vary significantly based on the type of base equipment it is used with.

Therefore, we seek public comments on addressing situations where an accessory or supply identified by a HCPCS code is included in one or more PCs under competitive bidding for use with more than one type of base equipment. In these situations, we propose to calculate the SPA for each CBA by weighting the SPAs from each PC in that CBA by national allowed services. This would result in the calculation of a single SPA for the item for each CBA. The single SPA per code per CBA would then be used in applying the payment adjustment methodologies proposed above. For example, HCPCS code Exxx1 describes a tray used on a wheelchair. Exxx1 was included in a PC for manual wheelchairs in all CBAs and in a separate, second PC for power wheelchairs in all CBAs. SPAs for Exxx1 under the manual wheelchair PC are different than the SPAs for Exxx1 under the power wheelchair PC.

Under the proposal, national allowed services would be used to compute a weighted average of the SPAs for Exxx1 in each of the CBAs. So, rather than having 2 different SPAs for the same code in the same CBA, we would have 1 SPA for the code for the CBA. If the item is included in only one PC, we propose to use the SPAs for the item from that PC in applying the payment adjustment methodologies proposed above.

We are soliciting comments on these proposals.

4. Adjustments to Single Payment Amounts That Result From Unbalanced Bidding

Within the HCPCS there are instances where there are multiple codes for an item that are distinguished by the addition of a hierarchal feature(s). For example, one code may describe an enteral nutrition infusion pump with an alarm and another code may describe a less sophisticated pump without an alarm. Under competitive bidding, the code with the higher utilization would receive a higher weight and the bid for this item would have a greater impact on the composite bid and competitiveness of the supplier's overall bid for the PC within the CBP than the bid for the less frequently used alternative. This can result in unbalanced bidding where the bids and SPAs for the item without the additional features is higher than the bids and SPAs for the item with the additional features due to the fact that the item with the features is utilized more than the item without the features and therefore receives a higher weight. We believe that it is not inherently reasonable for payment amounts for equipment with fewer features or functionality to be higher than payment amounts for equipment with additional features or functionality.

For example, HCPCS code B9000 describes an enteral nutrition infusion pump without alarm, whereas code B9002 describes an enteral nutrition infusion pump with alarm. Both codes have identical fee schedule amounts. Based on paid claims data, only 176 Medicare beneficiaries received the pump without the alarm in 2012, whereas 52,531 Medicare beneficiaries received the pump with the alarm in 2012. Both pumps are included in the PC for enteral nutrients, supplies, and equipment. As a result of the significantly higher utilization of code B9002, this code received a much higher item weight under the CBP than code B9000, and, as a result, a supplier could submit a much higher bid for B9000 than for B9002 with virtually no impact on their composite bid. Under Round 2, unbalanced bidding resulted in SPAs for code B9000 without the alarm being 6 percent higher on average than the SPAs for code B9002 with alarm. Unbalanced bidding also occurred under Round 2 in the case of standard power wheelchairs, with SPAs for infrequently used Group 1, standard weight power wheelchairs (codes K0815 and K0816) being 16 percent higher on average than the SPAs for the much more frequently used Group 2 versions (codes K0822 and K0823). Based on paid claims data, only 474 Medicare beneficiaries received Group 1 power wheelchairs described by codes K0815 and K0816 in 2012, whereas 196,968 Medicare beneficiaries received higher performing Group 2 power wheelchairs described by codes K0822 and K0823 in 2012. The long term solution for avoiding cases of unbalanced bidding is to eliminate duplicate codes in the HCPCS. For the purpose of implementing section 1834(a)(1)(G) of the Act, and in making adjustments to payment amounts under sections 1834(a)(1)(F)(ii), 1834(h)(1)(H)(ii), and 1842(s)(3)(B) of the Act, we propose that the payment amounts for infrequently used codes that describe items and services with fewer features than codes with more features be adjusted so that they are no higher than the payment amounts for the more frequently used codes with more features. For example, the adjusted fee schedule amounts for code B9000 would be set so that they are no higher than the adjusted fee schedule amounts for code B9002. We believe that without this provision, unbalanced bidding could result in fee schedule amounts for items that essentially represent lower levels of service being higher than fee schedule amounts for items representing higher levels of service, based on bids being higher for infrequently used items with lower weights and less features than bids for frequently used items with higher weights and more features. This could result in beneficiaries receiving the item with fewer features and functionality simply because the supplier has a financial incentive to furnish that item. This is especially important in light of the fact that use of the inherent reasonableness authority provided by section 1842(b)(8) and (9) of the Act cannot be used to further adjust payment amounts that are adjusted based on the mandate of section 1834(a)(1)(F)(ii) and the authority provided by sections 1834(h)(1)(H)(ii) and 1842(s)(3)(B) of the Act.

We seek public comments on this issue and our proposed provision to address this issue.

5. National Mail Order Program—Northern Mariana Islands

While Section 1847(a)(1)(A) of the Act provides that CPBs be established throughout the United States, the definition of United States at section 210(i) of the Act does not include the Northern Mariana Islands. We therefore previously determined that the Northern Mariana Islands are not considered an area eligible for inclusion under a national mail order CBP. For the purpose of implementing the requirements of section 1834(a)(1)(F)(ii) of the Act, we are proposing that the payment amounts established under a national mail order CBP would be used to adjust the fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands. We propose that the adjusted fee schedule amounts would be equal to 100 percent of the amounts established under the national mail order CBP.

We are soliciting comments on these proposals.

6. Updating Adjusted Payment Amounts

In accordance with section 1834(a)(1)(F)(iii) of the Act, the adjusted payment amounts for DME must be updated as additional items are phased in or information is updated. We propose to add regulation text indicating that we would revise the adjusted payment amounts for DME, enteral nutrients, supplies, and equipment, and OTS orthotics each time a SPA is updated following one or more new competitions, which may occur at the end of a contract period, as additional items are phased in, or as new programs in new areas are phased in. This is required by section 1834(a)(1)(F)(iii) for DME. Since we believe it is reasonable to assume that updated information from CBPs would better reflect current costs for furnishing items and services, we are proposing regulations to require similar updates for enteral nutrients, supplies, and equipment, and OTS orthotics.

As we indicated above, if the only SPAs available for an item are those that were established under CBP that are no longer in effect, we propose to use these SPAs to adjust payment amounts using the methodologies described above and we propose to do so following application of inflation adjustment factors. We propose that the inflation adjustment factor would be based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last

year the SPAs were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect. The adjusted payment amounts would continue to be updated every 12 months using the percentage change in the CPI–U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect. Use of the CPI–U as the update factor is consistent with how pricing amounts for DMEPOS have been updated since October 1, 1985, when the CPI–U was used in calculating the IIC for use in calculating reasonable charges. The CPI–U was used in updating reasonable charge data for use in calculating the initial fee schedule amounts and is used in determining the covered item update factors at sections 1834(a)(14), 1834(h)(4)(A), 1834(i)(1)(B), 1842(s)(1)(B) of the Act. If CBPs are subsequently established for the item, we propose that the SPAs established under these programs would be used in applying the payment adjustment methodologies described above.

If finalized, the payment amounts that would be adjusted in accordance with sections 1834(a)(1)(F)(ii) and (iii) of the Act for DME, section 1834(h)(2)(H)(ii) of the Act for orthotics, and section 1842(s)(2)(B) of the Act for enteral nutrients, supplies, and equipment shall be used to limit bids submitted under future competitions of the DMEPOS CBP in accordance with regulations at § 414.414(f). Section 1847(b)(2)(A)(iii) prohibits the awarding of contracts under a CBP unless we are sure that total payments made to contract suppliers in the CBA are less than the payment amounts that would otherwise be made. In order to assure savings under a CBP, the fee schedule amount that would otherwise be paid is used to limit the amount a supplier may submit as their bid for furnishing the item in the CBA. If finalized, the payment amounts that would be adjusted in accordance with sections 1834(a)(1)(F)(ii) and (iii) of the Act for DME, section 1834(h)(2)(H)(ii) of the Act for orthotics, and section 1842(s)(2)(B) of the Act for enteral nutrients, supplies, and equipment would be the payment amounts that would otherwise be made if payments for the items and services were not made through implementation of a CBP. Therefore, the adjusted fee schedule amounts would become the new bid limits.

We are soliciting comments on these proposals.

7. Summary of Proposed Methodologies

To summarize, under the proposed methodology in subsection 1 above which applies to items and services included in more than 10 CBAs, adjusted fee schedule amounts would be determined based on RSPAs limited by a national floor and ceiling. The RSPA would be established using the average of the SPAs for an item from all CBAs that are fully or partially located in the region. The payment amount for the item, with limited exceptions for areas outside the contiguous United States, would be equal to its RSPA but not less than 90 percent and not more than 110 percent of the national average, which is the average of the RSPAs weighted by the number of states in the region. The proposed methodology is modeled closely after the regional fee schedule payment methodology in effect today for P&O. For the purpose of establishing the regional boundaries, we propose to use 8 regions developed by the Bureau of Economic Analysis (BEA) within the Department of Commerce: New England, Mideast, Great Lakes, Plains, Southeast, Southwest, Rocky Mountain, and Far West. For rural and frontier states, we propose that the payment amount would be 110 percent of the national average. For areas outside the contiguous United States, the payment amount would be the greater of the average of the SPAs in the non-contiguous areas or 110 percent of the national average. As described in subsection 2 above, we propose a different methodology for low volume items with a limited number of SPAs. In addition, we propose to apply update factors to SPAs no longer in effect to adjust fee schedule amounts if no other data is available. Finally, we propose that adjustments would be made to account for SPAs for lower levels of service that are higher than SPAs for higher levels of service.

A summary of the proposed methodologies is provided in Table 37 below.

TABLE 37—SUMMARY OF PROPOSED METHODOLOGIES FOR ADJUSTING PAYMENT IN NON-BID AREAS

Proposed methodology	Calculations
1) Adjustments for Items Included in More than 10 CBAs*	
Regional Adjustments Limited by National Parameters for Items Furnished Within the Contiguous United States.	Adjusted payment equal to the RSPA (calculated using the un-weighted average of SPAs from CBAs that are fully or partially located with a BEA region) limited by a national floor and ceiling. The national ceiling and floor would be set at 110 percent and 90 percent, respectively, of the national weighted RSPA average (average of the RSPAs applicable to each of the 48 contiguous states and DC).
Adjustments for Rural and Frontier States ..	Adjusted payment for designated States based on 110 percent of the national weighted RSPA average.
Adjustments for Items Furnished Outside the Contiguous United States.	Adjusted payment for non-contiguous areas (e.g., Alaska, Guam, Hawaii) based on the higher of the average of SPAs for CBAs in areas outside the contiguous U.S. or 110 percent of the national weighted RSPA average applied to adjustments within the contiguous U.S.
2) Adjustments for Lower Volume or Other Items Included in 10 or Fewer CBAs*.	Adjusted payment based on 110 percent of the un-weighted average of the SPAs for the areas where CBPs are implemented for contiguous and non-contiguous areas of the United States.
3) Adjustments for Items Where the Only Available SPA is from a CBP No Longer in Effect.	Payment based on adjusted payment determined under 1) or 2) above and adjusted on an annual basis based on the CPI–U update factors from the mid-point of the last year the SPAs were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect.
4) Adjustments for Accessories Used with Different Types of Base Equipment	
Adjustments for Accessories Included in One CBP Product Category.	SPAs for the item from that one Product Category would be used in determining the adjusted payment amounts under methodologies 1) or 2).
Adjustments for Accessories Included in One or More CBP Product Category.	A weighted average of the SPAs for the item in each CBA where the item is included in more than one Product Category would be used to determine the adjusted payment amounts under methodologies 1) or 2).

TABLE 37—SUMMARY OF PROPOSED METHODOLOGIES FOR ADJUSTING PAYMENT IN NON-BID AREAS—Continued

Proposed methodology	Calculations
5) Payment Adjustments to Northern Mariana Islands Using the National Mail Order SPAs.	Fee schedule amounts adjusted to equal the SPAs under the national mail order CBP.

* Note: We are also proposing to adjust the SPAs for a lower level of service item to not exceed the SPAs of a higher level of service item prior to applying the methodologies in 1) and 2) above in instances where the SPA for the lower level of service item exceeds the higher level of service item.

VI. Proposed Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished Under the Competitive Bidding Program

A. Background

The payment rules for DME have changed significantly over the years since 1965, resulting in the replacement of the original monthly rental payment methodology with lump sum purchase and capped rental payment rules, as well as separate payment for repairs, maintenance and servicing, and replacement of expensive accessories for beneficiary-owned equipment. In our experience, these payment rules have been burdensome to administer and have added program costs associated with expensive wheelchair repairs and payment for loaner equipment, and have significantly increased costs associated with frequent replacement of expensive accessories at regular intervals for items such as CPAP devices. We estimate that separate payments for CPAP accessories have increased annual expenditures by approximately $200 million. In some cases, the costs associated with maintaining DME owned by beneficiaries equals or exceeds any savings that might be generated from capping rental payments. In the case of repairs, suppliers are not mandated to service the equipment they furnish once title transfers to the beneficiary—any supplier can provide these services. This could create a hardship for the beneficiary since they must find a supplier willing to repair the equipment and their separate coinsurance payments could be substantial if the repair services are extensive. According to § 414.408(h)(3) of our regulations, payment on a capped rental basis also results in the restart of periods of continuous use for capped rental items, and according to § 414.408(i)(2) of our regulations, an extension in the rental cap periods for oxygen equipment when a beneficiary transitions from a non-contract supplier to a contract supplier at the start of a new CBP. These issues were discussed in the February 26, 2014, ANPRM noted above (79 FR 10758). It is not clear, however, the extent to which the capped rental requirement, combined with separate payments for supplies, accessories, repairs, and program administration, overall results in net savings or net costs to the Medicare program, particularly if we examine the effects of the policy on specific DME items and services.

Under the Social Security Amendments of 1965 (Pub. L. 89–97) enacted on July 30, 1965, Medicare Part B covered only rental of DME items. The Social Security Amendments of 1967 (Pub. L. 90–248), approved January 2, 1968, revised the statute to provide authority for making payment for DME on a purchase basis as well as on a rental basis. On May 12, 1972, the Government Accountability Office (GAO) issued a report to the Congress entitled ''Need for Legislation to Authorize More Economical Ways of Providing Durable Medical Equipment under Medicare'' (B–164031(4), May 12, 1972) that led to Social Security Amendment (section 245) in 1972. Section 245 of the Social Security Amendments of 1972 (Pub. L. 92–603) enacted on October 30, 1972, modified the payment provisions for specific equipment items to LCL of reasonable charges to contain the costs of DME. This law allowed the Department of Health and Human Services (HHS) to experiment with reimbursement approaches and implement any purchase approach found to be feasible and economical in order to avoid prolonged rental payments for expensive DME. Furthermore, section 16 of the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95–142), enacted on October 25, 1977, amended section 1833(f) of the Act to read as follows:

> In the case of durable medical equipment to be furnished an individual as described in section 1861(s)(6), the Secretary shall determine, on the basis of such medical and other evidence as he finds appropriate (including certification by the attending physician with respect to expected duration of need), whether the expected duration of the medical need for the equipment warrants a presumption that purchase of the equipment would be less costly or more practical than rental. If the Secretary determines that such a presumption does exist, he shall require that the equipment be purchased, on a lease-purchase basis or otherwise, and shall make payment in accordance with the lease-purchase agreement (or in a lump sum amount if the equipment is purchased other than on a lease-purchase basis); except that the Secretary may authorize the rental of the equipment notwithstanding such determination if he determines that the purchase of the equipment would be inconsistent with the purposes of this title or would create an undue financial hardship on the individual who will use it.

This law required HHS to make lease-purchase decisions on a case-by-case basis based on whether purchase would be less costly or more practical than rental and reimburse on the basis of a lump-sum purchase or a lease/purchase arrangement. To implement the change in the law, HHS issued final regulations (45 FR 44287) on July 1, 1980. This regulation provided that the purpose of the lease purchase payment arrangement for new and used DME was to reduce program costs caused by long and costly rentals of the equipment and reduce beneficiary expenses for annual deductibles and coinsurance for unnecessarily long rentals. However, the regulations were not implemented until 1985 because of uncertainty as to whether they would result in program savings. During the same time period, amidst growing concerns by the agency about prolonged and excessive rentals, Williams College under a grant administered by HCFA (now CMS) issued a report entitled ''Determinants of Current and Future Expenditures on Durable Medical Equipment by Medicare and its Program Beneficiaries'' on April 1983. This report estimated the excess rentals at about 14 percent of rental payments. Following this report, a GAO report titled ''Procedures for avoiding excess rental payments for durable medical equipment should be modified'' issued on July 30, 1985, showed that excess rentals represented about 54 percent of the amounts allowed for lower cost items ($120 or less) and 34 percent for higher cost items. In the GAO report, excess rental payments represented the difference between total Medicare rental payments for an item of equipment and Medicare reimbursement for the item if it had been purchased. GAO data showed substantially fewer short-term rentals

than Williams' data (22 percent versus 64 percent for episodes lasting 1 or 2 months) and substantially more long-term rentals (33 percent. versus 8 percent for episodes lasting more than 12 months).

GAO concluded that savings would result for reimbursing low-cost items on a purchase basis because about two-thirds of the rented items in its study costing $100 or less would have been cheaper to buy. GAO also found that sufficient data was not available to reliably predict when purchasing a high cost item would be less costly than renting it. The report indicated that purchase price was reached by about month 7, with additional monthly rental payments beyond month 7 resulting in excess rental payments cost thereafter. Because of the uncertainty with respect to the high-cost items, GAO recommended alternative reimbursement approaches such as adjustment of the rental rate and requirements that suppliers accept whatever percentage is adopted.

The report further discussed HHS and supplier comments on the GAO report draft. HHS also commented that the cap proposal did not address the issues associated with ownership of DME after the maximum amount of the cap had been reached. The supplier comments included recommendations from National Association of Medical Equipment Suppliers (NAMES) proposal for considering alternative methods that limited rental payments after a specified number of months such as 24 months for non-oxygen-related DME items (wheelchairs and hospital beds). At the end of the 2-year period, any item still being rented would be subject to a monthly maintenance fee in lieu of rental based on 30 percent of the latest allowable rental charge. Title to the items would remain with the supplier, and the item would be returned when no longer needed.

Section 4062 of the Omnibus Budget Reconciliation (OBRA) Act of 1987 (Pub. L. 100–203), was enacted on December 22, 1987. This legislation added section 1834(a) to the Act, which mandated payment categories and rules for DME that dictated whether payment would be made on a rental and/or purchase basis for items in each category. These changes were intended to align payment rates and achieve savings in the Medicare program. The new payment categories mandated by section 1834(a) of the Act were promulgated via regulation at § 414.210. Sections 1834(a)(2) through (a)(5) and 1834(a)(7) of the Act set forth separate payment categories of DME and describe how the fee schedule for each of the following categories is established: Inexpensive or other routinely purchased items; Items requiring frequent and substantial servicing; Customized items; Oxygen and oxygen equipment; and Other items of DME or capped rental items.

Section 13543 of the Omnibus Budget Reconciliation Act (OBRA) of 1993 (Pub. L. 103–66), was enacted on August 10, 1993, and amended section 1834(a) to reclassify nebulizers, CPAP devices, aspirators or suction pumps, and intermittent assist or respiratory assist devices from the category of items requiring frequent and substantial servicing to the capped rental payment category. It also mandated separate payment for accessories used in conjunction with these items. Section 4315 of the Balanced Budget Act of 1997 (Pub. L. 105–33), enacted on August 5, 1997, added section 1842(s) to the Act, to authorize a fee schedule for PEN, which was promulgated via regulations at § 414.100 (66 FR 45173, August 28, 2001). In 42 CFR Part 414, Subpart C of the regulations, govern payment on a fee schedule basis for PEN nutrients, equipment and supplies. Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

Section 1847 of the Act establishes the Medicare DMEPOS Competitive Bidding Program (CBP) (''Competitive Bidding Program''). Under the CBP, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in CBAs based on bids submitted by qualified suppliers and accepted by Medicare. For competitively bid items, these new payment amounts, referred to as ''single payment amounts,'' replace the fee schedule payment amounts. Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is made on an assignment-related basis equal to 80 percent of the applicable SPA amount, less any unmet Part B deductible.

Payment errors and increased costs can occur as a result of paying separately for equipment, repairs, accessories, and routine maintenance and servicing associated with beneficiary ownership of DME after the 13-month capped rental period or initial lump sum purchase, which have increased the risk for improper payments. The findings published in the August 2010 OIG report (OEI–07–08–00550) titled ''A review of claims for capped rental durable medical equipment'' reveal that from 2006 to 2008, Medicare erroneously paid separately for these services. Medicare paid $2.2 million for routine maintenance and servicing of capped rental DME; from 2006 to 2008, Medicare erroneously allowed nearly $4.4 million for repairs for beneficiary-owned capped rental DME that failed to meet payment requirements; and in 2007, Medicare allowed nearly $27 million for repair claims of beneficiary-owned capped rental DME that failed to meet payment requirements.

Based upon our experience, the ownership of equipment by beneficiary after lump sum purchase or after the end of 13 months capped rental period leads to complicated administrative procedures. The program must keep track of separate payment, coverage, medical necessity, and other rules for a number of related codes for replacement supplies and accessories used with the base equipment as well as labor and parts associated with repairing patient-owned equipment. In addition, claims processing systems must count rental months and contractors must identify when legitimate breaks in continuous use occur and can result in the start of new capped rental periods. This leads to costly and complicated claims processing systems edits for processing millions of claims for these items and services. Payment on a purchase or capped rental basis results in the need to process and pay separately for numerous items that are not DME but are related to furnishing DME such as repair of equipment or replacement of supplies and accessories used with patient-owned equipment necessary for the effective use of DME.

B. Proposed Provisions

We believe that we have general authority under section 1847(a) and (b) of the Act to establish payment rules for DME and enteral nutrition equipment that are different than the rules established under section 1834(a) of the Act for DME, section 1842(s) for enteral nutrients, supplies, and equipment, and, section 6112(b) of Omnibus Budget Reconciliation (OBRA) Act of 1989 (Pub. L. 101–239) for enteral pumps. We believe that lump sum purchase and capping rentals for certain DME and enteral nutrition may no longer be necessary to achieve savings under the program when competitive bidding can be used to establish a reasonable monthly payment. We also believe that payment on a continuous rental basis—that is, ongoing monthly payments not subject to a cap—could help to ensure that medically necessary DME and enteral nutrition equipment is kept in good working order for the entire duration of medial need and would make it easier for beneficiaries to change

from one supplier to another since the new supplier would not be faced with a finite number of rental payments. Currently, there is no requirement that a supplier take responsibility for repairing equipment once it is owned by a beneficiary, which may cause difficulties for the beneficiary to find a supplier to undertake such services. We believe that continuous rental payment would eliminate such issues because the supplier of the rented equipment would always be responsible for keeping the equipment in good working order. We do not believe that continuous monthly rental payments for DME and enteral nutrition would negatively impact access to items and services and could potentially be implemented in a manner that does not increase program expenditures since suppliers would be paid based on bids for furnishing the same general items and services they would otherwise provide. In addition, since Medicare payment for rental of DME and enteral nutrition equipment include payment for maintenance and servicing of the rented equipment, the suppliers would be directly responsible for meeting the monthly needs of the beneficiary in terms of keeping the rented equipment in good working order.

As indicated in section IV above, CMS issued an ANPRM: Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) using Information From Competitive Bidding Programs on February 26, 2014 (79 FR 10754). As part of this ANPRM, comments were solicited on whether payment on a bundled, continuous rental basis for DME and enteral nutrition should be adopted under the DMEPOS CBP. Some commenters were concerned that services such as replacement of CPAP masks and equipment repairs would not be provided if they were not paid for separately. Some commenters supported bundling payments for oxygen and enteral nutrition. Some commenters suggested that the bundling methodology be tested first before it is utilized on a wide scale basis. Thirteen commenters that included beneficiaries, beneficiary advocacy organizations, occupational therapists, and physical therapists raised concerns that access to items such as highly configured wheelchairs and speech generated devices might be disrupted under a continuous monthly bundled rental payment that includes equipment rental, replacement accessories and repairs. They felt that payment on a rental basis would result in patients losing access to these devices when they entered institutions such as hospitals and skilled nursing facilities where separate payment for DME is prohibited by section 1861(n) of the Act.

For items that continue to be paid for on a lump sum purchase basis or a capped rental basis where ownership of equipment transfers to the beneficiary following the capped rental period, we solicited comments on whether the supplier of the equipment should be responsible for repairing the equipment following transfer of title. Some commenters were opposed to the idea of making contract suppliers of purchased equipment responsible for ongoing repairs of equipment following transfer of title to the beneficiary. They stated that it would be a significant burden on suppliers to provide ongoing maintenance of equipment they furnished on a purchase basis, especially if the beneficiary moved out of the area.

After carefully considering comments received in response to the ANPRM, we are proposing to update the regulations to include proposed special payment rules described below that would be utilized in paying claims for certain DME or enteral nutrition under a limited number of CBPs. As explained in more detail in the sections that follow below, we propose to revise the regulation by adding a new section at 42 CFR 414.409 with special payment rules to replace specific payment rules at § 414.408 for these items and services in these CBPs. We also propose to revise § 414.412 regarding submission of bids for furnishing items and services paid in accordance with these special payment rules. We seek comments on these proposals.

We propose to phase-in the special payment rules described in sections 1 and 2 below in a limited number of areas for a limited number of items initially to determine whether it is in the best interest of the Medicare program and its beneficiaries to phase these rules in on a larger scale based on evaluation of the rules' effects on Medicare program costs, and quality of/access to care. In order to monitor the impact of phasing in the special payment rules in no more than 12 CBAs, we propose that, at a minimum, we would utilize evaluation criteria that are consistent with the current evaluation criteria for monitoring the impact of the CBP on utilizers of items and services in CBAs. To evaluate the quality of care for beneficiaries affected by the special payment rules, we propose that, at a minimum, we would utilize health status outcomes based criteria that would measure specific indicators such as mortality, morbidity, hospitalizations, emergency room and other applicable indicators unique to each product category. To evaluate beneficiary access to necessary items and services we propose that, at a minimum, we would monitor utilization trends for each product category and track beneficiary complaints related to access issues. To evaluate the cost of the program, we propose that, at a minimum, we would analyze the claims data for allowed services and allowed cost for each product category and the associated accessories, supplies and repair cost in the 12 CBAs and the comparator CBAs. We propose to analyze the effect of the proposed payment rules on beneficiary cost sharing.

We propose that in any competition where these rules are applied, suppliers and beneficiaries would receive advance notice about the rules at the time the competitions that utilize the rules are announced. The combined, total number of CBAs where the proposed rules in either section 1 or 2 would apply would be limited to twelve. In other words, it would not be twelve CBAs for the rules in section 1 and an additional twelve CBAs for the rules in section 2, but 12 CBAs total. In addition, we propose that the PCs listed below would be phased in to include one or more of the CBAs that would number no more than twelve total. In addition, if a determination is made to phase-in these rules on a larger scale in additional areas and for additional items based on program evaluation results regarding cost, quality, and access, the process for phasing in the rules and the criteria for determining when the rules would be applied would be addressed in future notice and comment rulemaking. This rulemaking would also address how the methodology for using these SPAs to adjust fee schedule amounts would need to be revised.

The Affordable Care Act (Patient Protection and Affordable Care Act of 2010, Pub. L. 111–148 (March 23, 2010), Sec. 3021) establishes the Center for Medicare and Medicaid Innovations (CMMI) which is authorized to test models to reduce Medicare and Medicaid expenditures while preserving or improving quality for beneficiaries of those two programs. The provision includes appropriations of $10 billion for fiscal years 2011 through 2019. We solicit comments on the option for testing the above special payment rules for DME and enteral nutrition using the CMMI demonstration authority in no more than 12 CBAs that would allow us to test and evaluate the special payment rules on a wider scale and determine

whether the special payment rules reduce Medicare expenditure while preserving or improving the quality for Medicare beneficiaries. Regardless of the authority used to phase in or test these special payment rules, we would undertake rigorous evaluation to determine the rules' effects on program costs, quality, and access.

We seek comments on the specific proposals below.

1. Payment on a Continuous Rental Basis for Select Items

We propose to revise the regulation at 42 CFR 414.409 to allow for payment on a continuous monthly rental basis under future competitions in no more than 12 CBAs for one or more of the following categories of items and services: enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, CPAP and respiratory assist devices, and hospital beds. We believe that 12 CBAs represents a limited number of CBAs yet would allow testing in different regions of the country. We propose that the SPAs established under the special payment rules would be based on bids submitted and accepted for furnishing rented DME and enteral nutrition on a monthly basis. We propose that the SPAs would represent a monthly payment for each month that rented DME or enteral nutrition is medically necessary. The SPA for the monthly rental of DME would include payment for each item and service associated with the rental equipment including the ongoing maintenance and servicing of the rental equipment, and replacement of supplies and accessories that are necessary for the effective use of the equipment. In the case of enteral nutrition, we propose that the monthly SPA would include payment for all nutrients, supplies and equipment. Suppliers would be responsible for furnishing all items and services in the applicable CBA needed each month based on the physician's order. For example, in addition to furnishing the CPAP device, the supplier would be responsible for furnishing the accessories used with the device such as masks, tubing, headgear, humidifiers, etc., as well as all maintenance and servicing of the equipment. For wheelchairs, the supplier would be responsible for furnishing the type of wheelchair and all options and accessories used with the wheelchair that are needed by the patient, as well as well as all maintenance and servicing of the equipment. For hospital beds, the supplier would be responsible for furnishing the type of hospital bed and all accessories used with the hospital bed (for example, mattresses, side rails, trapeze bars, etc.) needed by the patient, as well as all maintenance and servicing of the equipment. As discussed in more detail below, phasing in these rules would help us determine the impact on Medicare expenditures as well as beneficiary access to items and services and other possible costs and benefits.

We seek comments on this proposal.

a. Enteral Nutrition

We propose to implement future competitions for enteral nutrition in no more than 12 CBAs, where payment would be based on bids submitted for furnishing all enteral nutrients, supplies, and equipment needed on a monthly basis. We propose that the suppliers would submit a single bid for each CBA for furnishing all items and services related to furnishing such enteral nutrients, supplies, and equipment in the applicable CBA needed by a beneficiary on a monthly basis. We are soliciting comments on whether alternatives to submitting a single bid for enteral nutrition should be considered, such as having separate categories based on mode of delivery (syringe fed, pump fed, or gravity fed) or separate categories based on the type of nutrients delivered. We selected the category of enteral nutrition because we believe that payment on a separate, piecemeal basis for daily supplies, calories of nutrients furnished, and monthly rental of equipment the pumps is unnecessary and overly complex. For example, for a pump-fed patient, the beneficiary must choose whether they wish to rent the pump or purchase the pump. If the beneficiary chooses to rent the pump, the supplier is required to continue furnishing the pump until the capped rental period is over, but then is allowed to bill for maintenance and servicing of the pump once every 6 month, but only if maintenance and servicing is needed and furnished. The supplier must also submit claims for daily supply kits as well as feeding tubes furnished in addition to billing for every 100 calories of enteral nutrient furnished. Finally, the supplier must bill for the pole used to hold the pump; however, the monthly rental payments for the pole are not subject to the cap on rentals that the statute specifically requires for the pump and this is confusing. In addition, issues have been raised regarding replacement parts and supplies for beneficiary-owned enteral nutrition infusion pumps when the manufacturer elects to discontinue the brand and model of pump owned by the beneficiary. Neither the beneficiary nor the supplier is able to obtain supplies that the manufacturer no longer sells and the Medicare rules would generally not allow for the purchase of a new pump since this would be duplicate equipment. We seek comments on this proposal.

b. Oxygen and Oxygen Equipment

We propose to implement future competitions for oxygen and oxygen equipment in no more than 12 CBAs, where payment would be based on bids submitted for furnishing all oxygen and oxygen equipment needed on a monthly basis. We propose that the suppliers would submit a single bid for each CBA for furnishing all items and services needed on a monthly basis, including all rented equipment and related accessories such as regulators, flowmeters, nasal cannulas, masks, tubing, humidifier bottles, tank stands and carts, and transtracheal catheters, as well as all maintenance and servicing of the equipment and delivery of oxygen contents. We selected the category of oxygen and oxygen equipment because we believe the rental cap for oxygen equipment generates very little savings under CBPs. A small percentage of beneficiaries, approximately 25 percent based on our review of Medicare claims, reach the 36-month cap, which is extended by as much as 9 months at the start of a CBP, and the SPAs for oxygen contents furnished after the cap are roughly the same as the SPAs for furnishing oxygen and oxygen equipment during the 36-month rental cap period. In addition, recent issues related to suppliers abandoning beneficiaries after the rental cap has resulted in the need to pay for lost oxygen and oxygen equipment, eliminating any savings the rental cap might have achieved. Although section 1834(a)(5)(F)(ii)(I) of the Act mandates that the supplier receiving payment for the 36th month of continuous use must continue to furnish the oxygen and oxygen equipment for any period of medical need for the duration of the reasonable useful lifetime of the equipment, certain suppliers have failed to continue providing oxygen and oxygen equipment despite this requirement.

Section 414.226 provides that for oxygen and oxygen equipment, Medicare payments are modality neutral, with the exception that the portable oxygen equipment add-on payment for oxygen generating portable equipment (OGPE) is higher than the add-on payment for liquid and gaseous portable oxygen equipment. The Medicare monthly payment for oxygen and oxygen equipment includes payment for stationary equipment

(concentrators, liquid, or gaseous stationary equipment) as well as payment for oxygen contents (stationary and portable). The add-on payment is only for the portable oxygen equipment and does not include payment for the portable oxygen contents. This fact is often confused and the portable oxygen add-on payment is erroneously viewed as a payment for portable oxygen contents as well as portable oxygen equipment. In a majority of cases, beneficiaries receive both stationary oxygen and oxygen equipment and portable oxygen and oxygen equipment, so having a separate add-on payment for portable oxygen equipment only seems unnecessary. Under our proposal, for oxygen and oxygen equipment payment under the select CBPs, we propose to eliminate the 36-month cap on equipment payments and eliminate separate add-on payments for portable equipment and separate payment for oxygen contents. Under our proposal, the contract suppliers would continue to be responsible for furnishing equipment consistent with the requirements in § 414.420.

We seek comments on this proposal.

c. Standard Manual Wheelchairs

We propose to implement future competitions for standard manual wheelchairs in no more than 12 CBAs, where payment would be based on bids submitted for furnishing standard manual wheelchairs and all accessories used in conjunction with the wheelchairs on a monthly basis. We propose that the suppliers would submit a single bid for each HCPCS code describing the wheelchair for each CBA for furnishing the wheelchair and all accessories and services needed on a monthly basis. We are soliciting on this proposal as well as comments on whether all standard manual wheelchairs should be described under one HCPCS code in order to simplify bidding and claims processing procedures. The current HCPCS codes for standard manual wheelchairs include standard, hemi (low seat), lightweight, high strength lightweight, heavy duty, and extra heavy duty wheelchairs described by codes K0001 thru K0004, K0006, and K0007 in the HCPCS. In view of comments to the ANPRM expressing concern regarding beneficiary impact of bundled arrangements for users of highly configured manual wheelchairs, we are requesting comment on what safeguards and monitoring approaches we should use to ensure that access to these items is not disrupted for individuals transitioning between settings and/or residing in remote areas. We seek comments on this proposal.

d. Standard Power Wheelchairs

We propose to implement future competitions for standard power wheelchairs in no more than 12 CBAs, where payment would be based on bids submitted for furnishing standard power wheelchairs and all accessories used in conjunction with the wheelchairs on a monthly basis. We propose that the suppliers would submit a single bid for each HCPCS code describing the wheelchair for each CBA for furnishing the wheelchair and all accessories (including batteries) and services needed on a monthly basis. We are soliciting comments on whether all standard power wheelchairs should be described under one HCPCS code in order to simplify bidding and claims processing procedures. The current HCPCS codes for standard power wheelchairs include all group 1 and group 2 power wheelchairs that cannot accommodate rehabilitative accessories and features described by codes K0813 thru K0829 in the HCPCS. In view of comments to the ANPRM expressing concern regarding beneficiary impact of bundled arrangements for users of highly configured manual wheelchairs, we are requesting comment on what safeguards and monitoring approaches we should use to ensure that access to these items is not disrupted for individuals transitioning between settings and/or residing in remote areas.

We selected the categories of standard manual and power wheelchairs because we believe that payment on a separate, piecemeal basis for hundreds of various wheelchair options and accessories is unnecessary and overly complex. In addition, issues have been raised regarding access to repair of beneficiary-owned wheelchairs following the 13-month capped rental period. For example, there are hundreds of codes for various wheelchair accessories and separate payment for each of these items in addition to the payment for the wheelchair. The separate billing, processing and payment of these claims would not be necessary given that the supplier can factor the costs of accessories into their bid for furnishing the rented equipment. In addition, the beneficiary's needs may change such that the beneficiary needs a different type of accessory from the one that was initially furnished by the supplier. Under the current rules, the accessory may not be covered if it is similar to the one that was already paid for by Medicare. If payments for all types of accessories are included in an ongoing, monthly rental amount for the wheelchair, the beneficiary can receive other accessories included in the program, provided such accessories are medically necessary.

We seek comments on this proposal.

e. CPAP and Respiratory Assist Devices

We propose to implement future competitions for CPAP and respiratory assist devices in no more than 12 CBAs, where payment would be based on bids submitted for furnishing the CPAP or respiratory assist device and supplies, accessories, and services needed on a monthly basis. We propose that the suppliers would submit a single bid for each device for each CBA for furnishing all items and services needed on a monthly basis. We are soliciting comments on our proposal as well as whether all CPAP and respiratory assist devices should be described under one HCPCS code in order to simplify bidding and claims processing procedures. We selected the category of CPAP and respiratory assist devices because we believe the cost of paying separately for the expensive accessories used with these devices may exceed the amount of savings achieved from capping the rental payments for the equipment. We seek comments on this proposal.

f. Hospital Beds

We propose to implement future competitions for hospital beds in no more than 12 CBAs, where payment would be based on bids submitted for furnishing hospital beds and all accessories used in conjunction with the hospital beds on a monthly basis. We propose that the suppliers would submit a single bid for each HCPCS code describing the hospital bed for each CBA for furnishing the hospital bed and all accessories and services needed on a monthly basis. We are soliciting comments on whether all hospital beds should be described under one HCPCS code in order to simplify bidding and claims processing procedures. We selected the category of hospital beds to allow us to determine the impact of the continuous monthly rental payment rule under CBP on beneficiary access, utilization rate and cost for an item that currently does not have beneficiary access issues or issues related to excessive cost for repair and accessories. We seek comments on this proposal.

g. Transition Rules

We propose to revise the regulation at 42 CFR 414.409 to include supplier transition rules for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, CPAP and respiratory

assist devices, and hospital beds that would be paid in accordance with the rules proposed in this section. We also propose to revise the regulation at 42 CFR 414.408 to provide a cross reference to proposed § 414.409. We propose that changes in suppliers from a non-contract supplier to a contract supplier at the beginning of the CBP where the proposed payment rules would apply would simply result in the contract supplier taking on responsibility for meeting all of the beneficiary's monthly needs while receiving payment for each month of service. We developed these proposed rules based on that fact that for capped rented DME and oxygen and oxygen equipment, since rental caps would not apply under the proposed rules, there would be no need to restart or extend capped rental periods when a beneficiary transitions from a non-contract supplier to a contract supplier. We propose that supply arrangements for oxygen and oxygen equipment, and rental agreements for standard manual wheelchairs, standard power wheelchairs, CPAP devices, respiratory assist devices, and hospital beds entered into before the start of a CBP and application of the payment rules proposed in this section would be allowed to continue so long as the supplier agrees to furnish all necessary supplies and accessories used in conjunction with the rented equipment and needed on a monthly basis. We propose that non-contract suppliers in these cases would have the option to continue rental agreements; however, we propose that as part of the process of allowing the rental agreements to continue, the grandfathered supplier would be paid based on the payment rules proposed in this section and based on the SPAs established under the CBPs incorporating the proposed rules.

We solicit comments on this proposed process.

We propose that in the event that a beneficiary relocates from a CBA where the rules proposed in this section apply to an area where rental cap rules apply, that a new period of continuous use would begin for the capped rental item, enteral nutrition equipment, or oxygen equipment as long as the item is determined to be medically necessary. We believe these rules that would result in a new period of continuous use are necessary to safeguard beneficiary access to covered items and services and plan to closely monitor the impact these rules have on beneficiary cost sharing before phasing in these rules in more than a limited number of CBAs.

We seek comments on these proposals.

h. Beneficiary-Owned Equipment

We propose that separate payment for all repairs, maintenance and servicing, and replacement of supplies and accessories for beneficiary-owned DME or enteral nutrition equipment would cease in the CBAs where the payment rules proposed under this section are in effect. We propose that if the beneficiary has a medical need for the equipment, the contract supplier would be responsible for furnishing new equipment and servicing that equipment. This option would ensure that beneficiaries continue to receive medically necessary equipment, including the supplies, accessories, maintenance and servicing that may be needed for such equipment. Please note that this would not apply to items which are not paid on a bundled, continuous rental basis. We propose to revise the regulations at § 414.409 to specify that any beneficiary who owns DME or enteral nutrition equipment and continues to have a medical need for the items should these rules take effect in a CBA where they reside, would have the option to obtain new equipment, if medically necessary, and related servicing from a contract supplier. We are requesting comment as to whether a transitional process should be considered when claims are selected for review to determine whether they are reasonable and necessary and other safeguards are required to ensure timely delivery of the replacement DME so that individuals' mobility and ability to live independently is not adversely impacted by delays. While this could potentially increase beneficiary cost sharing, it would eliminate issues associated with repair of beneficiary-owned equipment. We plan to closely monitor the impact of this proposed provision, should it be finalized.

We seek comments on this proposal, including issues related to the ability of low income beneficiaries to afford additional cost sharing, and how best to monitor beneficiary impact within the 12 CBAs in which these new rules would be phased in.

2. Responsibility for Repair of Beneficiary-Owned Power Wheelchairs Furnished Under CBPs

We propose to revise the regulation at 42 CFR 414.409 to add a new payment rule that would apply to future competitions for standard power wheelchairs in no more than 12 CBAs where payment is made on a capped rental basis and not on the basis of the rules proposed under § 1 above. In these CBPs, we propose that contract suppliers for power wheelchairs would be responsible for all necessary repairs and maintenance and servicing of any power wheelchairs they furnish during the contract period under the CBP, including repairs and maintenance and servicing of power wheelchairs after they have transferred title to the equipment to the beneficiary. We propose that this responsibility would end when the reasonable useful lifetime established for the power wheelchair expires, medical necessity for the power wheelchair ends, the contract period ends, or the beneficiary relocates outside the CBA. We propose that the contract supplier would not receive separate payment for these services and would factor the costs of these services into their bids. We believe that based on existing maintenance and servicing requirements, suppliers could project the cost of continuing to repair and service equipment of various ages once title to the equipment has transferred to the beneficiary. As indicated above, under existing rules, the supplier that transfers title to the equipment to the beneficiary after the 13 month period of continuous use is not held responsible for repairing the equipment they furnish after the beneficiary takes over ownership of the equipment. Therefore, we believe the propose rule would safeguard the beneficiary and better ensure that the beneficiary continues to have equipment in good working order to meet their needs. We propose that the contract supplier would not be responsible for repairing power wheelchairs they did not furnish. We propose that services to repair beneficiary-owned equipment furnished prior to the start of the contract period would be paid in accordance with the standard payment rules at § 414.210(e).

We seek comments on this proposal.

3. Phasing in the Proposed Payment Rules in CBAs

We propose that the CBAs where the proposed rules in §§ 1 or 2 above would be applied would be for MSAs with a general population of at least 250,000 and a Medicare Part B enrollment population of at least 20,000 that are not already included in Round 1 or 2. Based on 2012 population estimates from the Census Bureau and 2011 Medicare enrollment data, there are approximately 80 MSAs that would satisfy this criteria. Selecting MSAs not already included in Round 1 or 2 would allow competitions and rules associated with these competitions to begin after the final rule would take effect in areas that are comparable to existing CBAs. We propose that the boundaries of the CBAs would be established in accordance with the rules set forth at

§§ 414.406 and 414.410. We propose that additional CBPs for the items identified in §§ 1 and 2 above be established in ''comparator'' CBAs concurrent with CBPs where the proposed rules would be applied. Payment for items and services in the comparator CBAs would be made in accordance with the existing payment rules in § 414.408. We propose that these additional comparator CBAs and CBPs be established to facilitate our analysis of the effect of the payment rules proposed in sections 1 and 2 above compared to the effect of the existing payment rules in § 414.408. We propose that for each CBP where either the rules in section 1 or 2 above are implemented, a comparator CBA and CBP would be established. We propose that the comparator CBAs be selected so that they are located in the same state as the CBA where the special payment rules would apply and are similar to the CBAs in which the proposed payment rules would be implemented based on a combination of factors that could include geographic location (region of the country), general population, beneficiary population, patient mix, and utilization of items. We are proposing to establish the comparator CBAs and CBPs to enable us to review the impact of the proposed payment rules on expenditures, quality, and access to items and services in order to determine whether to pursue future rulemaking to expand the proposed payment rules to additional areas and or items.

We seek comments on this proposal.

4. Submitting Bids for Items Paid on a Continuous Rental Basis

In accordance with section 1847(b)(2)(A)(iii) of the Act, before contracts can be awarded, a determination must be made that the total amounts to be paid to contract suppliers under a CBP are expected to be less than the total amounts that would otherwise be paid. In accordance with § 414.414(f) of the regulations, under the DMEPOS CBP, bids amounts for an item or service are limited to the fee schedule amount that would otherwise be paid for the item or service. We propose that in order to apply the proposed rental payment rules, we would establish the bid limits for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, and hospital beds that would be paid in accordance with the proposed payment rules in sections 1 and 2 above based on average monthly expenditures per beneficiary in an area for the items and services related to furnishing the DME. For example, the bid limit for the continuous monthly rental of a standard manual wheelchair in a CBA would be based on the total payment amounts per month in the area for the wheelchair, repair, maintenance and servicing of the wheelchair, and accessories used with the wheelchair, divided by the unduplicated number of beneficiaries receiving these items and services. We propose to revise § 414.412 to specify that the supplier's bid for furnishing enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, and hospital beds on a continuous monthly rental basis could not be higher than the average monthly payment made in the area for the items and services prior to the start of the competition. In the case of CPAP devices and respiratory assist devices, these items were paid on a bundled, continuous rental fee schedule basis from 1989 thru 1993, based on the rules mandated by section 4062(b) of OBRA 87, prior to the change by section 13543 of OBRA 93 that moved them from the payment class for items requiring frequent and substantial servicing to the payment class for capped rental items. Payment on a bundled, continuous rental fee schedule basis was mandated by OBRA 87 from 1989 thru 1993. The fee schedule for 1993 is the most current fee schedule where payment was based on a bundled, continuous rental basis. We propose to revise § 414.412 to specify that the supplier's bid for furnishing CPAP devices and respiratory assist devices on a continuous monthly rental basis could not be higher than the 1993 fee schedule amounts for these items, increased by the covered item update factors provided for these items in section 1834(a)(14) of the Act. We seek comments on this proposal.

We seek public comments on phasing in the proposed rules described in section 1 through 4 above.

VII. Scope of Hearing Aid Coverage Exclusion

A. Background

Section 1862(a)(7) of the Act states notwithstanding any other provision of title XVIII, no payment may be made under part A or part B for any expenses incurred for items or services ''where such expenses are for . . . hearing aids or examinations therefor. . . .'' This policy is codified in the regulation at 42 CFR 411.15(d), which specifically states that hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are excluded from Medicare coverage. At the time of passage of the Social Security Amendments of 1965 (Pub. L. 97, 89th Congress), which added the Medicare coverage exclusion for hearing aids at section 1862(a)(7) of the Act, all hearing aids utilized functional air and/or bone conduction pathways to facilitate hearing.

In general, to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. With regard to section 1862(a)(7) of the Act, we consider that a hearing aid provides assistance or ''aid'' to hearing that already exists via a functioning ear. Cochlear implants were the first hearing device that was not considered a hearing aid and met the benefit category of a prosthetic device. Prosthetic devices are a Medicare benefit category defined at section 1861(s)(8) of the Act which, in part, states a ''prosthetic devices (other than dental) which replace all or part of an internal body organ.'' A cochlear implant is considered a prosthetic device primarily because it replaces the function of the cochlea. A cochlear implant device differs from a hearing aid in that it is an electronic instrument, part of which is implanted surgically to directly stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze and code sound. Both cochlear devices and brain stem implants, which function in a similar manner, create the perception of sound rather than aid hearing that already exists. We interpret the statute as excluding devices that provide aid to extant hearing (or hearing aids) rather than devices that create the perception of sound and hearing, given that devices with technology that utilize either air or bone conduction via mechanical stimulation to aid extant hearing were primarily utilized when the statute was written. Moreover, we believe that prosthetic hearing devices are not ''hearing aids'' given that such devices do more than ''aid'' in hearing and instead replace the function of an internal body organ (i.e., a part of the ear).

Historically, CMS has periodically addressed the scope of the Medicare hearing aid coverage exclusion through program instructions and national coverage policies or determinations. We briefly discuss the relevant changes that have occurred over time with regard to Medicare coverage and payment of hearing devices.

Cochlear implants were the first device covered for Medicare payment for adult beneficiaries in October 1986, when no other hearing device was being covered under Medicare, and such

coverage was supported by the Office of Health Technology Assessment's ''Public Health Service Assessment of Cochlear Implant Devices for the Profoundly Hearing Impaired'', dated June 30, 1986 found at *https://archive.org/stream/cochlearimplantd00feig/cochlearimplantd00feig_djvu.txt.* Medicare coverage was restricted to cochlear implants that treated patients with post lingual, profound, bilateral, sensorineural deafness who are stimulable and who lack the unaided residual auditory ability to detect sound.

Effective January 1, 2003, we clarified that the hearing aid exclusion broadly applied to all hearing aids that utilized functional air and/or bone conduction pathways to facilitate hearing (see section 15903, Hearing Aid Exclusion, Medicare Carriers Manual, Part 3—Claims Process (HCFA-Pub. 14–3), which was later moved to section 100, Hearing Aids and Cochlear Implants, of Chapter 16, of the Medicare Benefit Policy Manual, CMS-Pub. 100–02). Any device that does not produce at its output an electrical signal that directly stimulates the auditory nerve is a hearing aid for purposes of coverage under Medicare. Devices that produce air conduction sound into the external auditory canal, devices that produce sound by mechanically vibrating bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window are considered hearing aids and excluded from Medicare coverage.

Effective April 4, 2005, Medicare's national coverage policy for cochlear implants was modified through the NCD process (see section 65–14 of the Medicare Coverage Issues Manual (HCFA-Pub. 6), which was later moved to section 50.3, Cochlear Implantation, of Chapter 1, Part 1 of the Medicare National Coverage Determinations Manual (CMS-Pub. 100–03)). Our findings under the NCD, in part, state that ''CMS has determined that cochlear implants fall within the benefit category of prosthetic devices under section 1861(s)(8) of the Social Security Act.'' Medicare is a defined benefit program. An item or device must not be statutorily excluded and fall within a benefit category as a prerequisite to Medicare coverage. We believe that prosthetic hearing devices are not ''hearing aids'' given that such devices do more than ''aid'' in hearing and instead replace the function of an internal body organ (i.e., a part of the ear). Additional changes, regarding coverage criteria, have been made to NCD 50.3 over time, however, the NCD decision regarding benefit category and Medicare coverage for cochlear implantation has remained consistent. The NCD states that a cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

The regulations at 42 CFR 419.66 were revised to add new requirements, effective January 1, 2006, for transitional pass-through payments for medical devices. The auditory osseointegrated device, referred to as a bone anchored hearing aid (BAHA), was determined to be a new device category according to the new requirements for transitional pass-through payment. Medicare coverage was also expanded to cover auditory osseointegrated and auditory brainstem devices as prosthetic devices. Currently, section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02) reads as follows:

> Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.
>
> Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.
>
> The following are considered prosthetic devices:
>
> • Cochlear implants and auditory brainstem implants, that is, devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.
>
> • Osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.

B. Current Issues

We have received several benefit category determination requests in recent years for the consideration of non-implanted, bone conduction hearing aid devices for single-sided deafness, as prosthetic devices under the Medicare benefit. We have received similar requests for several other types of implanted and non-implanted devices as well. In response to these requests, we have re-examined the scope of the statutory hearing aid exclusion. Currently, we consider all air or bone conduction hearing devices, whether external, internal, or implanted, including, but not limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea, as hearing aids. All of these devices provide traditional ''aid'' to hearing and are excluded in accordance with section 1862(a)(7) of the Act. In order for an item to be covered by Medicare, it must fall into a Medicare benefit category and not be statutorily excluded. Not only are these devices statutorily excluded they do not fall in a benefit category. Specifically, they do not meet the statutory definition of a prosthetic device found at section 1861(s)(8) of the Act which, in part, states a ''prosthetic devices (other than dental) which replace all or part of an internal body organ.'' They do not replace the function of an internal body organ and thus are not considered prosthetic devices under Medicare payment policy. In regard to BAHA, it is a bone conduction hearing aid device that is osseointegrated. There are currently only two hearing devices that are not statutorily excluded and are a covered Medicare item that fall into the prosthetic benefit category; namely, the cochlear implant and the auditory brainstem device. These two devices meet the definition of a prosthetic device in that they replace the function of the inner ear consistent with the definition of prosthetic devices described in section 1861(s)(8) of the Act.

C. Proposed Provisions

After further considering the statutory Medicare hearing aid exclusion under section 1862(a)(7) of the Act, and re-examining the different types of external and implanted devices, we propose to interpret the term ''hearing aid'' to include all types of air or bone conduction hearing aid devices, whether external, internal, or implanted, including, but not limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea. We believe, based on our understanding of

how such devices function, that such devices are hearing aids that are not otherwise covered as prosthetic devices, in that they do not replace all or part of an internal body organ. Therefore, we propose to modify the regulation at § 411.15(d)(1) to specify that the hearing aid exclusion encompasses all types of air conduction and bone conduction hearing aids (external, internal, or implanted). Osseointegrated devices such as the BAHA are bone conduction hearing aids that mechanically stimulate the cochlea; therefore, we believe that the hearing aid exclusion applies to these devices and propose that Medicare should not cover these devices, consistent with our interpretation of section 1862(a)(7) of the Act. In addition, an NCD was issued for cochlear implant devices with the result that this determination and recent requests to expand coverage of hearing devices raises serious questions about the intent and scope of the Medicare coverage exclusion for hearing aids. It is for these reasons that we are addressing the hearing aid coverage exclusion in notice and comment rulemaking, and believe that the BAHA device qualifies as a hearing aid because it functions like other bone conduction hearing aids that are subject to the Medicare statutory coverage exclusion for hearing aids.

We continue to believe that the hearing aid exclusion does not apply to brain stem implants and cochlear implants because these devices directly stimulate the auditory nerve, replacing the function of the inner ear rather than aiding the conduction of sound as hearing aids do. Therefore, we are not proposing any changes to our current policy about brain stem implants and cochlear implants and how such implants fall outside of the hearing aid statutory exclusion (that is, such devices would fall outside the Medicare coverage exclusion for hearing aids and remain covered subject to the Medicare NCD 50.3 found at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part1.pdf*). We propose, however, to modify § 411.15(d)(2) to specifically note that such devices do not fall within the hearing aid exclusion.

We seek public comment on this proposal.

VIII. Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

A. Background

Section 1847 (a)(1)(A) of the Act mandates the implementation of CBPs throughout the United States for awarding contracts for furnishing competitively priced items and services, including OTS orthotics described in section 1847(a)(2)(C) of the Act (leg, arm, back or neck braces described in section 1861(s)(9) of the Act for which payment would otherwise be made under section 1834(h)) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. The regulation at 42 CFR 414.402 currently defines ''minimal self-adjustment'' as ''an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual who is certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.'' This current definition was proposed in the 71 FR 25669 (May 1, 2006) Notice for Proposed Rulemaking (NPRM) but did not include the term ''individual with specialized training.'' The definition was finalized in the 72 FR 18022 (April 10, 2007) Final Rule with the term ''individual with specialized training'' added after receiving comments that disagreed with the May 2006 definition and pointed out that occupational therapists, physical therapists, and physicians are licensed and trained to provide orthotics.

B. Current Issues

Since adoption of the minimal self-adjustment definition there has been some concerns raised by industry and other stakeholders regarding who is considered an individual with specialized training. We have had many inquiries and comments that this term is too ambiguous and left open for interpretation. In order to identify OTS orthotics for the purpose of implementing CBPs for these items and services in accordance with the statute, we need a clearer distinction between OTS orthotics and those that require more than minimal self-adjustment and expertise in custom fitting. In doing so, we believe it is essential to identify the credentials and training a supplier needs to have in order to be considered a supplier with expertise in custom fitting; therefore, we believe the term ''individual with specialized training'' must be clarified. We believe these professionals must have specialized training equivalent to a certified orthotist for the provision of custom fitted orthotic devices such that these professionals satisfy requirements concerning higher education, continuing education requirements, licensing, and certification/registration requirements so that they meet a minimum professional skill level in order to ensure the highest standard of care and safety for Medicare beneficiaries.

This would also help to prevent any supplier without expertise in custom fitting orthotics from potentially circumventing the competitive bidding process by furnishing custom fitting they are not qualified to provide in the event that they are not awarded a contract for furnishing OTS orthotics in their service area as the custom fitted devices are not statutorily included in the CBP.

In addition, for claims processing and payment system purposes under the CBP, we need to identify OTS orthotics, which we accomplish with codes in the HCPCS. The HCPCS codes are used on claims to identify the items and services furnished to the beneficiary, that is, to identify orthotics that are furnished OTS and subject to the CBP and to identify orthotics that have been custom fitted by suppliers with expertise. On February 9, 2012, CMS issued initial guidance identifying specific HCPCS codes considered OTS orthotics and provided a 60-day comment period posted at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/OTS_Orthotics.html.* We received 185 comments. There was no general consistency between the various commenters on which specific HCPCS codes the commenters believed were appropriately deemed OTS. Many commenters expressed their support for the proposed list while others made numerous useful recommendations to improve the OTS list. We considered each comment and performed a thorough review of the individual HCPCS codes and devices included in the codes to assess appropriate orthotic categorization. Through this process we identified HCPCS codes that described items that we believe are never furnished OTS, HCPCS codes that described items that are always furnished OTS, and HCPCS codes that described items that may or may not be furnished OTS, depending on whether more than minimal fitting and adjustment of a particular device by an expert is necessary for a particular patient. In order to address this issue we decided to create HCPCS codes for items that may or may not be custom fitted, depending on individual patient's needs, into separate codes that described the item when it has been furnished OTS and when it has been custom fitted. The new HCPCS codes

were published and became effective January 1, 2014 and are published at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/OTS_Orthotics.html.*

C. Proposed Provisions

Prefabricated orthotics are either furnished OTS or with custom fitting and are identified in the HCPCS. As noted above, with regard to minimal self-adjustment, § 414.402 in part identifies an individual with expertise in fitting as a certified orthotist or an individual with specialized training. Recently a DME Medicare Administrative Contractor (MAC) Web site Article entitled ''Correct Coding—Definitions used for Off-the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces)—Revised,'' was published March 27, 2014, and included: A physician, a treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements. The DME MAC published this article following the change in 2014 HCPCS codes for OTS and custom fitted orthotics as an education tool for Medicare enrolled DMEPOS suppliers. We believe physicians, treating practitioners, occupational therapists, and physical therapists are considered ''individuals with specialized training'' that possess training equivalent to a certified orthotist for the provision of custom fitted orthotic devices through their individual degree programs and continuing education requirements. In addition, physicians, treating practitioners, occupational therapists, and physical therapists possess equivalent or higher educational degrees, continuing education requirements, licensing, and certification and/or registration requirements. We believe these professionals meet a minimum professional skill level in order to ensure the highest standard of care and safety for Medicare beneficiaries. Each of these professionals has undergone medical training in various courses such as kinesiology and anatomy. For example, through coursework the named medical professionals gain a clinical understanding of the human body, proper alignment, normal range of motion, agonist and antagonist relationship, and biomechanics necessary to modify a custom fitted orthotic device properly.

Clinical providers such as assistants, fitters, and manufacturer representatives that work under the supervision of the individual with specialized training must do so as required under their governing body Code of Ethics and supervision standards as well as state licensure requirements. These individuals are not considered to have specialized training for the purposes of providing custom fitting; therefore, orthotics adjusted by these individuals but not by individuals with specialized training would still be considered OTS.

The current regulation of orthotic provision in the U.S. is inconsistent between individual States. There are currently 17 States that require licensure in P&O. In States that do require licensure for the provision of orthotics, individual states do not all recognize certified orthotic fitters and do not provide licensure for this level of provider. This inconsistency also prompts us to provide clarification on the individuals who are recognized as having specialized training for the purposes of determining what constitutes minimal self-adjustment of OTS orthotics.

We propose to update the definition of minimal self-adjustment in § 414.402 to codify an individual with specialized training includes: a physician defined in section 1861(r) of the Act, a treating practitioner defined at section 1861(aa)(5) (physician assistant, nurse practitioner, or clinical nurse specialist), an occupational therapist defined at 42 CFR 484.4, or physical therapist defined at 42 CFR 484.4, who is in compliance with all applicable Federal and State licensure and regulatory requirements for reasons discussed above. We seek comments on this proposal.

IX. Revision To Change of Ownership Rules To Allow Contract Suppliers To Sell Specific Lines of Business

A. Background

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary to establish and implement CBPs in CBAs throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs mandated by section 1847(a) of the Act are collectively referred to as the ''Medicare DMEPOS Competitive Bidding Program.'' The 2007 DMEPOS competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other Issues published in the **Federal Register** on April 10, 2007 (71 FR 17992)), required CBPs for certain Medicare Part B covered items of DMEPOS throughout the United States. The CBP, which was phased in over several years, utilizes bids submitted by qualified suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items for beneficiaries receiving services in designated CBAs.

CMS awards contracts to those suppliers who meet all of the competitive bidding requirements and whose composite bid amounts fall at or below the pivotal bid (the bid at which the capacity provided by qualified suppliers meets the demand for the item). These qualified suppliers will be offered a competitive bidding contract for that PC, provided there are a sufficient number of qualified suppliers (there must be at a minimum of 2) to serve the area. Contracts are awarded to multiple suppliers for each PC in each CBA and will be re-competed at least once every 3 years.

CMS specifies the duration of the contracts awarded to each contract supplier in the Request for Bid Instructions. We also conduct extensive bidder education where we inform bidders of the requirements and obligations of contract suppliers. Each winning supplier is awarded a single contract that includes all winning bids for all applicable CBAs and PCs. A competitive bidding contract cannot be subdivided. For example, if a contract supplier breaches its contract, the entire contract is subject to termination. In the Physician Fee Schedule final rule published on November 29, 2010, we stated that ''once a supplier's contract is terminated for a particular round due to breach of contract under the DMEPOS CBP, the contract supplier is no longer a DMEPOS contract supplier for any DMEPOS CBP PC for which it was awarded under that contract. This termination applies to all areas and PCs because there is only one contract that encompasses all CBAs and PCs for which the supplier was awarded a contract.'' (75 FR 73578)

A competitive bidding contract cannot be sold. However, CMS may permit the transfer of a contract to an entity that merges with or acquires a competitive bidding contract supplier if the new owner assumes all rights, obligations, and liabilities of the competitive bidding contract pursuant to regulations at 42 CFR 414.422(d).

For the transfer of a contract to be considered, the CHOW must include the assumption of the entire contract, including all CBAs and PCs awarded under the contract.

B. Proposed Provisions

We propose to revise § 414.422(d) to permit transfer of part of a competitive bidding contract under specific

circumstances. We believe requiring a transfer of the entire contract to a successor entity in all circumstances may be overly restrictive, and may be preventing routine merger and acquisition activity. To maintain integrity of the bidding process we award one contract that includes all the CBA/PCs combinations for which the supplier qualifies for and accepts as a contract supplier. This proposed rule would establish an exception to the prohibition against transferring part of a contract by allowing a contract supplier to sell a distinct company (for example, an affiliate, subsidiary, sole proprietor, corporation, or partnership) which furnishes one or more specific PCs or serves one or more specific CBAs and transfer the portion of the contract initially serviced by the distinct company, including the PC(s), CBA(s), and location(s), to a qualified successor entity who meets all competitive bidding requirements (i.e., financial standards, licensing, and accreditation). The proposed exception would not apply to existing contracts but would apply to contracts issued in all future rounds of the program, starting with the Round 2 Recompete. As required in § 414.422(d) we are also requiring a contract supplier that wants to sell a distinct company which furnishes one or more specific PCs or serves one or more specific CBAs to notify CMS 60 days before the anticipated date of a change of ownership. If documentation is required to determine if a successor entity is qualified that documentation must be submitted within 30 days of anticipated change of ownership, pursuant to § 414.422(d)(2)(ii). We propose that CMS would then modify the contract of the original contract supplier by removing the affected PC(s), CBA(s) and locations from the original contract. For CMS to approve the transfer, we propose that several conditions would have to be met. First, we propose that every CBA, PC, and location of the company being sold must be transferred to the new owner. Second, we propose that all CBAs and PC's in the original contract that are not explicitly transferred by CMS must remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW. Third, we propose that all requirements in 42 CFR 414.422(d)(2) must be met. Fourth, we propose that the sale of the company must include all of the company's assets associated with the CBA and/or PC(s). Finally, we propose that CMS must determine that transferring part of the original contract will not result in disruption of service or harm to beneficiaries. No transfer will be permitted for purposes of this program if we determine that the new supplier does not meet the competitive bidding requirements (such as financial requirements) and does not possess all applicable licenses and accreditation for the product(s). In order for the transfer to occur, the contract supplier and successor entity must enter into a novation agreement with CMS and the successor entity must accept all rights, responsibilities and liabilities under the competitive bidding contract. Part of a novation agreement requires successor entity to ''seamlessly continue to service beneficiaries.'' We believe that these proposed conditions are necessary for proper administration of the program, to ensure that payments are made correctly and also to ensure continued contract accountability and viability along with continuity of service and access to beneficiaries. We specifically invite comments on whether more or different conditions would be appropriate.

In addition, we are proposing to update the current CHOW regulation, § 414.422(d) to clarify the language to make it easier to comprehend. The proposed changes reformat the regulation so that the requirements applicable to successor entities and new entities are listed separately. These proposed changes to the regulation are technical, and not substantive in nature. CMS seeks comments on all changes proposed for § 414.422.

X. Proposed Changes to the Appeals Process for Termination of Competitive Bidding Contract

We propose to modify the DMEPOS CBP's appeals process for termination of competitive bidding contracts under § 414.423. First, we propose to modify the effective date of termination in the termination notice CMS sends to a contract supplier found to be in breach of contract. Currently, the regulation at 42 CFR 414.423(b)(2)(vi) indicates that the effective date of termination is 45 days from the date of the notification letter unless a timely hearing request ''has been'' filed or corrective action plan ''has been'' submitted within 30 days of the effective date of the notification letter (emphasis added). We propose to change these references to provide additional clarification. This change would emphasize that the contract will automatically be terminated if the supplier does not time file a hearing request or submit corrective action plan. This proposed change is also being addressed at 42 CFR 414.423(l). We propose deleting the lead-in sentence, as it does not properly lead into the first paragraph. Additionally, we propose inserting language from the lead-in sentence in the second paragraph to indicate that the contract supplier, ''whose contract has been terminated,'' must notify beneficiaries of the termination of their contract. Second, we propose to modify the deadline by which a supplier whose competitive bidding contract is being terminated must notify affected beneficiaries that it is no longer a contract supplier. Current regulations at 42 CFR 414.423(l)(2)(i) require a contract supplier to provide this notice within 15 days of receipt of a final notice of termination. We propose to change the beneficiary notification deadline to no later than 15 days prior to the effective date of termination. This proposed change is intended to provide beneficiaries with the protection of advanced notice prior to a contract supplier being terminated from the CBP so they have sufficient time to plan/coordinate their current and future DMEPOS needs.

XI. Technical Change Related To Submitting Bids for Infusion Drugs Under the DMEPOS Competitive Bidding Program

The standard payment rules for drugs administered through infusion pumps covered as DME are located at section 1842(o)(1)(D) of the Act, and mandate that payment for infusion drugs furnished through a covered item of DME on or after January 1, 2004, is equal to 95 percent of the average wholesale price for such drug in effect on October 1, 2003. The regulations implementing section 1842(o)(1)(D) of the Act are located at 42 CFR 414.707(a), under Subpart I of Part 414. Section 1847(a)(2)(A) of the Act mandates the establishment of CBPs for covered items defined in section 1834(a)(13), for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME. Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under a CBP unless the total amounts to be paid to contract suppliers are expected to be less than would otherwise be paid. The regulations implementing section 1847(b)(2)(A)(iii) of the Act with respect to items paid on a fee schedule basis under Subparts C and D of Part 414 are located at 42 CFR 414.412(b)(2), and specify that ''the bids submitted for each item in a PC cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part.'' In addition, the regulations regarding the conditions for awarding

contracts under the DMEPOS CBP at 42 CFR 414.414(f) state that ''a contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a CBP are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D.'' The regulations implementing of section 1847(b)(2)(A)(iii) of the Act did not address payments for drugs under subpart I, which was an oversight. We therefore propose to revise §§ 414.412(b)(2) and 414.414(f) to include a reference to drugs paid under subpart I in addition to items paid under subparts C or D. We propose to revise § 414.412(b)(2) to specify that the bid amounts submitted for each drug in a PC cannot exceed the payment limits that would otherwise apply to the drug under subpart I of part 414. This concerns certain infusion drugs with payment limits equal to 95 percent of the average wholesale price for the drug in effect on October 1, 2003, in accordance with § 414.707(a)(3). See *http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=7065f17b411e37b3788b6e7fce21f89&rgn=div8&view=text&node=42:3.0.1.1.1.9.1.3&idno=42*. We propose to revise § 414.414(f) to specify that a contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for infusion drugs provided with respect to external infusion pumps under a CBP are expected to be less than the amounts that would otherwise be paid to suppliers for the same drug under subpart I of part 414. We seek comments on this proposal.

XII. Accelerating Health Information Exchange

HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange''). The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (HIT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of HIT and HIE services through Medicare and Medicaid payment policies, (2) adoption of common standards and certification requirements for interoperable HIT, (3) support for privacy and security of patient information across all HIE-focused initiatives, and (4) governance of health information networks. These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive programs, and are designed to improve care delivery and coordination across the entire care continuum. For example, the Transition of Care Measure #2 in Stage 2 of the Medicare and Medicaid EHR Incentive Programs requires HIE to share summary records for at least 10 percent of care transitions. In addition, to increase flexibility in ONC's regulatory certification structure and expand HIT certification, ONC has proposed a voluntary 2015 Edition EHR Certification rule to more easily accommodate HIT certification for technology used by all health care settings to facilitate greater HIE across the entire care continuum.

We believe that HIE and the use of certified EHRs can effectively and efficiently help ESRD facilities and nephrologists improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures (eCQMs). More information on the 2015 Edition EHR certification rule can be found at: *http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations*.

XIII. 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 section II.F of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2015. 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

The information collection requirements associated with the ESRD QIP are currently approved under OMB control number 0938–0386.

a. Data Validation Requirements for the PY 2017 ESRD QIP

Section III.F.9 in this proposed rule outlines our data validation proposals for PY 2017. 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). According to the Bureau of Labor Statistics, the mean hourly wage of a registered nurse is $33.13/hour. Since we anticipate that nurses (or administrative staff who would be paid at a lower hourly wage) would submit this data, we estimate that the aggregate cost of the CROWNWeb data validation would be $24,847.50 (750 hours × $33.13/hour) total or $82.83 ($24,847.50/300 facilities) per facility in the sample.

Under the proposed 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 that the burden associated with this feasibility study will be the time and effort necessary for each selected facility to compile and submit to CMS a quarterly list of positive blood cultures drawn from its patients. We estimate that it will take each participating facility approximately two hours per quarter to comply with this submission. If nine facilities are asked to provide lists, we estimate the quarterly burden for these facilities would be 72 hours per year (9 facilities × 2 hours/quarter × 4 quarters/year). Again, we estimate the mean hourly wage of a registered nurse to be $33.13/hour, and we anticipate nurses (or administrative staff who would be paid at a lower hourly wage) would be responsible for preparing and submitting the list. Because we anticipate nurses (or administrative staff who would be paid at a lower hourly rate) would compile and submit these data, we estimate that the aggregate annual cost of the feasibility study to validate NHSN data would be $2,385.36 (72 hours × $33.13/hour) total or $265.04 per facility ($2,385.36/9 facilities).

b. Proposed NHSN Healthcare Personnel Influenza Vaccination Reporting Measure for PY 2018

We are proposing to include, beginning with the PY 2018 ESRD QIP, a measure requiring facilities to report healthcare personnel influenza vaccination data to NHSN. The NHSN is a secure, Internet-based surveillance system which is maintained and managed by CDC. Many dialysis facilities already submit NHSN Bloodstream Infection clinical measure data to NHSN. Specifically, we are proposing to require facilities to submit on an annual basis an HCP Influenza Vaccination Summary Form to NHSN, according to the specifications available in the NHSN Healthcare Personnel Safety Component Protocol. We estimate the burden associated with this measure to be the time and effort necessary for facilities to complete and submit the HCP Influenza Vaccination Summary Form on an annual basis. We estimate that approximately 5,996 facilities will treat ESRD patients in PY 2018. We estimate it will take each facility approximately 75 minutes to collect and submit the data necessary to complete the Healthcare Personnel Influenza Vaccination Summary Form on an annual basis. Therefore, the estimated total annual burden associated with reporting this measure in PY 2018 is 7,495 hours [(75/60) hours × 5,996 facilities]. Again, we estimate the mean hourly wage of a registered nurse to be $33.13, and we anticipate nurses (or administrative staff who would be paid at a lower hourly wage) would be responsible for this reporting. In total, we believe the cost for all ESRD facilities to comply with the reporting requirements associated with the NHSN Healthcare Personnel Influenza Vaccination reporting measure would be approximately $248,309 (7,495 hours × $33.13/hour) total, or $41.37 ($248,309/5,996 facilities) per facility.

XIV. 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.

XV. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We examined the impacts of this proposed rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 11, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits of reducing costs, harmonizing rules, and promoting flexibility. This rule has been designated economically significant under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the proposed rule. We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

This rule proposes a number of routine updates for renal dialysis services in CY 2015 and proposes several policy changes to the ESRD PPS. The routine updates include proposed updates to the wage index values, the wage index budget-neutrality adjustment factor, and the outlier payment threshold amounts. The proposed policy changes to the ESRD PPS include the revisions to the ESRDB market basket, changes in the CBSA delineations, changes to the labor-related share, clarifications in the low-volume payment adjustment, and additions and corrections to the ICD–10 codes that will be used for the comorbidity payment adjustment when compliance with ICD–10 is required beginning October 1, 2015. In addition, this rule implements sections 1881(b)(14)(F)(i) and (I), as amended by section 217 (b)(1) and (2) of PAMA, under which the drug utilization adjustment transition is eliminated and a 0.0 percent update to the ESRD PPS base rate is imposed in its place. This rule also implements the delay in payment for oral-only drugs used for the treatment of ESRD under the ESRD PPS until January 1, 2024 as required by section 217(a) of PAMA. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2015.

This rule proposes to implement requirements for the ESRD QIP by proposing to adopt measure sets for the PYs 2017 and 2018 programs, as directed by section 1881(h) of the Act. Failure to propose requirements for the PY 2017 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2016. In addition, proposing requirements for the PY 2018 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

This proposed rule proposes to establish a methodology for adjusting DMEPOS payment amounts using information from the Medicare DMEPOS CBP. The proposed rule would also phase in special payment rules for certain DME and enteral nutrition in a limited number of areas

under the Medicare DMEPOS CBP. This proposed rule also proposes to clarify the Medicare hearing aid coverage exclusion under section 1862(a)(7). In addition, this proposed rule would modify the definition of minimal self-adjustment at § 414.402 to indicate what specialized training is needed by suppliers to provide custom fitting services if they are not certified orthotists. Finally, if finalized, this proposed rule would provide clarification of the CHOW under the Medicare DMEPOS CBP.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in an increase of approximately $30 million in payments to ESRD facilities in CY 2015, which includes the amount associated with updates to outlier threshold amounts, updates to the wage index, changes in CBSA delineations, and the labor-related share.

For PY 2017, we estimate that the proposed requirements related to the ESRD QIP will cost approximately $27 thousand total, and the payment reductions will result in a total impact of approximately $16 million across all facilities. For PY 2018, we estimate that the proposed requirements related to the ESRD QIP will cost approximately $248 thousand total, and the payment reductions will result in a total impact of approximately $6.4 million across all facilities, resulting in a total impact from the proposed ESRD QIP of approximately $6.6 million.

We estimate that the proposed methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs would save over $7 billion over FY 2016–2020. The savings would be primarily achieved from the reduced payment amounts for items and services.

We estimate the special payment rules would not have a negative impact on beneficiaries and suppliers, or on the Medicare program. Contract suppliers are responsible for furnishing items and services needed by the beneficiary, and the cost to suppliers for furnishing these items and services generally would not change based on whether or not the equipment and related items and services are paid for separately under a capped rental payment method. Because the supplier's bids would reflect the cost of furnishing items in accordance with the new payment rules, we expect the overall savings generally would be the same as they are under the current payment rules. Furthermore, as indicated above, the special payment rules would be phased in under a limited number of areas first to determine impact on the program, beneficiaries, and suppliers, including their effects on cost, quality, and access before expanding to other areas after notice and comment rulemaking, if supported by evaluation results. We believe that the special payment rules would give beneficiaries more choice and flexibility in changing suppliers. We estimate the proposed clarification of the statutory Medicare hearing aid coverage exclusion leading to withdrawal of coverage for bone anchored hearing aid (BAHA) devices would not have a significant fiscal impact on the Medicare program because the Medicare program expenditure for BAHA paid under Medicare during the period CY2005 through CY 2013 was less than 9,000,000 per year. This proposed regulation would provide guidance as to coverage of DME with regard to the statutory exclusion. The proposed rule proposes to specify that cochlear implants and brain stem implants are not hearing aids subject to the statutory exclusion and therefore, proposes no change to the current Medicare coverage status for these items.

We estimate that the proposed clarification of the definition of minimal self-adjustment would have no significant impact on program expenditures or access to orthotics. This proposed clarification would impact suppliers furnishing custom fitted orthotics that do not have the expertise necessary to make more than minimal adjustments to an orthotic that a beneficiary or caregiver could be trained to make. The impact on these few suppliers will vary according to the caseload of custom fitted orthotics provided by an individual supplier. However, we believe the majority of custom fitted devices are currently being furnished by an individual with expertise.

We estimate clarifying the CHOW under the Medicare DMEPOS CBP would have no significant impact to DMEPOS suppliers.

B. Detailed Economic Analysis

1. CY 2015 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 2014 to estimated payments in CY 2015. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2014 and CY 2015 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 2013 update of CY 2013 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2013 claims to 2014 and 2015 using various updates. The updates to the ESRD PPS base rate are described in section II.B of this proposed rule. Table 38 shows the impact of the estimated CY 2015 ESRD payments compared to estimated payments to ESRD facilities in CY 2014.

TABLE 38—IMPACT OF PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES OR CY 2015 PROPOSED RULE

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2015 changes in outlier policy %	Effect of 2015 changes in wage indexes, CBSA designations and labor-related share %	Effect of 2015 changes in payment rate update %	Effect of total 2015 changes %
	A	B	C	D	E	F
All Facilities	5,996	39.1	0.3	0.0	0.0	0.3
Type:						
Freestanding	5,520	36.6	0.3	0.0	0.0	0.3
Hospital based	476	2.5	0.3	0.2	0.0	0.5
Ownership Type:						

TABLE 38—IMPACT OF PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES OR CY 2015 PROPOSED RULE—Continued

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2015 changes in outlier policy %	Effect of 2015 changes in wage indexes, CBSA designations and labor-related share %	Effect of 2015 changes in payment rate update %	Effect of total 2015 changes %
	A	B	C	D	E	F
Large dialysis organization	4,150	27.5	0.3	−0.1	0.0	0.2
Regional chain	871	5.9	0.2	0.2	0.0	0.4
Independent	582	3.6	0.2	0.2	0.0	0.4
Hospital based [1]	393	2.1	0.3	0.1	0.0	0.4
Geographic Location:						
Rural	1,212	5.9	0.3	−0.8	0.0	−0.5
Urban	4,784	33.3	0.3	0.1	0.0	0.4
Census Region:						
East North Central	979	5.8	0.3	−0.3	0.0	0.0
East South Central	497	2.9	0.3	−1.2	0.0	−0.9
Middle Atlantic	661	4.8	0.3	0.9	0.0	1.1
Mountain	352	1.9	0.2	−0.1	0.0	0.1
New England	177	1.3	0.3	1.3	0.0	1.5
Pacific [2]	710	5.4	0.2	1.5	0.0	1.7
Puerto Rico and Virgin Islands	42	0.3	0.3	−3.9	0.0	−3.6
South Atlantic	1,333	9.1	0.3	−0.6	0.0	−0.3
West North Central	438	2.0	0.3	−0.2	0.0	0.0
West South Central	807	5.6	0.3	−0.6	0.0	−0.3
Facility Size:						
Less than 4,000 treatments [3]	1,086	2.7	0.3	−0.3	0.0	0.0
4,000 to 9,999 treatments	2,226	10.5	0.3	−0.3	0.0	0.0
10,000 or more treatments	2,523	25.7	0.3	0.1	0.0	0.4
Unknown	161	0.3	0.3	−0.1	0.0	0.2
Percentage of Pediatric Patients:						
Less than 2%	5,885	38.7	0.3	0.0	0.0	0.3
Between 2 and 19%	48	0.4	0.3	0.0	0.0	0.2
Between 20 and 49%	12	0.0	0.1	−0.4	0.0	−0.3
More than 50%	51	0.0	0.0	0.2	0.0	0.3

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.
[3] Of the 1,086 ESRD facilities with less than 4,000 treatments, approximately 422 would be expected to qualify for the low-volume adjustment in 2015. This estimate is based on actual claims for 2013 plus the number of hospital-based facilities that may newly qualify with a change in policy. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low-volume facilities is a 0.4 percent decrease 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.4 of this proposed rule is shown in column C. For CY 2015, the impact on all ESRD facilities as a result of the changes to the outlier payment policy will be a 0.3 percent increase in estimated payments. The estimated impact of the changes to outlier payment policy ranges from a 0.0 percent to a 0.3 percent increase. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2015 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the wage index, new CBSA delineations, and labor-related share on ESRD facilities and reflects the CY 2015 wage index values for the ESRD PPS payments. Facilities located in the census region of Puerto Rico and the Virgin Islands would receive a 3.9 percent decrease in estimated payments in CY 2015. 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 3.9 percent decrease to a 1.5 percent increase due to the update of the wage indexes, CBSA delineations and labor-related share.

Column E shows the effect of the ESRD PPS payment rate update of 0.0 percent as required by section 1881(b)(14)(F) and (I) as amended by section 217 of PAMA.

Column F reflects the overall impact (that is, the effects of the proposed outlier policy changes, the proposed wage index, the proposed CBSA delineations, the proposed labor-related share, and the effect of the payment rate update. We expect that overall ESRD facilities will experience a 0.3 percent increase in estimated payments in 2015. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive a 3.6 percent decrease in their estimated payments in CY 2015. 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 0.9 percent to increase of 1.7 percent in their 2015 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, ESRD facilities are paid directly for the renal dialysis bundle and other provider types such as laboratories, DME suppliers, and pharmacies, may no longer bill Medicare directly for renal dialysis services. Rather, effective January 1, 2011, such other providers can only furnish renal dialysis services under arrangements with ESRD facilities and must seek payment from ESRD facilities rather than Medicare. Under the ESRD PPS, Medicare pays ESRD facilities one payment for renal dialysis services, which may have been separately paid to suppliers by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2015, 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 2015 will be approximately $9.1 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 3.2 percent in CY 2015.

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 2015, we estimate that there will be an increase in beneficiary co-insurance payments of 0.3 percent in CY 2015, which translates to approximately $10 million.

e. Alternatives Considered

For this proposed rule, we proposed to implement a 50/50 blended wage index for CY 2015 that would apply to all ESRD facilities. Specifically, the proposal would transition all ESRD facilities experiencing an impact, or not, due to the implementation of the new CBSA delineations. We considered proposing to implement the new CBSA delineations without a transition; however we decided to mitigate the impact this change would have on ESRD facilities that may experience a decrease in payments due to the change.

In addition, for CY 2015 we proposed to implement a revised 50.673 percent labor-related share using a 2-year transition. This proposal would transition all ESRD facilities from the current labor-related share of 41.737 percent to the revised labor-related share of 50.673 percent. We considered proposing to implement the labor-related share without a transition; however we decided to mitigate the impact this change would have on ESRD facilities that may experience a decrease in payments due to the change.

2. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2017 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 2017 is described in section III.F.5 of this proposed rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2017 ESRD QIP would affect the facility's reimbursement rates in CY 2017.

We estimate that, of the total number of dialysis facilities (including those not receiving a TPS), approximately 20 percent or 1,227 of the facilities would likely receive a payment reduction in PY 2017. 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 5,996 dialysis facilities paid under the ESRD PPS. Table 39 shows the overall estimated distribution of payment reductions resulting from the PY 2017 ESRD QIP.

TABLE 39—ESTIMATED DISTRIBUTION OF PY 2017 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (percent)	Number of facilities	Percent of facilities
0.0	4,484	78.5
0.5	887	15.5
1.0	264	4.6
1.5	58	1.0
2.0	18	0.3

Note: This table excludes 285 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 2017, 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 40.

TABLE 40—DATA USED TO ESTIMATE PY 2017 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 2012—Dec 2012	Jan 2013—Dec 2013.
% Catheter	Jan 2012—Dec 2012	Jan 2013—Dec 2013.
Kt/V:		
Adult HD	Jan 2012—Dec 2012	Jan 2013—Dec 2013.
Adult PD	Jan 2012—Dec 2012	Jan 2013—Dec 2013.
Pediatric HD	Jan 2012—Dec 2012	Jan 2013—Dec 2013.
Hypercalcemia	May 2012—Dec 2012	Jan 2013—Dec 2013.

TABLE 40—DATA USED TO ESTIMATE PY 2017 ESRD QIP PAYMENT REDUCTIONS—Continued

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
SRR	Jan 2011—Dec 2011	Jan 2012—Dec 2012.

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.F.8 of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2013. 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 2017 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the one year period between January 2013 and December 2013 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 2013 through December 2013 times the estimated payment reduction percentage). For PY 2017, the total payment reduction for the 1,227 facilities estimated to receive a reduction is approximately $11.9 million ($11,873,127). Further, we estimate that the total costs associated with the collection of information requirements for PY 2017 described in section VIII.1.a of this proposed rule would be approximately $27 thousand for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $11.9 million ($27,232 + $11,873,127 = $11,900,359) in PY 2017, as a result of the PY 2017 ESRD QIP.

Table 41 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2017. 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 2017 ESRD QIP, the actual impact of the PY 2017 ESRD QIP may vary significantly from the values provided here.

TABLE 41—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2017

	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	5,996	39.1	5,711	1,227	−0.14
Facility Type:					
Freestanding	5,520	36.6	5,289	1,093	−0.13
Hospital-based	476	2.5	422	134	−0.24
Ownership Type:					
Large Dialysis	4,150	27.5	3,995	786	−0.12
Regional Chain	871	5.9	836	169	−0.14
Independent	582	3.6	534	157	−0.22
Hospital-based (non-chain)	393	2.1	346	115	−0.25
Facility Size:					
Large Entities	5,021	33.5	4,831	955	−0.12
Small Entities [1]	975	5.7	880	272	−0.23
Rural Status:					
1) Yes	1,212	5.9	1,167	187	−0.10
2) No	4,784	33.3	4,544	1,040	−0.15
Census Region:					
Northeast	792	5.8	770	160	−0.14
Midwest	1,341	7.7	1,276	314	−0.16
South	2,527	17.5	2,460	504	−0.12
West	1,015	7.1	966	159	−0.10
US Territories [2]	321	1.0	239	90	−0.33
Census Division:					
East North Central	979	5.8	909	249	−0.19
East South Central	497	2.9	475	92	−0.12
Middle Atlantic	661	4.8	632	139	−0.16
Mountain	352	1.9	335	55	−0.10
New England	177	1.3	168	29	−0.13
Pacific	710	5.4	671	119	−0.11
South Atlantic	1,333	9.1	1,279	314	−0.15
West North Central	438	2.0	417	81	−0.12
West South Central	807	5.6	783	125	−0.10
US Territories [2]	42	0.3	42	24	−0.42
Facility Size (# of total treatments):					

TABLE 41—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2017—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)*
Less than 4,000 treatments	1,086	2.7	928	211	−0.17
4,000–9,999 treatments	2,226	10.5	2,174	423	−0.12
Over 10,000 treatments	2,523	25.7	2,514	557	−0.14
Unknown	161	0.3	95	36	−0.38

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3] Based on claims and CROWNWeb data through December 2013.

b. Effects of the PY 2018 ESRD QIP

The methodology that we are proposing to use to determine a facility's TPS for the PY 2018 ESRD QIP is described in sections III.F.6 and III.F.7 of this proposed rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2018 ESRD QIP would apply to ESRD PPS payments made to the facility in CY 2018.

We estimate that, of the total number of dialysis facilities (including those not receiving a TPS), approximately 16 percent or 919 of the facilities would likely receive a payment reduction in PY 2018. 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 5,996 dialysis facilities paid through the PPS. Table 42 shows the overall estimated distribution of payment reductions resulting from the PY 2018 ESRD QIP.

TABLE 42—ESTIMATED DISTRIBUTION OF PY 2018 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (percent)	Number of facilities	Percent of facilities (percent)
0.0	4,989	84.4
0.5	729	12.3
1.0	132	2.2
1.5	35	0.6
2.0	23	0.4

Note: This table excludes 88 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 2018, 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 43.

TABLE 43-DATA USED TO ESTIMATE PY 2018 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 2012–Dec 2012	Jan 2013–Dec 2013.
% Catheter	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Kt/V:		
Adult HD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Adult PD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Pediatric HD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Pediatric PD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Hypercalcemia	May 2012–Dec 2012	Jan 2013–Dec 2013.
SRR	Jan 2011–Dec 2011	Jan 2012–Dec 2012.
STrR	Jan 2011–Dec 2011	Jan 2012–Dec 2012

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 an estimated minimum Total Performance Score and an estimated payment reduction table that were consistent with the proposals outlined in Section III.G.9 of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2013. 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 2018 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the one year period between January 2013 and December 2013 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 2013 through December 2013 times the estimated payment reduction percentage). For PY 2018, the total payment reduction for all of the 919 facilities expected to receive a reduction is approximately $7 million ($6,958,521). Further, we estimate that

the total costs associated with the collection of information requirements for PY 2018 described in Section VIII.1.b of this proposed rule would be approximately $248 thousand for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $7.2 million ($248,309 + $6,958,521 = $7,206,830) in PY 2018, as a result of the PY 2018 ESRD QIP.

Table 44 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2018. The table details 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 propose to use for the PY 2018 ESRD QIP, the actual impact of the PY 2018 ESRD QIP may vary significantly from the values provided here.

TABLE 44—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2018

	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	5,996	39.1	5,908	919	−0.10
Facility Type:					
Freestanding	5,520	36.6	5,455	818	−0.09
Hospital-based	476	2.5	453	101	−0.17
Ownership Type:					
Large Dialysis	4,150	27.5	4,115	580	−0.08
Regional Chain	871	5.9	858	127	−0.10
Independent	582	3.6	561	123	−0.15
Hospital-based (non-chain):	393	2.1	374	89	−0.19
Facility Size:.					
Large Entities	5,021	33.5	4,973	707	−0.08
Small Entities [1]	975	5.7	935	212	−0.16
Rural Status:					
(1) Yes	1,212	5.9	1,190	139	−0.07
(2) No	4,784	33.3	4,718	780	−0.10
Census Region:					
Northeast	792	5.8	784	111	−0.08
Midwest	1,341	7.7	1,318	226	−0.10
South	2,527	17.5	2,517	337	−0.07
West	1,015	7.1	1,008	109	−0.06
US Territories [2]	321	1.0	281	136	−0.43
Census Division:					
East North Central	979	5.8	952	202	−0.13
East South Central	497	2.9	493	67	−0.09
Middle Atlantic	661	4.8	650	106	−0.10
Mountain	352	1.9	349	43	−0.08
New England	177	1.3	172	21	−0.09
Pacific	710	5.4	703	90	−0.08
South Atlantic	1,333	9.1	1,315	232	−0.10
West North Central	438	2.0	426	53	−0.07
West South Central	807	5.6	806	90	−0.07
US Territories [2]	42	0.3	42	15	−0.25
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,086	2.7	1,032	215	−0.16
4,000–9,999 treatments	2,226	10.5	2,225	277	−0.07
Over 10,000 treatments	2,523	25.7	2,523	352	−0.07
Unknown	161	0.3	128	75	−0.59

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3] Based on claims and CROWNWeb data through December 2013.

3. DMEPOS Provisions

a. Effects of the Proposed Methodology for Adjusting DMEPOS Payment Amounts Using Information From Competitive Bidding Programs

We estimate that the proposed methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs would save over $7 billion over FY 2016 through 2020. The savings would be primarily achieved from price reductions for items. Therefore, most of the economic impact is expected from the reduced prices. We estimate that approximately half of the DMEPOS items and services furnished to Medicare beneficiaries are furnished to beneficiaries residing outside existing CBAs. (See Table 45.)

TABLE 45—IMPACT OF PRICING ITEMS IN NON-COMPETITIVE AREAS USING COMPETITIVE BIDDING PRICING

FY	Impact on the federal government in dollars (to the nearer ten million)	Impact on beneficiary cost sharing in dollars (to the nearer ten million)
2016	−880	−270
2017	−1,430	−470
2018	−1,520	−510
2019	−1,630	−540
2020	−1,750	−580

Although these transfers create incentives that very likely cause changes in the way society uses its resources, we lack data with which to estimate the resulting social costs or benefits.

b. Effects of the Proposed Special Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished Under the Competitive Bidding Program

We believe that the proposed special payment rules would not have a significant impact on beneficiaries and suppliers. Contract suppliers are responsible for furnishing items and services needed by the beneficiary, and the cost to suppliers for furnishing these items and services does not change based on whether or not the equipment and related items and services are paid for separately under a capped rental payment method. Because the supplier's bids would reflect the cost of furnishing items in accordance with the new payment rules, we expect the overall savings would be generally the same as they are under the current payment rules. Furthermore, as indicated above, we are proposing that the alterative payment rules would be phased in under a limited number of areas first to determine impact on the program, beneficiaries, and suppliers. If supported by evaluation results, a decision to expand the proposed special payment rules to other areas would be addressed in future rulemaking.

c. Effects of the Proposed Clarification of the Scope of the Medicare Hearing Aid Coverage Exclusion

This proposed rule proposes to clarify the scope of the Medicare coverage exclusion for hearing aids and proposes to no longer cover BAHAs. However, if finalized, this proposed rule would have no significant fiscal impact on the Medicare program, because Medicare program expenditures for BAHAs during the period CY2005 through CY 2013 have been insignificant. This proposed clarification would provide clear guidance about coverage of DME with regard to the statutory hearing aid exclusion. The proposed regulation, if finalized, would explicitly except cochlear implants and brain stem implants from the hearing aid exclusion, and therefore, Medicare coverage for these devices would continue.

We estimate that the proposed clarification of the scope of the Medicare hearing coverage exclusion would save Medicare approximately $80 million dollars over five years beginning in January 1, 2015 through September 30, 2019. The savings would be primarily achieved from removing coverage of the BAHA device. (See Table 46.)

TABLE 46—CLARIFICATION OF THE STATUTORY MEDICARE HEARING AID COVERAGE EXCLUSION

FY	Impact to the Federal Government (rounded to the nearer $10 millions)
2015	−10
2016	−10
2017	−20
2018	−20
2019	−20

d. Effects of the Proposed Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

The proposed rule would modify the definition of minimal self-adjustment to indicate that it means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or a physician as defined in section 1861(r) of the Act, a treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, an occupational therapist as defined in 42 CFR 484.4, or physical therapist as defined in 42 CFR 484.4 in compliance with all applicable Federal and State licensure and regulatory requirements. We estimate that the proposed clarification of the definition of minimal self-adjustment would have no significant impact on program expenditures or access to orthotics. This proposed clarification would impact suppliers furnishing custom fitted orthotics that do not have the expertise necessary to make more than minimal adjustments to an orthotic that a beneficiary or caregiver could be trained to make.

e. Effects of the Proposed Revision to Change of Ownership Rules To Allow Contract Suppliers To Sell Specific Lines of Business

This rule would clarify the change of ownership rules so as to not interfere with the normal course of business for DME suppliers. This rule would establish an exception under the CHOW rules to allow transfer of part of a competitive bidding contract when a contract supplier sells a distinct line of business to a qualified successor entity r under certain specific circumstances. This clarification would impact businesses in a positive way by allowing them to conduct everyday transactions without interference from our rules and regulations.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 47 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 47—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

Category	Transfers
ESRD PPS for CY 2015	
Annualized Monetized Transfers	$ 30 million.
From Whom to Whom	Federal government to ESRD providers.
Increased Beneficiary Co-insurance Payments	$10 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2017	
Annualized Monetized Transfers	−$11.9 million.
From Whom to Whom	Federal government to ESRD providers.
Category	**Costs**
Annualized Monetized ESRD Provider Costs	$27 thousand.
ESRD QIP for PY 2018	
Annualized Monetized Transfers	−$7 million.
From Whom to Whom	Federal government to ESRD providers.
Annualized Monetized ESRD Provider Costs	$248 thousand.

Pricing Items in Non-competitive Areas Using Competitive Bidding Pricing

Category	Transfer			
Annualized monetized transfer on beneficiary cost sharing	Estimates	Year dollar	Discount rate (percent)	Period covered
	−$464.5 million	2014	7	2016–2020
	−$469.9 million	2014	3	2016–2020
From Whom to Whom	Beneficiaries to Medicare providers.			
	Transfers			
Annualized monetized transfer payments	Estimates	Year dollar	Discount rate (percent)	Period covered
	−$1,415.4 million	2014	7	2016–2020
	−$1,430.5 million	2014	3	2016–2020
From Whom to Whom	Federal government to Medicare providers.			

Clarification of the Statutory Medicare Hearing Aid Coverage Exclusion

Category	Transfers			
Annualized monetized transfer payments	Estimates	Year dollar	Discount rate (percent)	Period covered
	−$15.6 million	2014	7	2015–2019
	−$15.8 million	2014	3	2015–2019
From Whom to Whom	Federal government to Medicare providers.			

XVI. 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 16 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 $35.5 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 $35.5 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 16 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 38. Using the definitions in this ownership category, we consider the 582 facilities that are independent and the 393 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 $35.5 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 0.4 percent increase in payments for CY 2015. An independent facility (as defined by ownership type) is also estimated to receive a 0.4 percent increase in payments for CY 2015.

We estimate that of the 1,217 ESRD facilities expected to receive a payment reduction in the PY 2017 ESRD QIP, 275 of those facilities would be ESRD small entity facilities. We present these findings in Table 39 (''Estimated Distribution of PY 2017 ESRD QIP Payment Reductions'') and Table 41 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2017'') above. We estimate that the payment reductions will average approximately $9,353 per facility across the 1,217 facilities receiving a payment reduction, and $8,698 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 payment reductions for the 275 small entity facilities with the aggregate ESRD payments to all small facilities. We estimate that there are a total of 885 small facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.23 percent in PY 2017.

We estimate that of the 1,320 ESRD facilities expected to receive a payment reduction in the PY 2018 ESRD QIP, 282 are ESRD small entity facilities. We present these findings in Table 39 (''Estimated Distribution of PY 2018 ESRD QIP Payment Reductions'') and Table 41 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2018'') above. We estimate that the payment reductions will average approximately $7,119 per facility across the 895 facilities receiving a payment reduction, and $6,294 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 209 small entity facilities with the aggregate ESRD payments to all small entity facilities. We estimate that there are a total of 975 small entity facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.16 percent in PY 2018.

We expect that the proposed methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs would have a significant impact on a substantial number of small suppliers. Although suppliers furnishing items and services outside CBAs do not have to compete and be awarded contracts in order to continue furnishing these items and services, the payment amounts for these items and services would be reduced using the methodology established as a result of the proposed rule. The statute requires that the methodology for adjusting payment amounts take into consideration the costs of furnishing items and services in areas where the adjustments will occur and these considerations are discussed in the preamble (refer to section IV(A)(5) of the preamble). The proposed methodology for making payment adjustments would allow for adjustments based on bids in different geographic regions to reflect regional variation in costs of furnishing items and services and the national floor for adjustments in states with unique costs. We believe that suppliers would be able to continue furnishing items and services to beneficiaries in areas outside the CBAs after the reductions in the payment amounts are applied without a significant change in the rate at which they accept assignment of Medicare claims for these items and services. Because section 1834(a)(1)(F)(ii) of the Act mandates that payment amounts for DME subject to competitive bidding be adjusted in areas where CBPs are not implemented, the only alternative we can consider other than paying based on adjusted fee schedule amounts is to implement CBPs in all areas. However, this approach would have an even greater impact on small suppliers.

We expect the proposed special payment rules for DME and enteral nutrition would not have a significant impact on small suppliers. We believe that these rules would benefit affected suppliers since payment for rental of DME and enteral nutrition infusion pumps would no longer be capped and suppliers would retain ownership to the equipment.

We expect that the proposal to modify the definition of minimal self-adjustment of orthotics would not have a significant impact on small suppliers. According to the Medicare Pricing, Data Analysis and Coding (PDAC) Contractor from FY 2010 through FY 2013 there were approximately 6,000 DMEPOS suppliers with a provider transaction access number (PTAN) registered with the National Supplier Clearinghouse to supply orthotics. In addition, there are a limited number of applicable HCPCS codes (approximately 77) that require a skilled individual's expertise. We believe that the majority of businesses providing orthotics already employ a ''skilled individual.'' However, for those few businesses that do not already have a skilled individual providing custom fitted orthotics they could comply with the proposed changes to the definition and requirements by hiring a skilled individual. For example, according to the Bureau of Labor Statistics Occupational Employment Statistics May 2013 the median pay for a certified orthotist was $30.27 an hour. The impact will vary according to the caseload of custom fitted orthotics provided by an individual supplier.

We expect that although the proposal which clarifies the scope of the Medicare statutory exclusion for hearing aids would withdraw the coverage for BAHAs, it would not have a significant impact on small suppliers since the volume of allowed services for bone anchored hearing aids covered by Medicare is very small (less than 2,000 nationwide) and would not account for a large percentage of any individual supplier's total revenue.

We expect that the proposed revisions to CHOW rules to allow contract suppliers to sell specific lines of business provision would have a positive impact on suppliers and no significant negative impact on small suppliers.

Therefore, the Secretary has determined that this proposed rule would 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 145 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 145 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 will not have a significant impact on the operations of a substantial number of small rural hospitals.

XVII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 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.

XVIII. 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.

XXI. 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.

XX. 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 Stephanie Frilling at (410) 786–4507.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays

42 CFR Part 411

Kidney diseases, Medicare, Physician Referral, and Reporting and recordkeeping requirements

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, and 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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§ 405.2102 [Amended]

■ 2. Section 405.2102 is amended by removing all the definitions, with the exception of two definitions, ''Network, ESRD'', and ''Network organization''.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 3. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 4. Section 411.15 is amended by revising paragraph (d) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(d) *Hearing aids* or examinations for the purpose of prescribing, fitting, or changing hearing aids.

(1) *Scope.* The scope of the hearing aid exclusion encompasses all types of air conduction and bone conduction hearing aids (external, internal, or implanted).

(2) *Devices not subject to the hearing aid exclusion.* Cochlear implants and auditory brainstem implants that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays. These devices produce the perception of sound and do not meet the definition of hearing aid.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 5. 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), and sec. 217 of Pub. L. 113–93.

§ 413.174 [Amended]

■ 6. In § 413.174, paragraph (f)(6) is amended by removing ''January 1, 2016'' and by adding in its place ''January 1, 2024.''

■ 7. Section 413.232 is amended revising paragraphs (b) introductory text and (f) and adding paragraph (h) to read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) Definition of low-volume facility. A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (h) of this section:

* * * * *

(f) Except as provided in paragraph (g) of this section, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor that the facility meets all the criteria established in this section. For calendar year 2012, the attestation must be provided by January 3, 2012. For calendar year 2015, the attestation must be provided by December 31, 2014.

* * * * *

(h) To receive the low-volume adjustment, an ESRD facility must include in their attestation provided pursuant to paragraph (f) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the Medicare Administrative Contractor (MAC) on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

(1) In the case of a hospital-based ESRD facility as defined in § 413.174(c), the MAC relies upon the attestation submitted pursuant to paragraph (f) of this section and may consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments that were furnished by the individual hospital-based ESRD facility seeking the adjustment; and

(2) In the case of an ESRD facility that has undergone a change of ownership that does not result in a new Provider Transaction Access Number for the ESRD facility, the MAC relies upon the attestation and when the change of ownership results in two non-standard cost reporting periods (less than or greater than 12-consecutive months), does one or both of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

§ 413.237 [Amended]

■ 8. In § 413.237, paragraph (a)(1)(iv) is amended by removing ''January 1, 2016'' and adding in its place ''January 1, 2024.''

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 9. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 10. Section 414.105 is added to read as follows:

§ 414.105 Application of Competitive Bidding Information and Limitation of Inherent Reasonableness Authority

(a) For enteral nutrients, equipment and supplies furnished on or after January 1, 2011, the fee schedule amounts may be adjusted based on information on the payment determined as part of implementation of the programs under subpart F using the methodologies set forth at § 414.210(g).

(b) In the case of such adjustments, the rules at § 405.502(g) and (h) of this chapter shall not be applied.

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

■ 11. The heading for subpart D is revised to read as set forth above.

■ 12. Section 414.202 is amended by:

■ A. Adding the definition of ''Frontier state''.

■ B. Revising the definition of ''Region''.

■ C. Adding the definition of ''Rural State''.

The additions and revision read as follows:

§ 414.202 Definitions.

* * * * *

Frontier state means a state where at least 50 percent of counties in the state have a population density of 6 people or less per square mile.

* * * * *

Region means, for the purpose of implementing § 414.210(g), geographic areas defined by the Bureau of Economic Analysis in the United States Department of Commerce for economic analysis purposes, and, for the purpose of implementing § 414.228, those contractor service areas administered by CMS regional offices.

Rural State means a state where more than 50 percent of the population is rural as determined through census data.

■ 13. Section 414.210 is amended by revising paragraph (a) and adding paragraph (g) to read as follows:

§ 414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c), (d), and (g) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§ 414.220 through 414.232

* * * * *

(g) *Application of Competitive Bidding Information and Limitation of Inherent Reasonableness Authority.* For items furnished on or after January 1, 2011, the fee schedule amounts may be adjusted based on information on the payment determined as part of implementation of the programs under subpart F, of this part, excluding information on the payment determined in accordance with the special payment rules at § 414.409. In the case of such adjustments, the rules at § 405.502(g) and (h) of this chapter shall not be applied

(1) *Payment adjustments for areas within the contiguous United States using information from competitive bidding programs.* For an item or service subject to the programs under subpart F, that payment amount for such item or services for areas within the contiguous United States shall be established as follows:

(i) CMS determines a regional price for each state in the contiguous United States and the District of Columbia equal to the un-weighted average of the single payment amount for an item or service established in accordance with § 414.416 for competitive bidding areas that are fully or partially located in the same region where the state or District of Columbia is located.

(ii) CMS determines a national average price equal to the average of the regional prices determined under paragraph (g)(1)(i) of this section.

(iii) A regional price determined under paragraph (g)(1)(i) of this section cannot be greater than 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section nor less than 90 percent of the national average price determined under paragraph (g)(1)(ii) of this section. In addition, a regional price determined under paragraph (g)(1)(i) of this section

for a state designated as a rural or frontier state cannot be less than 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) *Payment adjustments for areas outside the contiguous United States using information from competitive bidding programs.* For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States are adjusted based on the greater of—

(i) The average of the single payment amounts for the item or service for CBAs outside the contiguous United States.

(ii) 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section.

(3) *Payment adjustments for items and services included in no more than ten competitive bidding programs.* Notwithstanding paragraph (g)(1) of this section, for an item or service that is included in ten or fewer competitive bidding programs as defined at § 414.402, the fee schedule amounts applied for all areas within and outside the contiguous United States are adjusted based on 110 percent of the unweighted average of the single payment amounts for the item or service.

(4) *Payment adjustments using data on items and services included in competitive bidding programs no longer in effect.* In the case where adjustments to fee schedule amounts are made using any of the methodologies described, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the adjusted fee schedule amounts shall be increased on an annual basis using the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect. Following the initial adjustment to the fee schedule amounts, the adjusted fee schedule amounts would continue to be updated every 12 months using the percentage change in the CPI–U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

(5) *Adjusted payment amounts for accessories used with different types of base equipment.* In situations where a HCPCS code that describes an item used with different types of base equipment is included in more than one product category in a CBA under competitive bidding, a weighted average of the single payment amounts for the code is computed for each CBA, weighted based on national allowed services for the code when used with different equipment. The weighted average single payment amount per code per CBA would then be used in applying the payment adjustment methodologies proposed in this section.

(6) *Payment adjustments consistent with items and services furnished.* In the case where payment amounts are established under subpart F of this part for an item or service that are greater than the payment amounts established under subpart F of this part for a higher level item or service (i.e., one with additional features or functionality), the payment amounts for the lower level of service are adjusted so that they are no greater than the payment amounts for the higher level of service before making payment adjustments using any of the methodologies above.

(7) *Payment adjustments for mail order items furnished in the Northern Mariana Islands.* The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program.

(8) *Updating adjusted fee schedule amounts.* The adjusted fee schedule amounts are revised each time a single payment amount for an item or service is updated following one or more new competitions and as other items are added to programs established under subpart F of this part.

■ 14. Section 414.402 is amended by revising the definition of ''Minimal self-adjustment'' to read as follows:

§ 414.402 Definitions.

* * * * *

Minimal self-adjustment means an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification), or a physician as defined in 1861(r) of the Act, a treating practitioner which means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, an occupational therapist as defined in § 484.4 of this chapter, or physical therapist as defined in § 484.4 of this chapter who are in compliance with all applicable Federal and State licensure and regulatory requirements.

* * * * *

■ 15. Section 414.408 is amended by adding paragraph (l) to read as follows:

§ 414.408 Payment rules.

* * * * *

(l) *Exceptions for certain items and services paid in accordance with special payment rules.* The payment rules in paragraphs (f) thru (i), (j)(2), (j)(3), (j)(7), and (k) of this section do not apply to items and services paid in accordance with the special payment rules at § 414.409.

■ 16. Section 414.409 is added to read as follows:

§ 414.409 Special payment rules.

(a) *Payment on a bundled, continuous rental basis.* (1) In no more than 12 CBAs, in conjunction with competitions that begin on or after January 1, 2015, payment is made on a bundled, continuous monthly rental basis for enteral nutrients, supplies and equipment, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, CPAP and respiratory assist devices, and hospital beds. The CBAs and competitions where these payment rules apply are announced in advance of each competition, with the payment rules in this section used in lieu of the payment rules at § 414.408(f) thru (i), (j)(2), (j)(3), (j)(7), and (k). The single payment amounts are established based on bids submitted and accepted for furnishing rented DME and enteral nutrition on a monthly basis for each month of medical need during the contract period monthly single payment amount would include payment for all nutrients, supplies and equipment.

(2) Payment is made on a continuous monthly rental basis for DME. The single payment amount for the monthly rental of DME includes payment for the rented equipment, maintenance and servicing of the rented equipment, and replacement of supplies and accessories necessary for the effective use of the rented equipment. Separate payment for replacement of equipment, repair or maintenance and servicing of equipment, or for replacement of accessories and supplies necessary for the effective use of equipment is not allowed under any circumstances.

(3) Payment is made on a monthly basis for enteral nutrition. The single payment amount includes payment for all nutrients, supplies and equipment. Separate payment for replacement of equipment, repair or maintenance and servicing of equipment, or for replacement of accessories and supplies necessary for the effective use of equipment is not allowed under any circumstances.

(b) *Payment for grandfathered DME items paid on a bundled, continuous rental basis.* Payment to a supplier that elects to be a grandfathered supplier of DME furnished in CBPs where these special payment rules apply is made in accordance with § 414.408(a)(1).

(c) *Supplier transitions for DME and enteral nutrition paid on a bundled, continuous rental basis.* Changes from a non-contract supplier to a contract supplier at the beginning of a CBP where payment is made on a bundled, continuous monthly rental basis results in the contract supplier taking on responsibility for meeting all of the monthly needs for furnishing the covered DME or enteral nutrition. In the event that a beneficiary relocates from a CBA where these special payment rules apply to an area where rental cap rules apply, a new period of continuous use begins for the capped rental item, enteral nutrition equipment, or oxygen equipment as long as the item is determined to be medically necessary.

(d) *Responsibility for repair and maintenance and servicing of power wheelchairs.* In no more than 12 CBAs where payment for power wheelchairs is made on a capped rental basis, for power wheelchairs furnished in conjunction with competitions that begin on or after January 1, 2015, contract suppliers that furnish power wheelchairs under contracts awarded based on these competitions shall continue to repair power wheelchairs they furnish following transfer of title to the equipment to the beneficiary. The responsibility of the contract supplier to repair, maintain and service beneficiary-owned power wheelchairs does not apply to power wheelchairs that the contract supplier did not furnish to the beneficiary. For power wheelchairs that the contract supplier furnishes during the contract period, the responsibility of the contract supplier to repair, maintain and service the power wheelchair once it is owned by the beneficiary continues until the reasonable useful lifetime of the equipment expires, coverage for the power wheelchair ends, or the beneficiary relocates outside the CBA where the item was furnished. The contract supplier may not charge the beneficiary or the program for any necessary repairs or maintenance and servicing of a beneficiary-owned power wheelchair it furnished during the contract period.

■ 17. Section 414.412 is amended by revising paragraph (b)(2) and adding paragraphs (b)(3) through (5) to read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(2) The bids submitted for each item or drug in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C, Subpart D, or Subpart I of this part.

(3) The bids submitted for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, and hospital beds paid in accordance with the special payment rules at § 414.409(a) cannot exceed the average monthly payment for the bundle of items and services that would otherwise apply to the item under subpart C or subpart D of this part.

(4) The bids submitted for continuous positive airway pressure (CPAP) devices and respiratory assist devices paid in accordance with the special payment rules at § 414.409(a) cannot exceed the 1993 fee schedule amounts for these items, increased by the covered item update factors provided for these items in section 1834(a)(14) of the Act.

(5) Suppliers shall take into consideration the special payment rules at § 414.409(d) when submitting bids for furnishing power wheelchairs under competitions where these rules apply.

* * * * *

■ 18. Section 414.414 is amended by revising paragraph (f) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item or drug under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D or the same drug under subpart I based on 95 percent of the average wholesale price in effect on October 1, 2003.

* * * * *

■ 19. Section 414.422 is amended by revising paragraph (d) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(d) *Change of ownership.* (1) A contract supplier must notify CMS if it is negotiating a change in ownership no later than 60 days before the anticipated date of the change.

(2) CMS may transfer a contract to an entity that merges with, or acquires, a contract supplier if the entity meets the following requirements:

(i) A successor entity—

(A) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(B) Submits to CMS the documentation described under § 414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously submitted information is not need to make a financial determination. This documentation must be submitted no later than 30 days prior to the anticipated effective date of the change of ownership; and

(C) Submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(ii) A new entity—

(A) Meets the requirements of (d)(2)(i)(A) and (B) of this section; and

(B) Contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement as described in paragraph (d)(2)(iii) of this section for CMS review. The new entity submits to CMS, within 30 days after the effective date of the change of ownership, an executed novation agreement acceptable to CMS.

(3) Except as specified in paragraph (d)(4) of this section, CMS transfers the entire contract, including all product categories and competitive bidding areas, to a new entity.

(4) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company, (e.g., an affiliate, subsidiary, sole proprietor, corporation, or partnership) that furnishes a specific product category or services a specific CBA, CMS may transfer the portion of the contract performed by that company to a successor, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the new qualified owner who meets all competitive bidding requirements; i.e. financial, accreditation and licensure;

(iii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iv) All requirements of paragraph (d)(2) of this section are met; and

(v) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(vi) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

* * * * *

■ 20. Section 414.423 is amended by revising paragraphs (b)(1)(vi), (l)(2) introductory text, and (l)(2)(i) to read as follows:

§ 414.423 Appeals Process for Termination of Competitive Bidding Contract.

* * * * *

(b) * * *

(1) * * *

(vi) The effective date of termination is 45 days from the date of the notification letter unless a timely hearing request is filed or a corrective action plan (CAP) is submitted within 30 days of the date on the notification letter.

* * * * *

(l) * * *

(2) A contract supplier whose contract has been terminated must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(i) The notice to the beneficiary from the supplier whose contract is terminated must be provided no later than 15 days prior to the effective date of termination.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 24, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 27, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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