CMS-1614-F

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 411, 413, and 414

[CMS-1614-F]

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: Final rule.

SUMMARY: This final rule will update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. This rule also finalizes requirements for the ESRD quality incentive program (QIP), including for payment years (PYs) 2017 and 2018. This rule will also make a technical correction to remove outdated terms and definitions. In addition, this final rule sets 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); makes alternative payment rules for certain DME under the Medicare DMEPOS CBP; clarifies the statutory Medicare hearing aid coverage exclusion and specifies devices not subject to the hearing aid exclusion; will not update the definition of minimal self-adjustment; clarifies the Change of Ownership (CHOW) and provides for an exception to the current requirements; revises the appeal provisions for termination of a CBP contract, including the beneficiary notification requirement under the Medicare DMEPOS CBP, and makes a technical change to the regulation related to the conditions for awarding contracts for furnishing infusion drugs under

the Medicare DMEPOS CBP.

DATES: Effective on January 1, 2015.

FOR FURTHER INFORMATION CONTACT:

Stephanie Frilling, (410) 786-4507, for issues related to the ESRD PPS, the ESRD PPS CY 2015 Base Rate, Wage Indices, Drugs Used for the Treatment of ESRD, and Payment for Frequent Hemodialysis.

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

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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:

Electronic Access

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

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.

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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:

ACO	Affordable Care Organization
AHRQ	Agency for Healthcare Research and Quality
ANOVA	Analysis of Variance
ARM	Adjusted Ranking Metric
ASP	Average Sales Price
ATRA	The American Taxpayer Relief Act of 2012
AV	Arterial Venous
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
CMSQS	CMS Quality Strategy
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
Health IT	Health Information Technology
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
SRR	Standardized Readmissions Ratio
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 updates and makes 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) (Public Law 110-275), and section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act Public Law 111-148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L No. 112-240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2011, to reduce the single payment amount to reflect the Secretary's estimate of the change in 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. No 113-93). Section 217 of PAMA included 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 (78 FR 72161 through 72170) 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 Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

As discussed further below, section 212 of PAMA provides that the Secretary may not adopt ICD-10-CM prior to October 1, 2015. Accordingly, HHS published a final rule on August 4,

2014 that established October 1, 2015 as the new ICD-10 compliance date, and required the use of ICD-9 through September 30, 2015.

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

This final rule also sets 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 final rule finalizes 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 finalizes the phase-in of special payment rules in a limited number of competitive bidding areas (CBAs) under the CBP for certain specified DME at 42 CFR 414.408 and 414.409. This final rule clarifies the statutory Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act and the regulation at §411.15(d) to further specify the scope of this exclusion. In addition, this final rule will not finalize the definition of minimal self-adjustment at § 414.402 to identify certain individuals with specialized training with regard to off-the-shelf (OTS) orthotics under the CBP. This final rule revises 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 new qualified owner. This rule amends § 414.423 to clarify the effective date for terminations of competitive bidding contracts, and the deadline for contract

suppliers notifying its beneficiaries of its contract termination. Finally, this rule includes a technical change related to submitting bids for infusion drugs under the CBP.

B. Summary of the Major Provisions

1. ESRD PPS

- CY 2015 ESRD PPS base rate: For CY 2015, the ESRD PPS base rate is $239.43. 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 wage index budget-neutrality adjustment factor of 1.001729 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 rebasing and revising the ESRDB market basket; which entails an update to the base year of the ESRDB market basket from 2008 to 2012. The base year update results in a shift in relative costs from prescription drugs to compensation; mainly driven by the decreased utilization of drugs in furnishing ESRD treatments experienced from 2008 to 2012. Additionally, while we proposed to use PPI – Vitamin, Nutrient, and Hematinic Preparations as the pharmaceutical price proxy (instead of the current PPI – Pharmaceuticals for Human Use, Prescription), we are finalizing, based on comments, a blend of PPI – Biological Products for Human Use (78 percent) and PPI – Vitamin, Nutrient, and Hematinic Preparations (22 percent). The resulting CY 2015 market basket less MFP adjustment would have been 1.6 percent (2.1 percent ESRDB market basket update less 0.5 percent MFP adjustment); however, section 1881(b)(14)(F)(i) of the Act, as amended by section 217(b)(2) of PAMA requires the market basket less MFP adjustment to be 0.0 percent for CY 2015.

• CY 2015 ESRD PPS labor-related share: As a result of the ESRDB market basket rebasing and revision, outlined above, the CY 2015 labor-related share is 50.673 percent compared to the current labor-related share of 41.737 percent. This change to the labor-related share will 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 implementing the labor-related share of 50.673 with a 2-year transition.

• CY 2015 wage indices 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, the application of the wage index budget-neutrality adjustment factor will continue to apply to the base rate when computing payments under the ESRD PPS. In addition, 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 for CY 2015, as finalized in the CY 2014 ESRD PPS final rule (78 FR 72173 through72174).

• Update to wage index core-based statistical areas (CBSA): Beginning January 1, 2015, we will implement the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13-01, for all ESRD facilities, with a 2-year transition. Facilities will 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 new CBSA delineations. In CY 2016, facilities' wage index values will be based 100 percent on the new CBSA delineations.

• CY 2015 ESRD PPS outlier payment adjustment: We have updated the outlier services fixed-dollar loss and Medicare Allowable Payments (MAPs) amounts for adult and pediatric patients for CY 2015 using 2013 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries will increase from $54.01 to $54.35and the MAP

amount will increase from $40.49 to $43.57, as compared to CY 2014 values. For adult beneficiaries, the fixed-dollar loss amount will decrease from $98.67 to $86.19 and the MAP amount will increase from $50.25 to $51.29.

• Clarification for the low-volume payment adjustment (LVPA): We clarified two policies regarding Medicare Administration Contractor (MAC) verification for LVPA eligibility requirements and are implementing conforming changes to the LVPA regulation text at 42 CFR 413.232. 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.

• ICD-10-CM codes eligible for the ESRD PPS co-morbidity payment adjustment: Section 212 of PAMA provides that the Secretary may not adopt ICD-10-CM prior to October 1, 2015. An August 4, 2014 HHS final rule delayed the transition from ICD-9-CM to ICD-10-CM until October 1, 2015 and required the continued use of ICD-9 through September 30, 2015.Therefore, the ESRD PPS will continue to use ICD-9-CM through September 30, 2015, and will require the use of ICD-10-CM beginning October 1, 2015 for purposes of the co-morbidity payment adjustments. For CY 2015, we are correcting several typographical errors and omissions in the ICD-9-CM to ICD-10-CM crosswalk tables that appeared in the CY 2014 ESRD PPS final rule.

• Delay of payment for oral-only drugs under the ESRD PPS: 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-related drugs in the ESRD prospective payment system), prior to January 1, 2024." Accordingly, we are finalizing our proposal to amend the date in 42 CFR 413.174(f)(6) from January 1, 2016 to January 1, 2024, and to amend the date in §413.237(a)(1)(iv) regarding outlier payments for oral-only ESRD-related drugs made under the ESRD PPS to January 1, 2024.

2. ESRD QIP

This final rule implements requirements for the ESRD QIP, including measure sets for PYs 2017 and 2018.

- PY 2017 Measure Set: For PY 2017, we are removing one measure from the ESRD QIP, the Hemoglobin Greater than 12 g/dL clinical measure, on the basis that it is "topped out". We are also adopting the Standardized Readmission Ratio (SRR) clinical measure, which assesses care coordination.
- PY 2018 Measure Set: For PY 2018, we are adopting 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 converting 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 revising 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 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 Mineral Metabolism Reporting Measure: Beginning with the PY 2018 program year, we are revising 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 exempting 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: Beginning with PY 2018, we are using a new scoring methodology for the ESRD QIP. This scoring methodology creates the Clinical Measure Domain, within which facility scores on clinical measures will 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 will be summed to produce a facility's Clinical Measure Domain score. A facility's Clinical Measure Domain score will be weighted to comprise 90 percent of the facility's TPS, and the facility's scores on the reporting measures will be weighted equally to comprise the remaining 10 percent of the 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 finalizes 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 finalizes 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: This rule finalizes a phase-in of special payment rules for certain DME at 42 CFR 414.408 and 414.409 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 modifies 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 will not finalize changes to the "minimal self-adjustment" definition to specify certain "individuals with specialized training" with regard to the definition of OTS orthotics under the CBP.
- Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business: This rule establishes 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.
- Appeals Process for Termination of a Competitive Bidding Contract: This rule amends §414.423 to clarify the effective date for terminations of competitive bidding contracts,

and the deadline for contract suppliers notifying its beneficiaries of its contract termination.

C. Summary of Costs and Benefits

In section XIV of this final rule, we set forth a detailed analysis of the impacts of the finalized changes for affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section XIV.B.1 of this final 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 will increase by approximately $30 million from CY 2014 to CY 2015. This reflects a $0 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 $12 million in PY 2017 and $11.8 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 $11.6 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. Final methodology for making national price adjustments to DMEPOS fee schedule amounts based upon information gathered from the CBPs

The final regulation adjusts 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 $4.4 billion in gross payments for the 5-year period beginning January 1, 2016, and ending December 30, 2020. The estimated gross 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. Phase-in of special payment rules under the CBP for certain DME and enteral nutrition in certain CBAs

We believe that the special payment rules we are finalizing for certain DME 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 final special payment rules would be phased in 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. Clarification of the statutory Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act

This final rule clarifies the scope of the Medicare coverage exclusion for hearing aids. This rule will not have a fiscal impact on the Medicare program because there will be no change in the devices that are currently covered for Medicare payment purposes. This rule provides further guidance about coverage of DME with regard to the statutory hearing aid exclusion.

d. Definition of minimal self-adjustment at 42 CFR 414.402

This final rule will not finalize the definition of minimal self-adjustment at this time.

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

This rule finalizes changes to the CHOW rules in order to limit disruption to the normal course of business for DME suppliers. This final rule establishes 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 change 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) in which we made a number of routine updates for CY 2014, implemented the fourth and final year of the transition to the ESRD PPS, implemented sections 632(a) and (b)(1) of ATRA, and made several policy changes and clarifications. Specifically, we updated the ESRD PPS base rate to $239.02 per treatment to reflect 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 for CY 2014, or $8.16, and delayed the payment for oral-only ESRD-related drugs and biologicals until January

1, 2016. In addition, this rule also extends the gradual reduction of the wage index floor, delays application of ICD-10-CM diagnosis codes to the comorbidity payment adjustment and updates the fixed-dollar loss and MAP amounts for the outlier policy.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2015 ESRD PPS Proposed Rule

The proposed rule, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (79 FR 40208 through 40315), (hereinafter referred to as the CY 2015 ESRD PPS proposed rule), was published in the **Federal Register** on July 11, 2014, with a comment period that ended on September 2, 2014. In that proposed rule, for the ESRD PPS, we proposed routine updates to the payment system; proposed to implement the statutory provisions set forth in PAMA, and clarified policies for billing and payment of short frequent hemodialysis services and facility eligibility requirements for the low-volume payment adjustment (LVPA) available under the ESRD PPS. We received approximately 400 public comments on our proposals, including comments from: ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses. In addition, we received a several thousand signature petition requesting that CMS include "full coverage "of the cost of home hemodialysis patient training under Medicare. We note that we made no proposals in our CY 2015 ESRD PPS proposed rule regarding these issues, and therefore we are not finalizing a modification to them in this final rule. We will, however, consider the comments set forth in the petition and in other public comments in the future.

In addition, we received other comments regarding policies for the ESRD PPS for which we made no proposals. For example, a few comments from industry stakeholders and medical

associations encouraged CMS to consider race and ethnicity when assessing the cost of care. One commenter contended that African American dialysis patients require significantly more ESA utilization per treatment. Another commenter encouraged CMS to monitor race and ethnicity for the purpose of establishing a race adjustment factor in the future. We will consider these comments as we refine the payment system in CY 2016. Other comments requested that CMS clarify inconsistent manual language in Internet Only Manual Pub. 100-02 Medicare Benefit Policy, chapter 11 End-Stage Renal Disease. We appreciate these suggestions and will clarify our manual language through sub-regulatory guidance.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2015 ESRD PPS. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

C. Routine Updates and 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 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 utilization 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.

Comment: All commenters were supportive of CMS's interpretation of section 217 of PAMA and agreed that PAMA required a 0.0 percent market basket update in CY 2015. A few commenters expressed concern that the cumulative economic effect of ATRA's drug reduction, sequestration, and now PAMA's 0.0 percent update may be jeopardizing care and access for Medicare beneficiaries. Some commenters noted an unstainable Medicare payment trajectory and cited an independent analysis that estimates a mean gross margin of negative 7.4 percent for CY 2018.

Response: We thank the commenters for their support of our interpretation of section 217 of PAMA as requiring a 0.0 percent market basket update for CY 2015. We acknowledge the commenters' concern for the collective effects of reduced Medicare margins on care quality and patient access. However, PAMA, ATRA, and sequestration were congressionally mandated payment reductions and CMS must implement them. CMS has finalized policies that would mitigate the negative impacts of statutorily mandated reductions on facility margins. For example, we proposed and finalized a transition not to exceed four years for the ATRA drug utilization adjustment, thus reducing the CY 2014 payment reduction from $29.93 to $8.16. We adopted this transition policy to mitigate the negative economic impact for facilities (78 FR 72161 through72170), and to ensure our beneficiaries' access to quality care.

Comment: A few commenters requested greater transparency in the data used to establish

the annual update and other Medicare payment updates included in the ESRD PPS. One commenter noted that transparency in rate setting data gives the industry confidence in a predictable and fair payment methodology, and that facilities can only then make operational and investment decisions for the future. Other commenters provided a specific list of data files they need in order to replicate CMS's update calculations, and provided additional analysis to CMS: annual claims level rate setting files for the ESRD PPS; Medicare Part D Standard Analytic File (SAF); 100 percent SAF for physician services; and Medicare Part C SAF.

Response: We agree with commenters that transparency in rate setting is desirable. We posted the provider-level impact file with the proposed rule because we believe that furnishing an impact file, sorted by facility, is the most transparent method and enables facilities to assess the economic impact of policy changes at the facility level. In addition, beginning in CY 2015, we have made a Limited Data Set (LDS) of ESRD PPS facility claims used for CY 2015 rate settings available for purchase. A link to the LDS file was included in our proposed rule in section XIX titled Files Available to the Public via the Internet (79 FR 40311). Likewise, we included an updated LDS file with this final rule that is discussed in section XIX of this rule. The LDS files are available for purchase at http://www.cms.gov/research-statistics-data-and=systems/files-for-order/limiteddatasets/endstagerenal diseasesystemfile.html.
We note that interested parties may request Part D data from CMS at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/GuidePartD, and we will consider furnishing encounter data under Medicare Part C, and other Medicare claims files in the future.

b. Payment Rate Update for CY 2015

As discussed in section II.A of this final 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. In accordance with section 1881(b)(14)(F)(i)(III) of the Act, as added by PAMA section 217(b)(2)(C), we are finalizing a 0.0 percent update to the CY 2014 ESRD PPS base rate of $239.02 for CY 2015.

Comment: Generally, commenters were supportive of the CY 2015 proposed base rate. Some commenters cautioned that CMS "maintain financial integrity" of the ESRD PPS by addressing crucial components of the payment system that inappropriately reduce the base rate. A few commenters identified the ESRD PPS payment components of case-mix and the outlier policy as examples of payment adjustments that they believe are structurally broken. The commenters contend that these adjustments result in lowering overall payments to facilities, making it difficult for facilities to furnish high quality care to patients.

Response: We thank the commenters for their support of the proposed CY 2015 ESRD PPS base rate. While we do not agree with the commenters who contend that the case-mix and outlier adjustments are structurally broken, we believe that these adjustments have been underutilized in the payment system. We note that section 632 of ATRA requires CMS to review the case-mix payment adjustments and make appropriate modifications by CY 2016. We will consider these comments as part of that larger ESRD PPS refinement that will take place for CY 2016.

Comment: Other commenters cautioned CMS to correct what they term "flaws in standardization," calling upon CMS to use the most current data available in re-calculating the standardization factor in this final rule in order to mitigate losses facilities may have in CY

2015. As an alternative, commenters suggest that CMS make an interim reduction to the adjustor values that would take into account the decrease in drug utilization. With these values, CMS could reduce the dollars in the standardization factor for CY 2015. They estimated that the standardization factor discrepancy accounts for a loss of one to two percent in the base rate.

They also suggested that for 2015, CMS: (1) eliminate the co-morbidity case-mix adjustments because the facilities are unable to obtain the necessary documentation to substantiate a co-morbid diagnosis and thus, are unable to claim the adjustment; and (2) reduce the outlier percentage so that it reflects the percentage of cases paid as outlier cases (0.5 percent) and so that it is paid out annually in its entirety, or else provide for a zero percent outlier policy.

Response: We thank the commenters for their suggestions for protecting the integrity of the base rate and questioning the necessity for some payment adjustments available under the ESRD PPS. However, as we stated in the CY 2011 ESRD PPS final rule (75 FR 49081), to account for the overall effects of the proposed ESRD PPS patient- and facility-level adjustment factors and wage indexes, we had to standardize payments in order to ensure that total projected PPS payments were equal to what would otherwise have been paid had the ESRD PPS not been implemented, prior to application of the 98 percent budget-neutrality adjustment. The standardization factor was calculated by dividing total estimated payments in 2011 under the basic case-mix adjusted composite rate payment system by estimated payments under the final ESRD PPS in 2011.

We wish to remind commenters that we used the best data available for the development of the standardization factor and made a good faith effort to simulate payments under the ESRD PPS beginning in CY 2011. In addition, CMS plans to conduct a regression analysis for the CY 2016 ESRD PPS rulemaking cycle to reassess the appropriateness of the patient- and facility-

level payment adjustments applied under the ESRD PPS. This analysis will include a thoughtful assessment of utilization and economic impact of the various payment adjustments under the PPS to determine whether they should continue to apply, or if the magnitude of the adjustments is over or understated in the ESRD PPS.

We plan to consider all of the improvements suggested as part of the ESRD PPS refinement for CY 2016. We do not think it would be appropriate to eliminate any co-morbidity adjustments in isolation from a broader refinement that assesses all current and potentially significant adjustments.

c. CY 2015 ESRD PPS Wage Index Budget-Neutrality Adjustment

As discussed in section II.C of this final rule, for CY 2015 we apply the wage index budget-neutrality adjustment factor of 1.001729 to the CY 2014 ESRD PPS base rate (that is, $239.02), yielding a CY 2015 ESRD PPS wage index budget-neutrality adjusted base rate of $239.43 ($239.02 x 1.001729 = $239.43).

Comment: Commenters were supportive of the CY 2015 proposed wage index budget-neutrality adjustment. A few commenters noted the small payment increase for CY 2015, and thanked CMS for continuing to apply an updated wage index budget-neutrality adjustment in a year where a 0.0 percent market basket update was congressionally mandated.

Response: We thank the commenters for their support of our finalized wage index budget-neutrality factor, and note that the wage index budget-neutrality update is computed separately from the annual market basket update. Therefore, the wage index budget-neutrality update continues to apply even in years when a 0.0 market basket update is statutorily required.

d. Labor-Related Share

As discussed in section II.C.2 of this final rule, as part of the ESRDB market basket

rebase and revision, we are updating the labor-related share from 41.737 percent to 50.673 percent. We noted that some ESRD facilities are adversely affected by this update. For example, rural facilities and facilities located in core-based statistical areas (CBSA) with wage indexes below 1.0 will experience reduced payments due to an increase in the labor-related share, while other facilities located in CBSAs where wage indices are above 1.0 will experience increased payments. While we are finalizing the new labor-related share of 50.673 percent, we shall implement this value using a 2-year transition.

Therefore, for CY 2015 we will apply 50 percent of the value of the current labor-related share under the ESRD PPS (41.737 percent) and 50 percent of the value of the new labor-related share (50.673 percent), add the percentages together and divide by two, for a CY 2015 labor-related share of 46.205 percent ((41.737 +50.673)/2 = 46.205). Beginning in CY 2016, we will apply 100 percent of the total labor-related share of 50.673 percent. We shall continue to apply a labor-related share of 50.673 percent in computing a wage index-adjusted base rate for ESRD facilities until such time in the future the ESRDB market basket is again rebased or revised. This approach is similar to the transition finalized for the CY 2015 wage indexes and discussed in section II.3 of this final rule, and is intended to allow ESRD facilities time to adjust to the new labor-related share.

Comment: While the majority of commenters supported the updated labor-related share, some commenters expressed concern regarding the negative impact for rural facilities and any facility with a wage index value of less than 1.0, and noted that they will experience reduced ESRD PPS payments in CY 2015 as a result of the updated labor-related share. A few commenters contended that this update would be better received during a larger payment system refinement and encouraged CMS to delay the ESRDB market basket update, with the new labor-

related share, until CY 2016 where negative impacts could be offset with other payment system refinements. Another commenter noted that if the ESRDB market basket update was delayed until CY 2016, 2012 audited cost reports would be available to ensure better accuracy. The commenter noted that the PAMA legislation mandated the audits and provided $18 million to fund the effort.

Response: We thank the commenters for their support of our updated labor-related share. We share stakeholders' concern for negatively impacted facilities. Moreover, we agree with commenters that delaying the ESRDB market basket update until CY 2016 may have the advantage of offsetting some of the negative impact indicated in section XIV of this final rule. However, we believe the labor-related share has been undervalued in the payment system, especially after the ATRA drug utilization reduction finalized in the ESRD PPS CY 2014 final rule (78 FR 72161through 72170). Therefore, we are finalizing a labor-related share of 46.205 percent for CY 2015 and a labor-related share of 50.673 percent for CY 2016 and until such time in the future the labor-related share is updated.

Lastly, we wish to clarify for commenters that the audits of Medicare cost reports beginning during 2012 will not be available for CY 2016 rulemaking. Any cost report findings resulting from the statutorily-mandated audits of Medicare cost reports beginning during 2012 will be available for future ESRDB market basket updates.

Comment: Many commenters supported the update to the labor-related share and the 2-year transition to dampen the immediate impact of the change. A few commenters thanked CMS for appropriately recognizing shifting costs in furnishing dialysis services from drugs to labor.

Response: We thank the commenters for their support and note that we considered implementing the full amount of the revised labor-related share percentage of 50.673 for CY

2015, but that would have increased the CY 2015 proposed wage index budget-neutrality factor. Such an increase would have resulted in a further decrease in CY 2015 Medicare payments to rural facilities, and an additional increase to urban facilities. When we apply the transition labor-related share of 46.205 percent the disparity in impacts for rural and urban facilities is reduced, resulting in a more stable economic environment for all facilities in general. We believe that offsetting the negative economic impact for rural facilities with the 2-year transition for the labor-share will enhance access to quality care for Medicare beneficiaries living in rural communities. (For more information of the CY 2015 Impact of Changes in Payments to ESRD Facilities for CY 2015 ESRD final rule, see section XIV of this final 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 rural and urban facilities in low wage index areas time to adjust to the new labor-related share.

Comment: A few commenters requested that CMS consider a longer transition to further mitigate the financial pressures on rural providers. One commenter encouraged CMS to provide a longer transition period, "such as 3 or 4 years." Another commenter encouraged CMS to extend the transition to 3 years to give rural facilities more time to adjust to the lower reimbursement and "get them closer to the end of the PAMA cuts."

Response: We thank the commenters for their concern for the economic impacts on rural and urban facilities located in areas with low wage indices. In addition, we acknowledge the commenter's suggestion to extend the transition period to 3 or 4 years to allow disadvantaged facilities time to adjust to the new labor-related share percentage. However, we continue to believe a 2-year transition strikes an appropriate balance between allowing ESRD facilities time to adjust to the new labor-related share while appropriately accounting for facility costs

associated with labor in furnishing renal dialysis services.

In summary, we are finalizing a CY 2015 ESRD PPS base rate of $239.43. This reflects, updated claims data used for rate setting, a 0.0 percent payment update consistent with section 1881(b)(14)(F)(i)(III) of the Act, as added by section 217(b)(2) of PAMA, a 2-year transition for the labor related share(46.205 percent for CY 2015 and 50.673 for CY 2016), and the CY 2015 wage index budget-neutrality adjustment factor of 1.001729.

2. ESRD Bundled Market Basket and Labor-Related Share

a. Rebasing and Revision of the ESRD Bundled Market Basket

In July, we proposed to rebase and revise the ESRD Bundled (ESRDB) market basket for CY 2015. 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 ESRDB 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 the CY 2015 ESRD proposed rule, we proposed to rebase and revise the ESRDB market basket for CY 2015, in accordance with, section 1881(b)(14)(F)(i) of the Act, which 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. The multi-factor productivity adjustment is applied to the ESRDB market basket update under the requirements of sections 1881(b)(14)(F)(i)(II) and 1886(b)(3)(B)(xi)(II) of the Act.

The 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 necessary for providing renal dialysis services. For further background information, see the CY 2011 final rule with comment period (75 FR 49151 through 49162).

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.

The market basket is constructed in three main 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 proxy index level for each spending category by the cost weight for that category. The sum of these products (that is, cost 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.

We proposed to use CY 2012 as the base year for the rebased and revised ESRDB market basket cost weights. The cost weights 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) for Kidney Dialysis Centers (NAICS 621492). 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.

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, we proposed 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 proposed both to rebase and revise the ESRDB market basket.

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

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 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 proposed 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 applied 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). For more information on the SAS data, see http://www.census.gov/services/sas/about_the_surveys.html.

We proposed to include a total of 20 detailed cost categories in the CY 2012-based ESRDB market basket, which is four more cost categories than the CY 2008-based ESRDB market basket. In addition, we proposed 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 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 also proposed 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. In addition, we proposed 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.

i. Cost Category Weights

Using Worksheets A and B from the CY 2012 Medicare cost reports, we 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 can be found in the CY 2015 Proposed Rule (79 FR 40217)

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 also proposed 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. For a detailed description of how the costs were further refined to yield the proposed 2012-based ESRDB cost weights please see (79 FR 40217 through 40221).

Table 1 lists all of the cost categories and cost weights in the CY 2012-based ESRDB market basket compared to the cost categories and cost weights in the CY 2008-based ESRDB market basket.

TABLE 1: COMPARISON OF THE CY 2012-BASED ESRDB MARKET BASKET COST CATEGORIES & WEIGHTS AND THE CY 2008-BASED ESRDB MARKET BASKET COST CATAGORIES & WEIGHTS.

2008 Cost Category	2008 Cost Weight	2012 Cost Weight	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
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. Price Proxies for the CY 2012 ESRDB Market Basket

For each cost category in the CY 2012-based ESRDB market basket, we selected the most appropriate wage and price proxies that measure the rate of price change for each expenditure category. An explanation of our rationale for the proposed price proxies used for each cost category can be found in the proposed rule (79 FR 40221 through 40224). With the exception of the pharmaceuticals cost category, all of the price proxies we proposed to use for each cost category weight are the same in this final rule. We based the price proxies on Bureau of Labor Statistics (BLS) data and grouped them into one of the following BLS categories:

- Employment Cost Indexes. Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour.

- 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.

- Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. 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.
- Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this ensures that the market basket updates are as transparent to the public as possible.
- Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

Pharmaceuticals

In the CY 2015 proposed rule, we proposed to change the price proxy used for the pharmaceuticals cost category from the one used for the 2008-based ESRDB market basket – the PPI: Pharmaceuticals for Human Use, Prescription (79 FR 40223). We referenced a recent Health and Human Services Office of the Inspector General (OIG) report titled "Update: Medicare Payment for End Stage Renal Disease Drugs" which 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]

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

Drug acquisition cost data is not publicly available, nor are 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 proposed to use the PPI: Vitamin, Nutrient, and Hematinic Preparations (BLS series code #WPU063807).

Based on public comments and, for the reasons articulated below in comments and responses, we have decided to finalize a price proxy blend as the price proxy for the pharmaceutical cost category. The blend we are using is 22 percent PPI: Vitamin, Nutrient, and Hematinic Preparations (BLS series code #WPU063807) and 78 percent PPI: Biological Products, Human Use (BLS series code #WPU063719). Table 2 lists all price proxies for the revised and rebased ESRDB market basket.

TABLE 2: 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%

Cost Category	Price Proxy	Cost Weight
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	Blend of PPI Biological Products for Human Use and 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 percent due to rounding

iii. 2012-Based ESRDB Market Basket Updates Compared to 2008-Based ESRDB Market Basket Updates

Beginning with the CY 2015 ESRD PPS update, we proposed 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 proposed CY 2012-based ESRDB market basket for CY

2015 was 2.0 percent while the proposed CY 2008-based ESRDB market basket for CY 2015 was 2.7 percent.

Table 3 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 was -1.8 percentage points. This is primarily the result of the proposed lower pharmaceutical cost share weight combined with the proposed revised price proxy for the pharmaceutical cost category. For the CY 2014 and CY 2015 forecasts, the differences in the market basket forecasts are mainly driven by the same factors as in the historical period.

TABLE 3: PROPOSED CY 2012-BASED ESRDB MARKET BASKET and CY 2008 BASED ESRDB MARKET BASKET, PERCENT CHANGES: 2011-2015

Calendar Year (CY)	Proposed 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
CY 2015	2.0	2.7

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

b. 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) of the Act 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 was 0.0 percent. We note that the proposed 2012-based ESRDB market basket update less the productivity adjustment for CY 2015 would have been 1.6 percent, or 2.0 percent less 0.4 percentage point, based on IGI's 1st quarter 2014 forecast of the ESRDB market basket and MFP.

c. 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 proposed to use the 2012-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities of 50.673 percent, as shown in Table 4 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 4: 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 proposed 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).

d. Responses to Comments on Proposed Market Basket Rebasing & Revision

Comment: Many commenters support rebasing the ESRDB market basket using the most current and accurate data that are available. Most commenters stated that an updated base year allows the market basket to better reflect the relative costs of running an ESRD facility under the PPS and accurately captures the decline in dialysis drug use that has occurred since 2008 (the base year of the current market basket).

Response: We thank the commenters who supported the rebasing of the ESRDB market basket to reflect cost data for 2012. The 2012 MCR data is the first year of data available under the bundled PPS system and reflects the changes to the relative costs associated with furnishing ESRD treatments. We agree that the decline in dialysis drug use since 2008 and its subsequent impact on the relative costs of other goods and services is an important update to consider when estimating price pressures faced by providers.

Comment: Several commenters requested that CMS delay the market basket rebasing until CY2016 so that the rebasing weights could be based on 2012 audited cost report data instead of the proposed unaudited reports. One commenter claimed that audits have historically shown that facilities' cost reports have included unallowable costs that either overstate or understate provider costs. They believe these errors could change the results of the cost share weights derived from the market basket data.

Response: We disagree with the commenters that the market basket rebasing should be delayed until CY 2016 in order to use audited cost report data rather than the unaudited reports.

First, the audits will begin in fiscal year 2015 and the processing and analysis of the audited data could take several years to complete and therefore would not be available to use for the CY 2016 updates. Additionally, although the audits might lead to different cost levels reported by some providers, we don't believe that different levels would result in substantial variation in the relative cost share weights derived from the unaudited data since the cost weights are based on shares of the total rather than on levels. Additionally the weights are derived from all providers and therefore for a change to appear in the market basket cost shares the misreporting would have to be prevalent across a significant percentage of providers. Therefore, we do not agree the upcoming audits are a reason to delay the update to the market basket weights for CY 2015. We believe the use of the 2012 Medicare Cost Report data to be a technical improvement to the use of the 2008 ESRD relative cost shares.

Comment: One commenter believes that rebasing the market basket goes against the intent of PAMA since the rebasing will result in decreased payments to some providers and increased payments to others. They believe that PAMA was passed to mitigate the adjustment to ESRD bundled payments for all dialysis facilities by dictating a market basket update for CY 2015 through 2018.

Response: The CY 2015 ESRD PPS update will be 0.0 percent as mandated by PAMA. For CY 2016 through CY 2018, PAMA mandates a reduction to the market basket increase to the ESRD PPS payment updates. PAMA did not specify what the annual updates would be for those years. It is critical that CMS estimate an appropriate market basket increase that reflects the inputs used to furnish ESRD treatments in order for the legislatively required reductions to be applied in CYs 2016 through 2018.

Comment: One commenter believes that the difference in the market basket rate using the 2008 data versus the 2012 data is significant. They compared rules where market basket rebasings have been proposed and finalized for other providers such as hospital and home health and found that the rebasings did not result in significant changes in current or historical market basket updates.

Response: We agree with the commenter that the rebasing of other market baskets has not, historically, resulted in significant changes to the market basket update rate. However, between 2008 and 2012 the dialysis market experienced considerable changes. Most notable was the change in the relative cost of pharmaceuticals; specifically, the cost category weight dropped from 25.052 percent to 16.510 percent, due largely to decreases in drug utilization. In addition, we updated the price proxy associated with the pharmaceutical cost category based in part on the recommendation of a Health and Human Services Office of the Inspector General (OIG) report titled "Update: Medicare Payment for End Stage Renal Disease Drugs." The combined changes to the pharmaceutical cost weight and the update of the pharmaceutical price proxy are the primary drivers of the changes to the market basket updates. For CY 2015, we note that the changes to the cost share weights from 2008 to 2012 account for about 50 percent of the difference while the change to the price proxy, as finalized, accounts for the other 50 percent of the difference.

Comment: One commenter requested clarification on several of the cost category calculations based on MCR data. First, the commenter requested we review the "Administrative and General" (A&G) and "Wages & Salaries" cost categories. The commenter specifically requested that CMS clarify the source of the percentage of non-direct wages associated with A&G that are obtained from Sheet A of the MCR as well as verify the method used on worksheet

B to estimate total costs for each cost center. Second, the commenter requested that CMS clarify whether estimated salary costs for capital-related machinery were reallocated to salaries or if they were not.

Response: Below we clarify the calculation of the Wages & Salaries cost share methodology as well as the method for inclusion of the Capital-Related Machinery cost center into the moveable capital cost share weight.

To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from worksheet A of the MCR. The estimated ratios were calculated as the ratio of salary costs (worksheet A, columns 1 & 2) to total costs (worksheet A, column 4). The ratios were calculated for seven distinct cost centers: 'Operations & Maintenance' combined with 'Machinery & Rental & Maintenance' (line 3 & 6), Housekeeping (line 4), EH&W Benefits for Direct Pt. Care (line 8), Supplies (line 9), Laboratory (line 10), Administrative & General (line 11), and Drugs (line 12). Each of the ratios for the seven cost centers was applied to the corresponding reimbursable costs center totals as reported on worksheet B. The worksheet B totals were based on the sum of reimbursable costs reported on lines 8-17. We did not use line 18, the subtotal line, as the commenter presumes. For example, the salary percentage for supplies (as measured by line 9 on worksheet A) was applied to the total expenses for the supply cost center (the sum of costs reported on worksheet B, column 7, lines 8-17).

Regarding the calculation of costs associated with 'Machinery & Rental & Maintenance', the estimated salary ratio for this category was calculated jointly with the ratio for 'Operations & Maintenance' expenses. Therefore the same ratio was applied to 'Operations & Maintenance' and 'Machinery & Rental & Maintenance'. This ratio was applied to the total of worksheet B,

column 4, lines 8-17. The salaries associated with the 'Machinery & Rental & Maintenance' costs were added to 'Total Salaries'. The remaining costs reported in worksheet B column 4, line 8-17 were considered moveable capital-related expenses (excluding salaries). We believe, the commenter's confusion was the result of the estimated salary share for the capital 'Machinery & Rental & Maintenance' costs being combined with the operation and maintenance costs before being added to salaries rather than being added separately. We hope this clarifies that the salary portion of 'Machinery & Rental & Maintenance' costs follows the same method as all other cost centers.

Comment: One commenter requested CMS revisit the allocation of laboratory costs from A&G once some of the providers have re-filed their cost reports. The commenter recommends that CMS not allocate A&G to the laboratory cost center and apply the lab price proxy only to directly reported lab costs. They note that allocating A&G to laboratory costs would overstate the proportion of lab costs based upon their understanding as to how some providers will allocate these costs once they re-file the cost reports.

Response: The lab costs included in the lab category in the rebased and revised ESRDB market basket do not include any allocation of administrative and general (A&G) costs. The costs are calculated based on lab expenses reported on Medicare Cost Report, worksheet B, lines 8-17, and column 8. We did not allocate any A&G costs to the lab category for the 2012 cost shares.

Comment: One commenter noted that what goes into each of the provided categories is not standardized. They believe that CMS should use consistent information from all providers to ensure the accuracy of the data. They note that smaller dialysis facilities, especially those in rural areas, will likely struggle to collect the information required to be reported on the MCR.

Response: We are sensitive to all reasonable cost report data being included in the calculation of the market basket cost share weights. We perform various trimming techniques to estimate the variability in the cost share weight results. Trimming the data removes providers that may have misreported costs or are extreme outliers. We analyze the results of the cost share weights for various samples of providers to ensure reasonability of the overall cost share weights. We also compare the results to other publicly available data sources for reasonableness of results. Our trimming methods rely on relative share outliers rather than dollar level outliers. Therefore, smaller dialysis facilities are subject to similar criteria as larger facilities to be included or excluded based on trimming methods. For example, we would exclude a provider in a 5 percent trim if the cost weight for the wages and salaries was plus or minus 2 standard deviations from the mean cost weight of all providers for wages and salaries. If costs are significantly misreported we are unable to use the data, as submitted. It is the facility's responsibility to work with the MACs to ensure proper reporting.

Comment: One commenter is concerned with CMS re-apportioning certain costs and increasing the labor-related share of the ESRD PPS base rate. The commenter notes that they have one of the lowest CBSA wage indexes in the continental United States and are therefore impacted adversely when the labor-related share increases. Their concern is based on CMS's reliance upon assumptions to re-apportion certain costs. The commenter believes these cost assumptions may not accurately reflect the percentage of the ESRD PPS base rate impacted by the wage rate. The commenter recommends that CMS determine how it may best collect specific data on the labor-related cost categories where CMS currently relies on assumptions.

Response: We believe the assumptions that we have made in determining the labor-related share are reasonable and follow a similar methodology and assumptions used in other

CMS PPS payment systems. The commenter's recommendation to review how we may gather detailed information on the ESRD PPS's labor-related cost categories is helpful in identifying future research opportunities. As part of CMS's ongoing efforts to update and refine the Medicare Cost Reports we can explore the opportunities for collecting more specific information. Beyond the Medicare Cost Reports, we can explore conducting new surveys that would help determine the costs that are influenced or vary with the local labor market, although these are subject to resource availability and approval through OMB's standard survey and auditing process (see "Standards and Guidelines for Statistical Surveys" http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/statpolicy/standards_stat_surveys.pdf and "Guidance on Agency Survey and Statistical Information Collections" http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/pmc_survey_guidance_2006.pdf).

Comment: Many commenters disagreed with the proposed price proxy for the drug cost category in the ESRDB market basket. They requested we reconsider the proposed proxy and use either a more appropriate index: the PPI Biological Products, Human Use (PPI-BPHU), or a composite proxy that would better reflect the costs of drugs and biologicals that are included in the ESRD bundle. Some commenters noted that ESAs account for over 80 percent of drug expenses and noted they are supplied by a sole source manufacturer that routinely imposes product price increases on facilities. Some commenters further point out that since ESAs are fully represented in, the PPI-BPHU, it is more relevant than the PPI Vitamin, Nutrient, & Hematinic Preparations (PPI-VNHP). Some commenters agreed that the PPI–Pharmaceutical for Human Use, Prescription (PPI-RX) is likely not the most appropriate proxy since it does not track well with the acquisition costs for ESRD drugs, as documented by the OIG study. Another

commenter notes that the drugs in the PPI-VHNP include non-prescription (over-the-counter) medicines.

Response: Given concerns raised by commenters and further analysis into the appropriateness of the proposed price proxy, we agree with the commenters that the proposed PPI-VNHP suffers some shortcomings that can be mitigated if we were to use the PPI –BPHU. Most importantly, the PPI-BPHU measures the price change of drugs that are prescriptions, and ESAs would be captured within this index if they are included in the PPI sample (although, because the PPI relies on confidentiality with respect to the companies and drugs/biologicals included in the sample, we do not know if these drugs are indeed reflected in this price index). However, we believe the PPI-BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI-BPHU. We did this by comparing the historical price changes in the PPI-BPHU and the ASP for ESAs and found the cumulative growth to be consistent over several years. We will continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI-BPHU is still an appropriate price proxy.

On the other hand, since the non-ESA drugs used in the treatment of ESRD are mainly vitamins and nutrients, we believe that the PPI–VNHP is the best available proxy for these types of drugs. While this index does include over-the-counter drugs as well as prescription drugs, a comparison of trends in the prices for non-ESA drugs shows growth to the proposed PPI-VNHP.

Therefore we think it is appropriate to use both the PPI-VNHP and the PPI-BPHU, and we will proxy the price change for drugs included in the ESRD bundle by a blended drug price proxy with 78 percent of the index measured by the PPI–BPHU and 22 percent of the index

measured by the PPI–VNHP. The shares within the blend are based on the 2012 ESRD Part B spending for ESA and non-ESA drugs included in the bundle. ESA drugs are those considered as a form of epoeitin alpha while the non-ESA drugs are the remaining drugs specified in the ESRD bundle.

Comment: One commenter claims that the OIG criticism of the current index as the drug price proxy – the PPI Pharmaceuticals for Human Use, Prescription – was based on a retrospective analysis of drugs price trends during a narrow 3-year window at a significant time of transition in the ESRD marketplace. They claim that if the OIG looked at a broader window of time (for example, 2003-2012), it would likely show that the PPI for prescription drugs has more closely tracked to cost changes for most drugs within the ESRD PPS. They note the OIG raised concerns with the use of the PPI-RX prior to the implementation of the ESRD PPS and CMS did not concur with the recommendation at that time and they noted that the OIGs figures were not suitable for inferring future price trends. The commenter recommends that CMS continue to use the PPI-RX as the proxy.

Response: At the time of the implementation of the ESRD market basket, we proposed and finalized the use of the PPI-RX since it is the proxy used in other CMS market baskets to proxy drug price growth and it would be representative of the average prescription drug price increase for the overall prescription drug market. However, analysis of the pricing trends of the drugs used in furnishing ESRD care (either the acquisition costs collected by OIG or by ASP data as collected by CMS) show relatively flat price growth over the 2008 – 2014 period (when taken on average) while the PPI RX has grown at a much faster rate. Additionally, there are a limited number of drugs included in the ESRD bundle and those drugs are mainly defined as biological products which are not captured in the PPI-RX. Therefore, as explained in the

proposed rule, we do not believe that the PPI-RX should continue to be used in the ESRDB market basket.

Comment: One commenter recommended that the pharmaceutical price proxy changes be suspended and CMS follow the OIG recommendation to determine how drug acquisition costs may be taken into consideration when updating the ESRD PPS base rate.

Response: The direct use of drug acquisition costs in the ESRD market basket is not possible, as noted in our response to the OIG recommendation: "We will consider these findings in our continual evaluation of the ESRD market basket, particularly during the next rebasing and revising of the index. As we have done for all of the market baskets developed by CMS, we will base the decision on which price proxy is used on four criteria: reliability, timeliness, availability, and relevance. We will be evaluating alternative data sources and methods to determine if we can improve the relevance of the ESRD drug price proxy while not sacrificing on the other three requirements. For instance, the data used in the OIG analysis is based on acquisition cost data, which is not data that is readily available in a public or timely manner. Additionally, the ESRD annual market basket updates are based on a projection and any price proxy ultimately will need to be forecasted. The more restrictive or specific a price series, the more difficult it can be to accurately forecast future price movements. Finally, the price proxy should also reflect price trends associated with an efficient market; therefore, to the extent market inefficiencies exist, there would be concerns with using direct cost or price data."2

Comment: Several commenters relayed the concern that CMS is making changes to the market basket that exacerbate the payment problems particularly for rural and low volume facilities while not contemporaneously addressing other changes to the ESRD payment. Other

2 https://oig.hhs.gov/oei/reports/oei-03-12-00550.pdf, Appendix D

commenters support the proposed revised labor-related share as it reflects the proportionate decline over the past three years in EPO utilization. They recognize the impact on nonprofit and small providers with wage adjustors less than 1.0, and therefore support a 2-year transition for labor changes and updated CBSAs.

Response: We believe that the proposed 2012-based ESRDB market basket is a technical improvement to the 2008-based ESRDB market basket and therefore should be implemented in CY 2015. A transition policy, for the revised labor-related share, was proposed and finalized that will help to mitigate the impact to providers for any given year.

e. Final ESRDB Market Basket and Labor-Related Share

In summary, we are finalizing the rebasing and revision of the ESRDB market basket effective for CY 2015. The cost share weights will be based on the 2012 cost shares detailed in the proposed rule (79 FR 40217 through 40221) and presented in this final rule. We are also finalizing a labor-related share of 50.673 percent as detailed in the proposed rule (79 FR 40225 through 40226) and presented in this final rule.

We are finalizing all price proxies, as proposed, with the exception of the price proxy for the pharmaceutical cost category. As detailed in our response to comments, we believe that the PPI-VNHP suffers some shortcomings that can be mitigated with the use of the PPI-BPHU, particularly for the ESA drugs. We will, however, continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI-BPHU is still an appropriate price proxy given the unique market conditions related to the manufacturing and production of these types of drugs. On the other hand we will use the PPI–VNHP for the remaining drugs included in the ESRDB market basket. While this index does include over-the-counter drugs as well as prescription drugs, a comparison of trends in the prices for non-ESA

drugs shows growth similar to the PPI-VNHP. Therefore, we are finalizing a blend of the PPI Biological Products, Human Use (PPI-BPHU) and the PPI Vitamin, Nutrient, & Hematinic Preparations (PPI-VNHP). The weights within the blend are based on 2012 estimated ESRD Part B spending for the drugs used in the bundle, which results in a split of 78 percent for ESAs (proxied by the PPI-BPHU) and 22 percent for non-ESAs (proxied by the PPI-VNHP).

Section 1881(b)(14)(F)(i)(III) of the Act, as added by section 217(b)(2) of PAMA requires a 0.0 percent market basket less productivity update for CY 2015. We are therefore finalizing 0.0 percent as the ESRDB market basket update less productivity adjustment for CY 2015. In the absence of PAMA, the CY2015 ESRDB market basket update less productivity would be 1.6 percent (2.1 percent market basket update less 0.5 percent MFP adjustment), based on the IHS Global Insight, Inc. (IGI) third quarter 2014 forecast with historical data through the second quarter of 2014. Table 5 compares the update of the proposed market basket to the final market basket; the only difference between the two arises from the change to the pharmaceutical price proxy.

TABLE 5: FINAL CY 2012-BASED ESRDB AND PROPOSED CY 2012-BASED ESRDB MARKET BASKET, PERCENT CHANGES: 2011-2015

Calendar Year (CY)	Final CY 2012-based ESRDB Market Basket	Final CY 2012-based ESRDB Market Basket
Historical data:		
2011	1.2	1.7
2012	1.4	1.5
2013	1.1	1.4
Average CY 2011-2013	*1.2*	*1.5*
Forecast:		
2014	1.4	1.6
2015	2.0	2.1

Source: IHS Global Insight, Inc. 3rd quarter 2014 forecast with historical data through 2nd quarter 2014

3. The 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 sections 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. 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 through 37252) and Census Bureau data." In this CY 2015 ESRD PPS final 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 final rule(79 FR 49951 through 49963), we finalized the implementation of the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13-01, beginning with the FY 2015 IPPS wage index. Similarly, in this CY 2015 ESRD PPS final rule, we are finalizing 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 final 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, 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 will become urban, beginning January 1, 2015, will generally experience an increase in their wage index values. We identified approximately 100 counties and 110 facilities that will move from rural to urban status when we adopt the new CBSA delineations beginning in CY 2015. Table 6: (CY 2015 Rural to Urban CBSA Crosswalk) shows the CBSA delineations for CY 2014 and the rural wage index values for CY 2015 based on those delineations, compared to the final CBSA delineations for CY 2015 and the urban wage index values for CY 2015 based on the new delineations, and the percentage change in these values for those counties that will change from rural to urban when we adopt the new CBSA delineations. Approximately 100 facilities will experience an increase in their wage index values.

TABLE 6: CY 2015 RURAL to URBAN CBSA CROSSWALK

County Name	State	ESRD PPS CY 2014 CBSA delineations			Final 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	0.6963	19300	URBAN	0.7248	4.09%
PICKENS	AL	01	RURAL	0.6963	46220	URBAN	0.8337	19.73%
COCHISE	AZ	03	RURAL	0.9125	43420	URBAN	0.8937	-2.06%
LITTLE RIVER	AR	04	RURAL	0.7311	45500	URBAN	0.7362	0.70%
WINDHAM	CT	07	RURAL	1.1251	49340	URBAN	1.1493	2.15%
SUSSEX	DE	08	RURAL	1.0261	41540	URBAN	0.9289	-9.47%
CITRUS	FL	10	RURAL	0.8006	26140	URBAN	0.7625	-4.76%
GULF	FL	10	RURAL	0.8006	37460	URBAN	0.7906	-1.25%
HIGHLANDS	FL	10	RURAL	0.8006	42700	URBAN	0.7982	-0.30%
SUMTER	FL	10	RURAL	0.8006	45540	URBAN	0.8095	1.11%
WALTON	FL	10	RURAL	0.8006	18880	URBAN	0.8156	1.87%
LINCOLN	GA	11	RURAL	0.7425	12260	URBAN	0.9225	24.24%
MORGAN	GA	11	RURAL	0.7425	12060	URBAN	0.9369	26.18%
PEACH	GA	11	RURAL	0.7425	47580	URBAN	0.7542	1.58%
PULASKI	GA	11	RURAL	0.7425	47580	URBAN	0.7542	1.58%
KALAWAO	HI	12	RURAL	1.0741	27980	URBAN	1.0561	-1.68%
MAUI	HI	12	RURAL	1.0741	27980	URBAN	1.0561	-1.68%
BUTTE	ID	13	RURAL	0.7398	26820	URBAN	0.8933	20.75%
DE WITT	IL	14	RURAL	0.8362	14010	URBAN	0.9165	9.60%
JACKSON	IL	14	RURAL	0.8362	16060	URBAN	0.8324	-0.45%
WILLIAMSON	IL	14	RURAL	0.8362	16060	URBAN	0.8324	-0.45%
SCOTT	IN	15	RURAL	0.8416	31140	URBAN	0.8605	2.25%
UNION	IN	15	RURAL	0.8416	17140	URBAN	0.9473	12.56%
PLYMOUTH	IA	16	RURAL	0.8451	43580	URBAN	0.8915	5.49%
KINGMAN	KS	17	RURAL	0.7806	48620	URBAN	0.8472	8.53%
ALLEN	KY	18	RURAL	0.7744	14540	URBAN	0.8410	8.60%
BUTLER	KY	18	RURAL	0.7744	14540	URBAN	0.8410	8.60%
ACADIA	LA	19	RURAL	0.7580	29180	URBAN	0.7869	3.81%
IBERIA	LA	19	RURAL	0.7580	29180	URBAN	0.7869	3.81%
ST. JAMES	LA	19	RURAL	0.7580	35380	URBAN	0.8821	16.37%
TANGIPAHOA	LA	19	RURAL	0.7580	25220	URBAN	0.9452	24.70%
VERMILION	LA	19	RURAL	0.7580	29180	URBAN	0.7869	3.81%
WEBSTER	LA	19	RURAL	0.7580	43340	URBAN	0.8325	9.83%
ST. MARYS	MD	21	RURAL	0.8554	15680	URBAN	0.8593	0.46%
WORCESTER	MD	21	RURAL	0.8554	41540	URBAN	0.9289	8.59%
MIDLAND	MI	23	RURAL	0.8207	33220	URBAN	0.7935	-3.31%
MONTCALM	MI	23	RURAL	0.8207	24340	URBAN	0.8799	7.21%

FILLMORE	MN	24	RURAL	0.9124	40340	URBAN	1.1398	24.92%
LE SUEUR	MN	24	RURAL	0.9124	33460	URBAN	1.1196	22.71%
MILLE LACS	MN	24	RURAL	0.9124	33460	URBAN	1.1196	22.71%
SIBLEY	MN	24	RURAL	0.9124	33460	URBAN	1.1196	22.71%
BENTON	MS	25	RURAL	0.7589	32820	URBAN	0.8991	18.47%
YAZOO	MS	25	RURAL	0.7589	27140	URBAN	0.7891	3.98%
GOLDEN VALLEY	MT	27	RURAL	0.9024	13740	URBAN	0.8686	-3.75%
HALL	NE	28	RURAL	0.8924	24260	URBAN	0.9219	3.31%
HAMILTON	NE	28	RURAL	0.8924	24260	URBAN	0.9219	3.31%
HOWARD	NE	28	RURAL	0.8924	24260	URBAN	0.9219	3.31%
MERRICK	NE	28	RURAL	0.8924	24260	URBAN	0.9219	3.31%
JEFFERSON	NY	33	RURAL	0.8208	48060	URBAN	0.8386	2.17%
YATES	NY	33	RURAL	0.8208	40380	URBAN	0.8750	6.60%
CRAVEN	NC	34	RURAL	0.7995	35100	URBAN	0.8994	12.50%
DAVIDSON	NC	34	RURAL	0.7995	49180	URBAN	0.8679	8.56%
GATES	NC	34	RURAL	0.7995	47260	URBAN	0.9223	15.36%
IREDELL	NC	34	RURAL	0.7995	16740	URBAN	0.9073	13.48%
JONES	NC	34	RURAL	0.7995	35100	URBAN	0.8994	12.50%
LINCOLN	NC	34	RURAL	0.7995	16740	URBAN	0.9073	13.48%
PAMLICO	NC	34	RURAL	0.7995	35100	URBAN	0.8994	12.50%
ROWAN	NC	34	RURAL	0.7995	16740	URBAN	0.9073	13.48%
OLIVER	ND	35	RURAL	0.7099	13900	URBAN	0.7216	1.65%
SIOUX	ND	35	RURAL	0.7099	13900	URBAN	0.7216	1.65%
HOCKING	OH	36	RURAL	0.8329	18140	URBAN	0.9539	14.53%
PERRY	OH	36	RURAL	0.8329	18140	URBAN	0.9539	14.53%
COTTON	OK	37	RURAL	0.7799	30020	URBAN	0.7918	1.53%
JOSEPHINE	OR	38	RURAL	1.0083	24420	URBAN	1.0086	0.03%
LINN	OR	38	RURAL	1.0083	10540	URBAN	1.0879	7.89%
ADAMS	PA	39	RURAL	0.8719	23900	URBAN	1.0104	15.88%
COLUMBIA	PA	39	RURAL	0.8719	14100	URBAN	0.9347	7.20%
FRANKLIN	PA	39	RURAL	0.8719	16540	URBAN	1.0957	25.67%
MONROE	PA	39	RURAL	0.8719	20700	URBAN	0.9372	7.49%
MONTOUR	PA	39	RURAL	0.8719	14100	URBAN	0.9347	7.20%
UTUADO	PR	40	RURAL	0.4000	10380	URBAN	0.4000	0.00%
BEAUFORT	SC	42	RURAL	0.8374	25940	URBAN	0.8708	3.99%
CHESTER	SC	42	RURAL	0.8374	16740	URBAN	0.9073	8.35%
JASPER	SC	42	RURAL	0.8374	25940	URBAN	0.8708	3.99%
LANCASTER	SC	42	RURAL	0.8374	16740	URBAN	0.9073	8.35%
UNION	SC	42	RURAL	0.8374	43900	URBAN	0.8277	-1.16%
CUSTER	SD	43	RURAL	0.8312	39660	URBAN	0.8989	8.14%
CAMPBELL	TN	44	RURAL	0.7365	28940	URBAN	0.7015	-4.75%
CROCKETT	TN	44	RURAL	0.7365	27180	URBAN	0.7747	5.19%
MAURY	TN	44	RURAL	0.7365	34980	URBAN	0.8969	21.78%

MORGAN	TN	44	RURAL	0.7365	28940	URBAN	0.7015	-4.75%
ROANE	TN	44	RURAL	0.7365	28940	URBAN	0.7015	-4.75%
FALLS	TX	45	RURAL	0.7855	47380	URBAN	0.8137	3.59%
HOOD	TX	45	RURAL	0.7855	23104	URBAN	0.9386	19.49%
HUDSPETH	TX	45	RURAL	0.7855	21340	URBAN	0.8139	3.62%
LYNN	TX	45	RURAL	0.7855	31180	URBAN	0.8830	12.41%
MARTIN	TX	45	RURAL	0.7855	33260	URBAN	0.8940	13.81%
NEWTON	TX	45	RURAL	0.7855	13140	URBAN	0.8508	8.31%
OLDHAM	TX	45	RURAL	0.7855	11100	URBAN	0.8277	5.37%
SOMERVELL	TX	45	RURAL	0.7855	23104	URBAN	0.9386	19.49%
BOX ELDER	UT	46	RURAL	0.8891	36260	URBAN	0.9225	3.76%
AUGUSTA	VA	49	RURAL	0.7674	44420	URBAN	0.8326	8.50%
BUCKINGHAM	VA	49	RURAL	0.7674	16820	URBAN	0.9053	17.97%
CULPEPER	VA	49	RURAL	0.7674	47894	URBAN	1.0403	35.56%
FLOYD	VA	49	RURAL	0.7674	13980	URBAN	0.8473	10.41%
RAPPAHANNOCK	VA	49	RURAL	0.7674	47894	URBAN	1.0403	35.56%
STAUNTON CITY	VA	49	RURAL	0.7674	44420	URBAN	0.8326	8.50%
WAYNESBORO CITY	VA	49	RURAL	0.7674	44420	URBAN	0.8326	8.50%
COLUMBIA	WA	50	RURAL	1.0892	47460	URBAN	1.0934	0.39%
PEND OREILLE	WA	50	RURAL	1.0892	44060	URBAN	1.1425	4.89%
STEVENS	WA	50	RURAL	1.0892	44060	URBAN	1.1425	4.89%
WALLA WALLA	WA	50	RURAL	1.0892	47460	URBAN	1.0934	0.39%
FAYETTE	WV	51	RURAL	0.7410	13220	URBAN	0.8024	8.29%
RALEIGH	WV	51	RURAL	0.7410	13220	URBAN	0.8024	8.29%
GREEN	WI	52	RURAL	0.9041	31540	URBAN	1.1130	23.11%

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 will become rural when we adopt the new CBSA delineations may experience a decrease in their wage index values. We identified approximately 35 counties and 30 ESRD facilities that will move from urban to rural status when we adopt the new CBSA delineations beginning in CY 2015. Table 7: (CY 2015 Urban to Rural CBSA Crosswalk) shows the CBSA delineations for CY 2014 and the urban wage index values for CY 2015 based on those delineations, compared with the 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, beginning in CY 2015, when we adopt the new CBSA delineations. We expect that when we adopt the new CBSA delineations illustrated in Table 7 below, approximately 30 facilities will experience a decrease in their wage index values.

TABLE 7: CY 2015 URBAN to RURAL CBSA CROSSWALK

County Name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
FRANKLIN	AR	22900	URBAN	0.7593	04	RURAL	0.7311	-3.71%
POWER	ID	38540	URBAN	0.9672	13	RURAL	0.7398	-23.51%
FRANKLIN	IN	17140	URBAN	0.9473	15	RURAL	0.8416	-11.16%
GIBSON	IN	21780	URBAN	0.8537	15	RURAL	0.8416	-1.42%
GREENE	IN	14020	URBAN	0.9062	15	RURAL	0.8416	-7.13%
TIPTON	IN	29020	URBAN	0.8990	15	RURAL	0.8416	-6.38%
FRANKLIN	KS	28140	URBAN	0.9419	17	RURAL	0.7779	-17.41%
GEARY	KS	31740	URBAN	0.8406	17	RURAL	0.7779	-7.46%
NELSON	KY	31140	URBAN	0.8593	18	RURAL	0.7748	-9.83%
WEBSTER	KY	21780	URBAN	0.8537	18	RURAL	0.7748	-9.24%
FRANKLIN	MA	44140	URBAN	1.0271	22	RURAL	1.1553	12.48%
IONIA	MI	24340	URBAN	0.8965	23	RURAL	0.8288	-7.55%
NEWAYGO	MI	24340	URBAN	0.8965	23	RURAL	0.8288	-7.55%
GEORGE	MS	37700	URBAN	0.7396	25	RURAL	0.7570	2.35%
STONE	MS	25060	URBAN	0.8179	25	RURAL	0.7570	-7.45%
CRAWFORD	MO	41180	URBAN	0.9366	26	RURAL	0.7725	-17.52%
HOWARD	MO	17860	URBAN	0.8319	26	RURAL	0.7725	-7.14%
WASHINGTON	MO	41180	URBAN	0.9366	26	RURAL	0.7725	-17.52%
ANSON	NC	16740	URBAN	0.9230	34	RURAL	0.7899	-14.42%
GREENE	NC	24780	URBAN	0.9371	34	RURAL	0.7899	-15.71%
ERIE	OH	41780	URBAN	0.7784	36	RURAL	0.8348	7.25%
OTTAWA	OH	45780	URBAN	0.9129	36	RURAL	0.8348	-8.56%
PREBLE	OH	19380	URBAN	0.8938	36	RURAL	0.8348	-6.60%
WASHINGTON	OH	37620	URBAN	0.8186	36	RURAL	0.8348	1.98%
STEWART	TN	17300	URBAN	0.7526	44	RURAL	0.7277	-3.31%
CALHOUN	TX	47020	URBAN	0.8473	45	RURAL	0.7847	-7.39%
DELTA	TX	19124	URBAN	0.9703	45	RURAL	0.7847	-19.13%
SAN JACINTO	TX	26420	URBAN	0.9734	45	RURAL	0.7847	-19.39%
SUMMIT	UT	41620	URBAN	0.9512	46	RURAL	0.9005	-5.33%
CUMBERLAND	VA	40060	URBAN	0.9625	49	RURAL	0.7554	-21.52%
DANVILLE CITY	VA	19260	URBAN	0.7963	49	RURAL	0.7554	-5.14%
KING AND QUEEN	VA	40060	URBAN	0.9625	49	RURAL	0.7554	-21.52%
LOUISA	VA	40060	URBAN	0.9625	49	RURAL	0.7554	-21.52%
PITTSYLVANIA	VA	19260	URBAN	0.7963	49	RURAL	0.7554	-5.14%
SURRY	VA	47260	URBAN	0.9223	49	RURAL	0.7554	-18.10%
MORGAN	WV	25180	URBAN	0.9080	51	RURAL	0.7274	-19.89%
PLEASANTS	WV	37620	URBAN	0.8186	51	RURAL	0.7274	-11.14%

We note that facilities in some urban CBSAs will 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 8 (CY 2015 Urban to a Different Urban CBSA Crosswalk) shows those counties that experienced a change in their wage index value when the CBSA delineations for CY 2014 and urban wage index values for CY 2015 based on those delineations, compared with the CBSA delineations and urban wage index values for CY 2015 based on those delineations, and the percentage change in these values for counties that will remain urban even though the CBSA boundaries and/or counties included in that CBSA will change.

TABLE 8: CY 2015 URBAN to a DIFFERENT URBAN CBSA CROSSWALK

County Name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
FLAGLER	FL	37380	URBAN	0.8462	19660	URBAN	0.8376	-1.02%
DE KALB	IL	16974	URBAN	1.0412	20994	URBAN	1.0299	-1.09%
KANE	IL	16974	URBAN	1.0412	20994	URBAN	1.0299	-1.09%
MADISON	IN	11300	URBAN	1.0078	26900	URBAN	1.0133	0.55%
MEADE	KY	31140	URBAN	0.8593	21060	URBAN	0.7701	-10.38%
ESSEX	MA	37764	URBAN	1.0769	15764	URBAN	1.1159	3.62%
OTTAWA	MI	26100	URBAN	0.8136	24340	URBAN	0.8799	8.15%
JACKSON	MS	37700	URBAN	0.7396	25060	URBAN	0.7896	6.76%
BERGEN	NJ	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
HUDSON	NJ	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
MIDDLESEX	NJ	20764	URBAN	1.0989	35614	URBAN	1.2837	16.82%
MONMOUTH	NJ	20764	URBAN	1.0989	35614	URBAN	1.2837	16.82%
OCEAN	NJ	20764	URBAN	1.0989	35614	URBAN	1.2837	16.82%
PASSAIC	NJ	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
SOMERSET	NJ	20764	URBAN	1.0989	35084	URBAN	1.1233	2.22%
BRONX	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
DUTCHESS	NY	39100	URBAN	1.1533	20524	URBAN	1.1345	-1.63%
KINGS	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
NEW YORK	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
ORANGE	NY	39100	URBAN	1.1533	35614	URBAN	1.2837	11.31%
PUTNAM	NY	35644	URBAN	1.3110	20524	URBAN	1.1345	-13.46%
QUEENS	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
RICHMOND	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
ROCKLAND	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
WESTCHESTER	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	-2.08%
BRUNSWICK	NC	48900	URBAN	0.8867	34820	URBAN	0.8620	-2.79%
BUCKS	PA	37964	URBAN	1.0837	33874	URBAN	1.0157	-6.27%
CHESTER	PA	37964	URBAN	1.0837	33874	URBAN	1.0157	-6.27%
MONTGOMERY	PA	37964	URBAN	1.0837	33874	URBAN	1.0157	-6.27%
ARECIBO	PR	41980	URBAN	0.4449	11640	URBAN	0.4213	-5.30%
CAMUY	PR	41980	URBAN	0.4449	11640	URBAN	0.4213	-5.30%
CEIBA	PR	21940	URBAN	0.4000	41980	URBAN	0.4438	10.95%
FAJARDO	PR	21940	URBAN	0.4000	41980	URBAN	0.4438	10.95%
GUANICA	PR	49500	URBAN	0.4000	38660	URBAN	0.4154	3.85%
GUAYANILLA	PR	49500	URBAN	0.4000	38660	URBAN	0.4154	3.85%
HATILLO	PR	41980	URBAN	0.4449	11640	URBAN	0.4213	-5.30%
LUQUILLO	PR	21940	URBAN	0.4000	41980	URBAN	0.4438	10.95%
PENUELAS	PR	49500	URBAN	0.4000	38660	URBAN	0.4154	3.85%

QUEBRADILLAS	PR	41980	URBAN	0.4449	11640	URBAN	0.4213	-5.30%
YAUCO	PR	49500	URBAN	0.4000	38660	URBAN	0.4154	3.85%
ANDERSON	SC	11340	URBAN	0.8744	24860	URBAN	0.9161	4.77%
GRAINGER	TN	34100	URBAN	0.6983	28940	URBAN	0.7015	0.46%
LINCOLN	WV	16620	URBAN	0.7988	26580	URBAN	0.8846	10.74%
PUTNAM	WV	16620	URBAN	0.7988	26580	URBAN	0.8846	10.74%

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 9 (CY 2015 Changes to the Statewide Rural Wage Index Crosswalk) shows the CBSA delineations for CY 2014 and the rural statewide wage index values for CY 2015, compared with the rural statewide wage index values for CY 2015, and the percentage change in these values.

TABLE 9: CY 2015 CHANGES to the STATEWIDE RURAL WAGE INDEX CROSSWALK

State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
	CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
AL	39	RURAL	0.8719	39	RURAL	0.8083	-7.3%
AZ	19	RURAL	0.7580	19	RURAL	0.7108	-6.2%
CT	51	RURAL	0.7410	51	RURAL	0.7274	-1.8%
FL	49	RURAL	0.7674	10	RURAL	0.8371	9.1%
GA	38	RURAL	1.0083	38	RURAL	0.9949	-1.3%
HI	34	RURAL	0.7995	34	RURAL	0.7899	-1.2%
IL	44	RURAL	0.7365	44	RURAL	0.7277	-1.2%
KS	01	RURAL	0.6963	01	RURAL	0.6914	-0.7%
KY	28	RURAL	0.8924	28	RURAL	0.8877	-0.5%
LA	17	RURAL	0.7806	17	RURAL	0.7779	-0.3%
MD	25	RURAL	0.7589	25	RURAL	0.7570	-0.3%
MI	33	RURAL	0.8208	33	RURAL	0.8192	-0.2%
MS	50	RURAL	1.0892	50	RURAL	1.0877	-0.1%
NC	45	RURAL	0.7855	45	RURAL	0.7847	-0.1%
NE	18	RURAL	0.7744	18	RURAL	0.7748	0.1%
NY	14	RURAL	0.8362	14	RURAL	0.8369	0.1%
OH	11	RURAL	0.7425	11	RURAL	0.7439	0.2%
OR	36	RURAL	0.8329	36	RURAL	0.8348	0.2%
PA	07	RURAL	1.1251	07	RURAL	1.1295	0.4%
TN	52	RURAL	0.9041	52	RURAL	0.9087	0.5%
TX	23	RURAL	0.8207	23	RURAL	0.8288	1.0%
UT	03	RURAL	0.9125	03	RURAL	0.9219	1.0%
VA	12	RURAL	1.0741	12	RURAL	1.0872	1.2%
WA	46	RURAL	0.8891	46	RURAL	0.9005	1.3%
WI	21	RURAL	0.8554	21	RURAL	0.8746	2.2%
WV	10	RURAL	0.8006	10	RURAL	0.8371	4.6%

While we believe that the new CBSA delineations will 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 will result in reduced payments to some facilities. In particular, approximately 30 facilities would experience reduced payments when we adopt the new CBSA delineations. At the same time, use of the new CBSA delineations will 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 finalizing the implementation the new CBSA delineations, as proposed, using a 2-year transition with a 50/50 blended wage index value for all facilities in CY 2015 and 100 percent of the wage index based on the new CBSA delineations in CY 2016.

Comment: Commenters largely agreed with the implementation of the new CBSAs and thanked CMS for offsetting any negative impacts with a 2-year transition. A few commenters expressed concerns for low wage areas and for areas where hospital wage data is not available, and where proxies are used to establish an areas wage index. Another commenter requested reclassification to address the Wheeling WV-OH wage index, as well as, other areas with very low wage indices. The commenter also suggested that we apply the rural floor policy that applies in the IPPS under which an urban area with a wage index below the statewide rural average would be paid the statewide rural average wage index value.

Response: We thank the commenters for their support and are finalizing the CY 2015 ESRD PPS wage indexes as proposed. We agree that some areas of the country will continue to have low wage values, despite the annual updated hospital wage data and the finalized new CBSA delineations. However, the purpose of updating the ESRD PPS wage indexes as part of our annual update is based upon the premise that our wage index value should reflect the costs of furnishing renal dialysis services in the area where those services are provided

In addition, the ESRD PPS uses “pre-floor” and “pre re-classified” hospital wage data in computing the wage indexes used in the ESRD PPS. That is, the ESRD PPS uses IPPS wage data that has not been adjusted based on hospital reclassifications or application of the IPPS rural floor policy. Because we do not collect ESRD facility wage data, we rely upon IPPS hospital wage data as the best wage proxy for ESRD facilities. We believe the IPPS hospital wage data

most closely reflects the costs of furnishing renal dialysis services in an area and it is the most accurate and up-to-date wage data. We understand that many rural areas generally have lower wage values than urban areas, and that in some cases rural facilities may have to compete with urban areas for staffing. In addition, a few areas do not have a hospital upon which to base a wage index and we apply a proxy wage index value as described in the CY 2014 ESRD PPS final rule (78 FR 72172). For these reasons, we plan to evaluate the effect of the IPPS rural floor policy, the wage index floor, and other wage index-related policies under the ESRD PPS.

c. Transition Period

We considered having no transition period and fully implementing the 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. 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.

Comment: Generally, commenters were supportive of our proposed transition to implement the new CBSA delineations and our CY 2015 wage indices. Many commenters agreed that the transition approach allowed all facilities the ability to adjust to their new status, without lowering the overall base rate for all providers. A few commenters noted that a longer

transition period would be helpful for rural providers.

Response: We thank the commenters for their support and agree that the transition period allows all facilities to adjust to their new CBSA status. We continue to believe that the transition period is sufficient to mitigate the economic impact for ESRD facilities as the impact analysis demonstrates an impact of less than 1 percent.

Therefore, we are finalizing a 2-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 new CBSA delineations. This results in an average of the two values. A facility's CY 2016 wage index values will be based 100 percent on the new CBSA delineations. 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 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 are finalizing a labor-related share of 50.673 percent, which we are implementing with a 2-year transition of 46.205 percent for CY 2015 and 50.673 percent for CY 2016. For a complete discussion of the changes in the CY 2015 ESRD PPS market basket and labor-related share, as well as the transition of the labor-related share. See section II.C of this final rule.

Comment: One commenter encouraged CMS to explore alternative payment mechanisms for small rural providers. Whereas a standard payment rate that is adjusted based on the national labor-related share may work for providers with moderate to high patient volumes, the same does not hold true for small rural providers. Small providers have a different cost structure than larger

counterparts. Specifically, small rural providers incur a higher share of non-labor costs than the national average. For example, a small facility with 20 patients may only need part-time employees. The small rural town may not have potential employees with the appropriate skill set who are willing to work part time. As a result, the ESRD facility will pay significant amounts for mileage and lodging for employees to travel from other sites, or the facility may hire contracted labor. The commenter encouraged CMS to evaluate the labor versus non-labor costs for small rural facilities compared to the national average and propose payment adjustments to address inequalities.

Response: We thank the commenters for their concern for rural facilities and appreciate the suggestions for alternative payment mechanisms for small rural ESRD facilities. We plan to consider these comments as part of the ESRD PPS refinement in CY 2016.

4. CY 2015 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. 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. Renal dialysis 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 § 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 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments. For CY 2014, the outlier services MAP amounts and fixed-dollar loss amounts were based on 2012 data (78 FR 72180). Therefore, the outlier thresholds for CY 2014 were based on utilization of renal dialysis items and services furnished under the ESRD PPS. Because of the utilization of ESAs and other outlier services have 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. CY 2015 Update to the Outlier Services MAP Amounts and Fixed-Dollar Loss Amounts

For CY 2015, we did not propose any changes to the methodology used to compute the MAP or fixed-dollar loss amounts. Rather, the proposed rule updated the outlier services MAP amounts and fixed-dollar loss amounts to reflect the utilization of outlier services reported on 2013 claims using the December 2013 claims file. For this final rule, the outlier services MAP amounts and fixed dollar loss amounts were updated using the 2013 claims from the June 2014 claims file. The impact of this update is shown in Table 10, which compares the outlier services MAP amounts and fixed-dollar loss amounts used for the outlier policy in CY 2014 with the updated estimates finalized in this rule. The estimates for the final CY 2015 outlier policy, which are included in Column II of Table 10, were inflation adjusted to reflect projected 2015 prices for outlier services.

TABLE 10:
OUTLIER POLICY: 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	$39.89	$52.98
Adjustments Standardization for outlier services[2]	1.1079	0.9866	1.1145	0.9878
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount[3]	$40.49	$50.25	$43.57	$51.29
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold[4]	$54.01	$98.67	$54.35	$86.19
Patient months qualifying for outlier payment	6.7%	5.3%	6.3%	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 MAPamounts are based on 2013 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that are in placeunder 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 andpediatric patient groups.
[3] This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP foreach patient.
[4] The fixed dollar loss amounts were calculated using 2013 data to yield total outlier payments that represent 1 percent of total projected paymentsfor the ESRD PPS.

As demonstrated in Table 10, 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 slightly 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 1 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 (6.3 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 slightly higher for the outlier policy for CY 2015 compared to the outlier policy for CY 2014.

The updated fixed-dollar loss amounts are added to the predicted MAP amounts per treatment, yielding the outlier thresholds for CY 2015 from $98.67 to $86.19 for adult patients and from $54.01 to $54.35 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 for both adult and pediatric patients, 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 ESAs 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. Recalibration of the thresholds, which use 2013 data, reflects the 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 update to the outlier MAP and fixed-dollar loss amounts for CY 2015 will increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy.

We note that recalibration of the fixed-dollar loss amounts in this final 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 ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would also increase for renal dialysis services eligible for outlier payments.

Comment: All commenters expressed disappointment that the outlier target percentage has not been achieved under the ESRD PPS. Some commenters encouraged CMS to revise the target so that the adjustment would be more attainable for facilities. Other commenters requested that CMS eliminate the adjustment from the payment system altogether and return the 1 percent back to the base rate for CY 2015. One commenter suggested that CMS could annually update the amount withheld in the outlier pool based on actual use in the two prior years. Still other commenters encouraged CMS to return the outlier "pool" to facilities, as the adjustment erroneously lowered the base rate in prior years.

Response: We thank the commenters for their suggestions in improving the ESRD PPS

outlier policy. With regard to the comment that we eliminate the outlier adjustment altogether, we note that, under section 1881(b)(14)(D)(ii) of the Act, the ESRD PPS must "include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management." Therefore, we would be unable to do so and comply with section 1881(b)(14)(D)(ii) of the Act. In addition, it is important to note that the ESRD PPS base rate captures the cost for the average patient. To the extent data analysis continues to show that certain patients, including certain racial and ethnic groups, receive more ESAs than average, we believe an outlier policy, even a small one, is an important payment adjustment to provide under the ESRD PPS. Concerning comments that we modify the outlier payment adjustment, we did not propose to do so, therefore, we will not finalize such an adjustment. However, we will consider the commenters' suggestions as part of the refinement process that we will undertake in the CY 2016 ESRD PPS proposed and final rules.

We share the industry's frustration that payments under the outlier policy have not reached 1 percent of total ESRD PPS payments. However, the outlier policy is a target percentage rather than a "pool." As we explained in the CY 2014 ESRD PPS final rule (78 FR 72165), each year we simulate payments under the ESRD PPS in order to set the outlier fixed-dollar loss and MAP amounts for adult and pediatric patients to try to achieve the 1 percent outlier policy. We do not increase the base rate to account for years where outlier payments were less than 1 percent of total ESRD PPS payments, nor would we reduce the base rate if the outlier payments exceed 1 percent of total ESRD PPS payments. Rather, we would simulate payments in the following year and adjust the fixed-dollar loss and MAP amounts to try to achieve outlier payments that meet the 1 percent outlier percentage. This approach to updating the outlier policy

is consistent with how we update outlier policies in other Medicare prospective payment systems, for example, the prospective payment system for inpatient psychiatric facilities.

We believe the 1 percent outlier percentage has not been reached under the payment system due to the significant drop, over 20 percent, in the utilization of high cost drugs such as Epogen. In fact, we believe the drop in utilization of ESAs and the QIP measures, have made it less likely that a patient's treatment costs would meet the outlier threshold, despite the fact we have lowered the MAP amounts as part of our annual update to the payment system since 2011. We believe that the 2013 data used to update the CY 2015 outlier policy are representative of stable drug utilization, and we believe that in the future the outlier policy will be an important payment adjustment compensating facilities for high cost services as the adjustment was intended.

D. 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 variation 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 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, is when the patient has a medical need for additional dialysis and the facility has furnished supporting medical justification of the patient's condition for the extra treatments. Modality choice does not constitute medical justification.

Comment: Commenters were generally supportive of our policy clarification for reporting short frequent hemodialysis treatments. Many commenters noted the importance of allowing Medicare payment for additional medically necessary weekly treatments. One commenter requested that CMS clarify that medical justification is subject to approval by the MAC's medical officer, as opposed to the MAC's local policy decisions.

Response: We thank the commenters for their support of our policy clarification and agree with commenters that when medically necessary additional dialysis treatments are warranted based upon the patients' medical conditions, Medicare should pay for those treatments. In addition, CMS has no national policy for medical justification for additional dialysis treatments, and we rely upon either a MAC's local coverage determination (LCD) policy or medical review by a physician working under the direction of the MAC's medical director.

Comment: One commenter expressed concern that the language in the proposed rule gives more authority to the MACs to determine medical necessity. The commenter cited to the proposed rule that states, "the MACs determine whether additional treatments furnished during a month are medically necessary," and encouraged CMS to communicate to the MACs that physicians are ultimately responsible for determining the medical justification of ESRD services

after considering the patient's health status and relevant evidence-based medicine. The MAC's responsibility is to review the documentation provided by the physician to ensure the medical justification meets the guidelines set forth by CMS.

Another commenter indicated that longer or more frequent schedules are purposefully prescribed by the physician to meet individual patient medical and lifestyle needs and because the patient would medically benefit based upon the ever-expanding base of clinical literature finding clinical benefit to these schedules compared to conventional dialysis schedules. The commenter believes that if such a regimen is prescribed based upon sound medical justification, it should be eligible for payment of the additional treatments under CMS's long-standing policy. The commenter believes this approach has worked effectively for many years during the modest growth of home hemodialysis (HHD) and there is no evidence of overutilization. The commenter believes this is the policy described in the proposed rule.

Other commenters pointed out that, while a growing body of research shows that more frequent dialysis improves patient outcomes overall, the payment policy for dialysis is limited based on three times per week HD treatments. The flexibility in permitting extra payments for HD treatments, when medical justification is provided, is a reasonable approach to ensuring those patients who need the extra treatments the most are able to get them.

Response: We agree with the commenter that, while we refer to MACs' approval for the payment of medically necessary additional weekly treatments, we do not mean that the MACs make these decisions unilaterally. Rather, necessity for these extra treatments is reviewed, and ultimately paid or unpaid, based upon the policy and payment guidance furnished by Medicare, the local policies and guidance of the MAC, and the information submitted by the patient's physician. It was not our intent to imply a change in our requirements for medical justification

for additional treatments, nor were we dismissing the importance of the assessment of the patient's physician. We will continue to follow research assessing the clinical benefits of more frequent dialysis schedules and monitoring the number of treatments furnished and paid per month.

In circumstances where a nephrologist has "prescribed" shorter, more frequent hemodialysis for their patient there should be no expectation of payment beyond three treatments per week. For prescribed dialysis regimes beyond three sessions per week, furnished in the home or in center, such as four, five, six or even seven times per week, payment for the additional weekly treatments is based on patient conditions, supported by medical documentation, that require additional dialysis.

Comment: One commenter believes that it is inconsistent for CMS to require that all dialysis treatments be reported, while limiting payment to three times per week.

Response: We thank the commenter for their comment; however, dialysis services furnished by a facility are reported to Medicare, for purposes of payment, on a monthly claim form. During a given month, weekly dialysis services may differ in terms of number of treatments, drug dosing, acute case-mix or other payment adjustments, laboratory services. Therefore, we require that all dialysis services be reported on the Medicare 72x type of bill so that all of the services furnished to the beneficiary will be identifiable on the claim form. More importantly, reporting all treatments furnished allows CMS to keep up with changes in dialysis schedules over time.

Comment: One commenter believes a reference we made in the proposed rule to "dialysis modalities that require more frequent dialysis" could be misconstrued or misunderstood. The commenter believes the reference implies a comparison of more frequent home HD to PD, where

daily exchanges are required in order to deliver a minimally adequate dose. The commenter pointed out that home HD, and the equipment that delivers this home therapy, may be prescribed with adequate dose delivery under a variety of treatment schedules, from the conventional thrice-weekly to longer or more frequent schedules. The commenter suggests that correlating short more frequent HD with PD should be avoided.

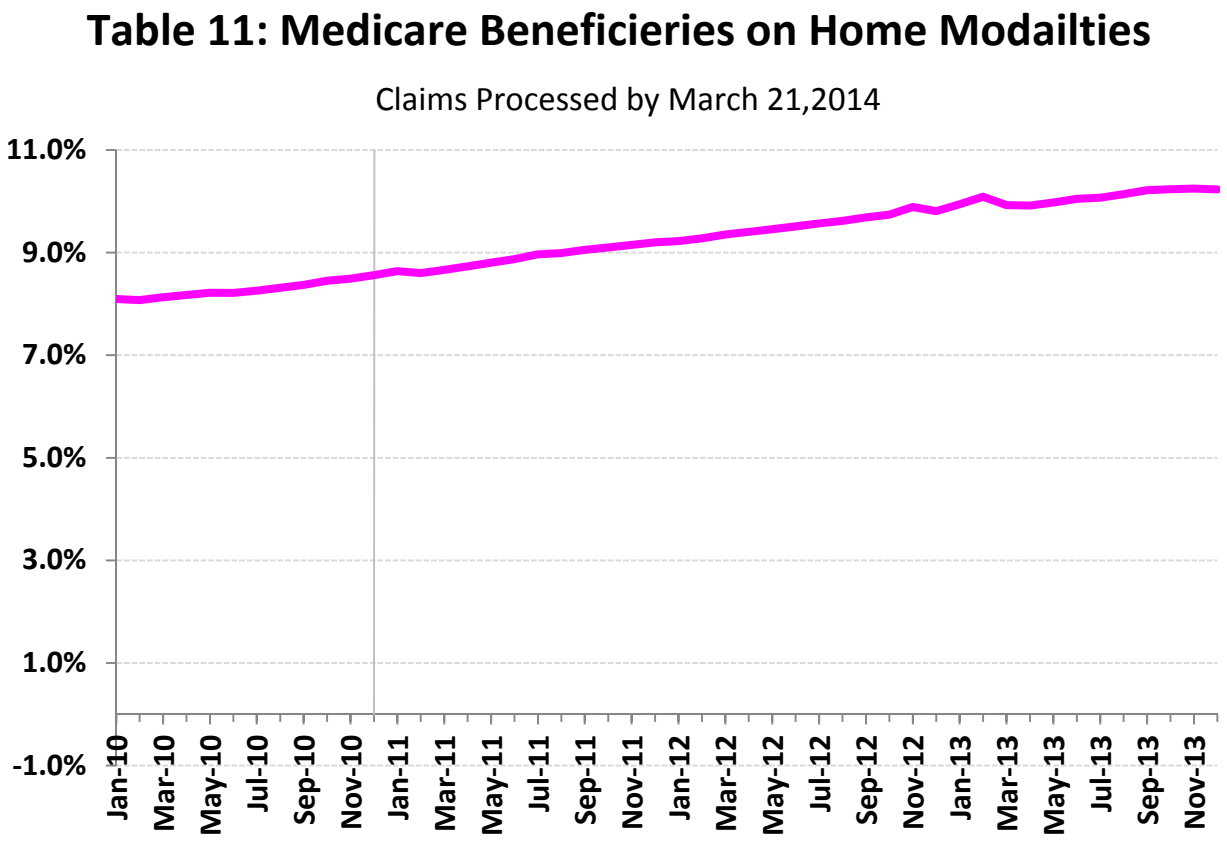
Response: We thank the commenter for this clarification and we will avoid such references in the future.

Comment: One commenter disagreed with CMS's policy and stated that it should not preclude modality choice as a medical justification for more frequent HD treatments, as precluding modality choice would likely have a significant adverse impact on the physical and emotional well-being of patients undergoing home hemodialysis currently, and would significantly limit Medicare beneficiaries' access to home HD. The commenter contends that this policy is counter to CMS and Congress's stated goal of promoting the use of home dialysis in lieu of continued growth of patients undergoing in-center hemodialysis. A few commenters encouraged CMS to continue to be flexible in providing beneficiaries with more than three treatments per week when medically necessary. Other commenters noted that they support our objectives in removing barriers for home dialysis modalities, including home hemodialysis, but only if our policies do not shift resources from in-center patients.

Response: Payments provided by MACs for additional hemodialysis weekly dialysis treatments that are furnished in-facility or in the home, have been audited by CMS. We recognize that some MACs were not requiring documented patient conditions for medical justification for additional weekly treatments and were inappropriately authorizing Medicare payment for additional dialysis services where no medical justification was included in the claim.

Thus, our intent in clarifying our policy was to remind facilities and MACs of the Medicare ESRD benefit, which only allows for the payment of three weekly dialysis treatments, and that additional weekly dialysis treatments may be paid for if there's documented medical justification. We believe that our policy clarification will result in a consistent Medicare benefit for all beneficiaries and eliminate the regional payment differences for HD.

Lastly, we thank the commenters who suggest that Medicare should remove the barriers to home modalities while not jeopardizing the Medicare base rate for in-facility services. We agree with these commenters and believe our ESRD PPS payment policies have contributed to the increase in utilization of home dialysis modalities as indicated in Table 11 below.



E. 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 for 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 shall implement this delay by modifying the effective date for providing payment for renal dialysis oral-only drugs and biologicals under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also shall 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.

We received no public comments on these proposals and therefore will finalize our regulatory changes to 42 CFR Part 413 as proposed.

In addition to the delay of payment for renal dialysis oral-only drugs, section 217(a)(2) of PAMA further amended 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 to do for the original ESRD PPS in implementing payment for renal dialysis oral-only 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.

Comment: We received many comments from industry stakeholders questioning CMS's authority to incorporate additional renal dialysis services into the payment bundle. A few commenters were encouraged by CMS's request for comments and outlined a comprehensive 7 principle drug designation process. Other commenters urged CMS to be cautious when adding renal dialysis services to the bundle and noted that separate payment for new services would be important until utilization and practice patterns have been established. Another commenter urged that the process should be transparent, predictable, and result in increases to the payment rate to reflect the cost of these therapies and to promote adoption of innovations with a demonstrated impact on patient outcomes.

One commenter recommends a collaborative process to determine when a product is no longer an oral-only drug, noting that MIPPA is unclear on this point for non-ESA medications. The commenter suggests that reasonable criteria for inclusion of previously oral-only agents in the bundle may be when a parenteral formulation has been adequately shown to be clinically superior in terms of efficacy and safety with acceptable cost and cost-effectiveness compared to already available oral medications. The commenter also believes it would be appropriate to include new products in the bundle if they are intended to be used in practice as substitutes for already bundled products or if their primary use reflects management of conditions specifically related to ESRD and its complications as evidenced by current use of bundled medications or oral but not bundled medications.

Response: We thank the commenters for the thoughtful comments regarding a drug

designation process. We will take these comments into consideration when we propose the drug designation process in the CY 2016 ESRD PPS proposed rule. In response to commenters who questioned CMS's authority, we believe CMS does have the authority to add services to the bundle. Our definition of renal dialysis services, which was adopted in our CY 2011 ESRD PPS final rule (75 FR 49036), is consistent with section 1881(b)(14)(B)(iii) of the Act that includes as renal dialysis services, "Other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before application of this [new ESRD PPS]) made separately under this title, and any oral equivalent form of such drug or biological." We continue to believe that we have the authority to add drugs and biologicals that are furnished to individuals for the treatment of ESRD to the payment bundle. We have done this in the case when new ESAs have been made available.

Lastly, we thank the commenters for the very thoughtful 7 principle drug designation process outlined in comments. Specifically, we are encouraged by recommendations regarding processes for coverage and payment, data collection, and protections for providers and beneficiaries so that facilities "are not forced to absorb the drug's new costs themselves."

F. 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 12 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 renal dialysis 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 renal dialysis oral-only drugs for which we are delaying 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 12: 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 renal dialysis conditions, such as, 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 reasons other than for the treatment of ESRD. 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 line reporting vancomycin to indicate that the drug was furnished for reasons other than for the treatment of ESRD. The presence of the AY modifier on the claim line 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 for the treatment of 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 for the treatment of ESRD. Once again, we instructed facilities to append claim lines reporting daptomycin furnished for reasons other than for the treatment of 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 updated the list of drug categories that are always considered renal dialysis drugs under the ESRD PPS by removing the drug category for anti-infectives. We included Table 13 (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 to be renal dialysis services 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. Beginning in CY 2011 when the ESRD PPS was implemented, Part D plan sponsors were encouraged to implement prior authorization requirements for drugs in the categories below in Table 13. In addition, the drug categories presented below are covered by the ESRD PPS payment regardless of whether the drug is expected to be taken at home or on non-dialysis days.

TABLE 13: 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 reasons other than for the treatment of ESRD were 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). Table 14 is included below for the purpose of this discussion. When any drug identified in the drug categories listed in Table 14 (antiemetics, 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. When these drugs are used for the treatment of ESRD, the facility may not furnish a prescription for such drugs with the expectation that a Medicare Part D payment would be made, as the payments for the injectable drugs, which are generally more expensive than oral substitutes, in those categories were included in computing the ESRD PPS base rate. Therefore, drugs in these categories furnished for the treatment of ESRD are covered by the ESRD PPS payment regardless of whether the drug is expected to be taken at home or on non-dialysis days.

If a drug represented by a drug category in Table 14 is furnished by ESRD facilities for reasons other than for the treatment of ESRD, a separate Medicare payment is permitted when the AY modifier is indicated on the claim line reporting the drug for payment. Prescriptions for oral versions of drugs used for non-ESRD conditions are appropriately billed to Part D.

TABLE 14: 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.

Comment: A few commenters, including national industry organizations, expressed appreciation for our efforts to clarify what drugs and biologicals are included in the ESRD PPS payment bundle. However, they expressed concern that current guidance has resulted in Part D plan sponsors' inappropriately refusing to cover oral drugs that are not renal dialysis services nor essential to the delivery of such services. Specifically, they noted that beneficiaries have had difficulties obtaining necessary medications such as oral antibiotics prescribed for pneumonia and pain medications prescribed for back pain.

A commenter believes that, prior to January 1, 2014, there appeared to be a clear understanding as to what drugs and biologicals should be reimbursed through the ESRD PPS and those that should appropriately be covered under Part D. The commenter noted that guidance issued by CMS in 2011 to all Part D plans correctly recognized that drugs used as substitutes for any of the drugs listed in Table C of the CY 2011 ESRD PPS final rule, or used to accomplish the same effect, would also be covered under the ESRD bundled payment and were, therefore, ineligible for separate payment.

However, implementation of the CY 2014 Part D Call Letter provision for prior authorization for drug categories that may be renal dialysis services but may also prescribed for other conditions has resulted in confusion for Part D plan sponsors and delays in beneficiaries obtaining essential medications at the pharmacy. Another commenter pointed out that patients should not be put in the middle of benefit determinations, and that they should receive their medications when they arrive at the pharmacy and payment disputes should be settled after the fact.

Response: There has been no change in CMS policy with respect to the drugs considered to be renal dialysis services and covered under the ESRD PPS since CY 2013 when we removed

daptomycin from the list of drug categories that are always considered to be renal dialysis services as discussed above. However, in response to increases in billing under Part D for drugs that may be for renal dialysis services but may also be prescribed for other conditions, we issued guidance in the CY 2014 Part D Call Letter to strongly encourage Part D sponsors to place beneficiary-level prior authorization edits on all drugs in the seven categories identified in the CY 2011 ESRD PPS final rule as drugs that "may be" ESRD-related for beneficiaries on dialysis (75 FR 49051). These include: antiemetics, anti-infectives, antipruritics, anxiolytics, excess fluid management, fluid and electrolyte management including volume expanders, and pain management (analgesics).

Since our new guidance took effect January 1, 2014, various stakeholders have raised concerns regarding the policy's impact on beneficiary access. We are considering various alternatives for dealing with this issue, as it has always been our intention to eliminate or minimize disruptions or delays for ESRD beneficiaries' receiving essential medications. We plan to issue guidance in the near future to address this issue.

Comment: A national industry organization commented that, prior to implementation of the ESRD PPS, most of the drugs that were listed as "may be related to the treatment of ESRD were also prescribed for patients to take, at home, on non-dialysis treatment days. The commenter pointed out that CMS did not reflect Medicare payments for those oral drugs in calculating the ESRD PPS base rate. Therefore, CMS should continue to allow payment under Part D for those drug categories, that may be for the treatment of ESRD, but that are prescribed for non-dialysis days. The commenter requested that we revise the regulation text to provide that prescription drugs and biologicals that may be within the bundle are covered under the Part B bundle only when they are directly related to the provision of renal dialysis services.

Another commenter pointed out that a reasonable criterion regarding which medications are covered under the bundled payment should be if the medication is essential to perform dialysis or whether the dialysis treatment could be altered or intensified in some way that it would make the medication unnecessary. For instance, lidocaine cream for access site pain with cannulation would be included in the bundle, while an anti-pruritic agent taken twice daily for chronic pruritus that persists despite adequate dialysis would not be included in the bundle.

Response: In order to maintain the integrity of the ESRD PPS base rate and the payment bundle implemented in CY 2011, the drugs and biologicals that we consider to be renal dialysis services are those that are routinely given to patients "for the treatment of ESRD" and were billed separately to Part B prior to implementation of the ESRD PPS and where the payments for the injectable versions was included in the base rate. Therefore, if a facility would have furnished an injectable drug and received separate payment for that drug under Part B prior to the ESRD PPS, it would not be appropriate today to unbundle the oral versions of those injectable drugs by providing a prescription for a substitute drug to be taken on non-dialysis days and expect that drug to be covered under Part D. For more information regarding the injectable drugs included in the ESRD PPS base rate, please refer to Table C of the CY 2011 ESRD PPS Final Rule (75 FR 49205).

G. Low-Volume Payment Adjustment (LVPA)

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 re-determining 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 making changes to 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 changing 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 shall 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.

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 § 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 are clarifying 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 ESRD facilities 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 shall 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.

Section 413.232(f) requires ESRD facilities to submit LVPA attestations by November 1 of each year. However, the changes we are finalizing 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 amending §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.

Comment: Commenters were largely supportive of our policy clarification and proposed regulation changes regarding the facility eligibility requirements for the LVPA available under the ESRD PPS. A few commenter encouraged CMS to "redesign" the LVPA adjustment during the CY 2016 rulemaking, which will include refinements of the payment system. One commenter encouraged CMS to consider a facility's distance to the nearest facility and develop and rural adjustment factor as part of the adjustment. . Other commenters urged CMS to implement the GAO recommendations. Some commenters encouraged CMS to consider travel time as well as distance in their consideration of the aggregate number of treatments furnished by ESRD facilities within 25 miles of each other under common ownership, and other commenters suggested that CMS identify critical access facilities and consider changes to the LVPA to protect access to isolated essential facilities. Another commenter asked that CMS consider a larger adjustment for those facilities that are more than 50 miles from the closest dialysis facilities, as

closure of these facilities would create particular hardship for patients.

Response: We thank the commenters for their support of our policy clarification and supporting regulation changes. We will finalize these provisions as proposed. In addition, we thank the commenters for their suggestions in computing a low-volume payment adjustment in the future, and we will consider these comments for purposes of refinement in CY 2016.

Comment: A few commenters thanked CMS for extending the attestation filing deadline to December 31 so that affected facilities would have enough time to gather any supporting documentation necessary for determining a facility's total treatment count. Another commenter suggested that CMS further clarify what years a facility is able to re-attest for LVPA eligibility. One commenter cited an independent study claiming that over 1,000 facilities with treatment counts of less than 3,200 were not identified as low-volume facilities under the ESRD PPS.

Response: We thank the commenters for their support and agree that extending the deadline by 60 days will allow facilitates to gather any documentation that supports a facility's treatment count. In addition, we clarify that facilities that believe they have been denied the LVPA payment adjustment under the ESRD PPS may attest to any of the payment years since CY 2011. We thank the commenter who furnished independent data and plan to consider treatment count thresholds as part of our policy refinement in CY 2016.

Comment: One commenter recommended that CMS specify which years MACs will be required to reassess for incorrect determinations. In addition, as some MACs have advised ESRD facilities not to submit an application due to perceived ineligibility, they recommend CMS allow these facilities that did not file attestations to do so for prior years and receive a determination from the MAC.

Response: ESRD facilities that did not submit an attestation for CY 2011 through CY 2014 due to perceived ineligibility, but which now believe they qualify for the LVPA based upon

our policy clarifications, should submit an attestation to their MAC for a determination. Likewise, facilities that submitted attestations and were denied, but now believe they qualify based upon the policy clarifications, should submit an attestation to their MAC for a redetermination.

Comment: One commenter supports allowing the submission of additional data for all types of facilities, not only those that are hospital-based, because the commenter indicated such data could help the contractors more effectively identify facilities that qualify for the LVPA. The commenter indicated that more can and should be done to make sure that MACs are appropriately evaluating facilities to ensure accurate determinations.

Response: We will consider this suggestion as part of the ESRD PPS refinement. In the meantime, we are planning to issue additional sub-regulatory guidance to MACs in an effort to ensure accurate LVPA determinations. We thank the commenter for their support and are finalizing the revision to §413.232(f) to extend the deadline for CY 2015 LVPA attestations until December 31, 2014.

H. Continued Use of ICD-9-CM Codes and Corrections to the ICD-10-CM Codes Eligible for the Co-morbidity 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 co-morbidities. Co-morbidities are specific patient conditions that coexist with the patient's principal diagnosis that necessitates dialysis. The co-morbidity payment adjustments recognize the increased costs associated with co-morbidities 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 co-morbidity 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 co-morbidity categories that are eligible for a co-morbidity 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 co-morbidity 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 co-morbidity 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 co-morbidities and the diagnoses within the co-morbidity categories that are eligible for a co-morbidity 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, that is, ICD-10-CM, 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 co-morbidity payment adjustment where they crosswalk from ICD-9-CM codes that are eligible for a co-morbidity payment adjustment, with two exceptions.

On April 1, 2014, PAMA was enacted. Section 212 of PAMA, titled "Delay in

Transition from ICD-9-CM to ICD-10-CM Code Sets," provides that "[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD-10-CM 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 §162.1002 of title 45, Code of Federal Regulations." On May 1, 2014, the Secretary announced that HHS expected to issue an interim final rule that would require use of ICD-10-CM 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.

Since the publication of the CY 2015 ESRD PPS proposed rule on July 11, 2014, HHS finalized the new compliance date of October 1, 2015 for ICD-10-CM and ICD-10-PCS in an August 4, 2014 final rule titled "Administrative Simplification: Change to the Compliance Date for the International Classification of Diseases, 10th Revision (ICD-10-CM and ICD-10-PCS)." The rule also requires HIPAA covered entities to continue to use ICD-9 through September 30, 2015.

Before the passage of PAMA, our policy required facilities to utilize ICD-10-CM codes to identify co-morbidities eligible for the co-morbidity 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 proposed to require use of ICD-10-CM to identify co-morbidities beginning on October 1, 2015, and, until that time, we would continue to require use of the ICD-9-CM codes to identify co-morbidities eligible for the co-morbidity payment adjustment. The ICD-9-CM codes that are eligible for the co-morbidity payment adjustment are listed in the crosswalk tables below.

Because facilities will begin using ICD-10-CM 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 finalizing 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 including 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 15 below reflecting the additional codes.

We note that the ICD-10-CM codes that facilities will be required to use to identify eligible co-morbidities when ICD-10-CM 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 15–ONE ICD-9-CM CODE CROSSWALKS TO ONE ICD-10-CM CODE (78 FR 72175 through 78 FR 72176)

Table 15 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 co-morbidity 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 in accurately identified. The table below has been amended to accurately identify ICD-9-CM diagnostic code 238.71

Essential thrombocythemia.

TABLE 15: ONE ICD-9-CM CODE CROSSWALKS TO ONE ICD-10-CM CODE

Gastrointestinal Bleeding			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
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			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
003.22	Salmonella pneumonia	A02.22	Salmonella pneumonia
482.0	Pneumonia due to Klebsiella pneumonia	J15.0	Pneumonia due to Klebsiellapneumoniae
482.1	Pneumonia due to Pseudomonas	J15.1	Pneumonia due to Pseudomonas
482.2	Pneumonia due to Hemophilusinfluenzae [H. influenzae]	J14	Pneumonia due to Hemophilusinfluenzae
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			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
420.91	Acute idiopathic pericarditis	I30.0	Acute nonspecific idiopathic pericarditis
Hereditary Hemolytic and Sickle Cell Anemia			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
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			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
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 16– ONE ICD-9-CM CODE CROSSWALKS TO MULTIPLE ICD-10-CM CODES (78 FR 72177 through 78 FR 72178)

Table 16 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 co-morbidity 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 in accurately 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 are including 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 co-morbidity 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 co-morbidity payment adjustment when the use of ICD-10-CM is required, on October 1, 2015.

TABLE 16: ONE ICD-9-CM CODE CROSSWALKS TO MULTIPLE ICD-10-CM CODES

Gastrointestinal Bleeding			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
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			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
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			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
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			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**

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
		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			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
273.1	Monoclonal paraproteinemia	D47.2	Monoclonal gammopathy
		D89.2	Hypergammaglobulinemia, unspecified
Myelodysplastic Syndrome			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
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 17– MULTIPLE ICD-9-CM CODES CROSSWALK TO ONE ICD-10-CM CODE (78 FR 72178)

Table 17 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 co-morbidity 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. Therefore, we are finalizing 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 finalize that the corresponding ICD-9-CM codes will be eligible for the comorbidity adjustment through September 30, 2015.

TABLE 17: MULTIPLE ICD-9-CM CODES CROSSWALK TO ONE ICD-10-CM CODE

Gastrointestinal Bleeding			
ICD-9	**Descriptor**	**ICD-10**	**Descriptor**
531.00	Acute gastric ulcer with hemorrhage, without mention of obstruction	K25.0	Acute gastric ulcer with hemorrhage
531.01	Acute gastric ulcer with hemorrhage, with obstruction		
531.20	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction	K25.2	Acute gastric ulcer with both hemorrhage and perforation
531.21	Acute gastric ulcer with hemorrhage and perforation, with obstruction		
531.40	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction	K25.4	Chronic or unspecified gastric ulcer with hemorrhage
531.41	Chronic or unspecified gastric ulcer with hemorrhage, with obstruction		
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation, without mention of obstruction	K25.6	Chronic or unspecified gastric ulcer with both hemorrhage and perforation
531.61	Chronic or unspecified gastric ulcer with hemorrhage and perforation, with obstruction		
532.00	Acute duodenal ulcer with hemorrhage, without mention of obstruction	K26.0	Acute duodenal ulcer with hemorrhage
532.01	Acute duodenal ulcer with hemorrhage, with obstruction		
532.20	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction	K26.2	Acute duodenal ulcer with both hemorrhage and perforation
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

Gastrointestinal Bleeding

ICD-9	Descriptor	ICD-10	Descriptor
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

ICD-9	Descriptor	ICD-10	Descriptor
482.30	Pneumonia due to Streptococcus, unspecified	J15.4	Pneumonia due to other streptococci
482.31	Pneumonia due to Streptococcus, group A		
482.39	Pneumonia due to other Streptococcus		
482.81	Pneumonia due to anaerobes	J15.8	Pneumonia due to other specified bacteria
482.89	Pneumonia due to other specified bacteria		

We received no comments on our proposals to amend or modify our ICD-9-CM/ICD-10-CM crosswalk and, therefore, we are finalizing these changes as proposed.

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). The proposed rule, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (79 FR 40208 through 40315), (hereinafter referred to as the CY 2015 ESRD PPS Proposed Rule), was published in the **Federal Register** on July 11, 2014, with a comment period that ended on September 2, 2014. In that proposed rule, we made proposals for the ESRD QIP, including adding new measures, revising existing measures;

refining the scoring methodology; modifying the program's public reporting requirements; continuing the data validation pilot program for CROWNWeb and introducing a validation feasibility study for the NHSN Bloodstream Infection clinical measure. We received 46 public comments on the ESRD QIP proposals, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the program. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section of this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section of this final rule.

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 Value Based Purchasing (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.[3]

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.

We received a number of general comments on our proposals, which we summarize and respond to here.

Comment*:* Some commenters were concerned about the number of measures used in the ESRD QIP. Commenters stated that as the number of measures in the ESRD QIP grows, so do

[3] 2013 Annual Progress Report to Congress: National Strategy for Quality Improvement in Health Care, http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm.

the costs to providers and CMS. Commenters also stated that implementing too many measures dilutes the impact of poor performance on individual measures in the ESRD QIP. Commenters recommended that CMS "strive to include measures that address multiple domains of CMS's VBP programs and are not duplicative."

Response*:* We understand that there are a number of measures we proposed to be added to the ESRD QIP. One of the reasons we proposed to adopt measures for both PY 2017 and PY 2018 in the CY 2015 ESRD PPS Proposed Rule this rule (and why the majority of the new measures were proposed for adoption in PY 2018) was to provide facilities with a sufficient amount of time to implement processes that would enable them to successfully report the measure data and achieve high scores on the measures. Although we recognize that adopting more measures in the ESRD QIP increases costs to facilities as well as CMS, we believe these increased costs are outweighed by the benefits to patients of incentivizing quality care in the domains that the measures cover. We further note that the new measures adopted for the ESRD QIP will not dilute the weight of the PY 2017 clinical measure set or the PY 2018 clinical measure set, as compared to the weights that we assigned to the PY 2016 clinical measure set. The PY 2017 program contains the same amount of clinical measures as the PY 2016 program, and the clinical measure sets receive the same weight in both programs. Additionally, the weight of the clinical measures in the PY 2018 program will be increased from 75 percent of a facility's TPS (as specified in the PY 2017 program) to 90 percent, and we believe that this added weight will preserve the program's strong incentives for facilities to achieve high scores on the clinical measures. Finally, we agree with commenters who recommend that, where possible, individual ESRD QIP measures should span multiple domains. We agree that adopting measures that span multiple domains, such as the SRR measure, allows us to address multiple aspects of quality,

reduces the total number of measures in the ESRD QIP, and presents less burden for facilities than adopting multiple measures that each address a single domain. Going forward, we will continue to strive to ensure that the ESRD QIP measure set is as parsimonious as possible.

Comment*:* Some commenters requested that CMS explore new methods of adjusting quality metrics for patient case mix, because ESRD QIP measures, as currently specified, place facilities treating sicker patients at a disadvantage. For example, dialysis patients who are admitted to nursing homes and long-term care hospitals (LTCHs) often still receive their ESRD treatment at the dialysis facility. These patients are "inherently sicker and require more care than the general dialysis population." Therefore, dialysis facilities that only treat patients who are admitted to LTCHs or nursing homes are at a disadvantage under the current methodology. Commenter stated that comparing facilities with similar case mixes would be a fairer way to evaluate facility performance.

Response*:* We appreciate the commenters' concerns regarding the exploration of new methods of adjusting for patient case mix to ensure facilities are not penalized for caring for sicker patients. The SRR and STrR clinical measures are risk-adjusted on the basis of patient case mix. We make an effort to adjust for case mix where clinical evidence and methodological rigor indicate doing so is appropriate, and we consider the appropriateness of risk-adjusting for case mix as part of our ongoing reevaluation of quality measures implemented in the ESRD QIP.

Comment*:* A commenter was concerned that many ESRD QIP measures include patients who are only treated at a facility for a short period of time in the facility. The commenter believes that outcomes for these patients should be attributed to other facilities (that is, other dialysis facilities and hospitals), rather than a facility that had a limited opportunity to provide care for a patient.

Response*:* We believe the measure specifications appropriately account for patients seen at a facility for a limited period of time by implementing exclusion criteria specific to quality measures as deemed appropriate. For example, the STrR measure excludes all patients who have not received treatment at a facility for 60 days. The Hypercalcemia measure requires 30 days of treatment in the facility. The Kt/V dialysis adequacy measures exclude patient-months where fewer than 7 treatments are billed for the patient, and the vascular access measures require a minimum of 4 months of claims. An analogous exclusion is not appropriate for the SRR, where facility attribution is defined by a hospital discharge, and not time in treatment at a facility.

Comment*:* One commenter recommended that CMS include the Standardized Mortality Ratio (SMR) in the ESRD QIP, because the "medical literature has shown SMR is more indicative of the quality of care received at a facility than Standardized Readmissions Ratio (SRR) or Standardized Transfusion Ratio (STrR)."

Response*:* We thank the commenter for the input. We will consider proposing to adopt the SMR measure for future payment years.

Comment*:* One commenter recommended that CMS include a measure of the percent of eligible patients on the transplant wait-list in the ESRD QIP, because this indicator of patient status "is under the immediate auspices of the dialysis team." Other commenters recommended that CMS develop one or more measures on fluid management because this area is a high priority concern for clinicians, patients, and facilities. Another commenter recommended that CMS develop a measure evaluating the employment rate among ESRD patients ages 18-54, because the ability to maintain regular employment is an indicator of both positive clinical and psychosocial outcomes in the ESRD population. Commenter stated that monitoring employment statistics among the ESRD population will shift facility focus toward patients' overall well-being

rather than just clinical outcomes.

Response*:* We thank the commenters for their input and will take their recommendations into consideration as we proceed with our measure development work.

Comment*:* One commenter recommended CMS fully test its system for calculating ESRD QIP scores because in the past 2 years scores on the National Health Safety Network (NHSN) Bloodstream Infection and Dialysis Adequacy measures have been miscalculated.

Response: We agree that it is essential to calculate ESRD QIP measure scores correctly. The purpose of the annual Preview Period process is to give facilities the opportunity to identify scoring issues and request score changes. We further note that scoring issues related to the NHSN and Dialysis Adequacy measures were resolved via the Preview Period processes, and we take this as an indication that the process is working as intended.

Comment*:* One commenter supported CMS's goal of improving coordination of care for ESRD patients, but stated that the adoption of measures that may implicate providers outside of the dialysis facility should be delayed until renal-specific accountable care organizations can be established because without an incentive to cooperate, other healthcare providers may not share necessary information with dialysis facilities. Commenters also stated that many facilities lack the tools necessary to effectively address care coordination. Commenters supported the Comprehensive ESRD Care Initiative currently in development, and recommended that CMS delay the adoption of any care coordination measures until results are available from that model.

Response*:* We appreciate stakeholder support of the ESRD Seamless Care Organization (ESCO) model. However, we do not believe that the ESCO's focus on coordination of care should preclude the ESRD QIP from implementing measures intended to improve care coordination, because collecting and analyzing results from the model will take a number of

years, and it may not be possible to extrapolate results obtained from the small sample of facilities included in the model to all facilities nationwide. In addition, by including measures on coordination of care in the ESRD QIP before the ESCOs are in place, we will be able to positively impact care coordination for a large percentage of ESRD patients in the near future, and will be able to collect important data on care coordination from a wide array of facilities, which would better inform its future model development efforts.

Comment*:* One commenter recommended that CMS develop new measures on anemia management because transfusions have increased as facilities' utilization of ESAs has declined.

Response*:* We agree with the commenter than anemia management is a major concern among patients with ESRD, and will continue to take this into account in future measure development. We also note that the ESRD QIP currently includes a measure on anemia management and ESA dosage, the Anemia Management reporting measure, and that the intention of the STrR measure we are adopting for the PY 2018 program is to monitor and prevent transfusions related to underutilization of ESAs.

Comment*:* Many commenters recommended modifying the Vascular Access Type measures such that facilities are not penalized when grafts are placed in certain patients (for example, diabetics with intrinsic vascular disease). Commenters stated that outcomes for these patients are comparable when grafts or fistulae are used, and that the absence of a graft measure in the Vascular Access Type measure topic disincentivizes a clinically appropriate access that is selected after consultation with patients. As an intermediate step, some commenters recommended assigning the catheter and fistula measures, respectively, two-thirds and one-third the weight of the Vascular Access Type measure topic.

Response*:* The current NQF-endorsed vascular access quality measures adopted for use

in the program (NQF #0257: Hemodialysis Vascular Access—Maximizing Placement of Arterial Venous Fistula (AVF) and NQF #0256: Hemodialysis Vascular Access—Minimizing Use of Catheters as Chronic Dialysis Access) consider Arterial Venous (AV) fistula use as a positive outcome, prolonged use of tunneled catheter as a negative outcome, and incorporates the clinical equipoise regarding AV grafts, effectively creating three categories of outcome (AV fistula = positive; AV graft = neutral; prolonged use of tunneled catheter = negative). We believe this paradigm to be generally appropriate. Positive incentives are provided for AV fistula creation, but dialysis providers must remain cognizant of the clinical impact of prolonged use of tunneled catheters because of the negative incentive provided for that outcome. This paired incentive structure reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First Project over the last decade. Furthermore, a recent large meta-analysis demonstrates poorer survival with AV graft compared to AV fistula, raising important questions about the commenter's assertion of clinical appropriateness of AV graft as an alternative to AV fistula.[4] We appreciate the commenters' suggestion to revise the relative weights of the catheter and fistula components of the Vascular Access Type measure topic to increase the focus on "catheter last". We will take this into consideration in as we continue to revise and refine the ESRD QIP measure set, and we may use future rulemaking to propose changes to the measures' relative weights.

Comment*:* One commenter recommended that CMS exclude patients with a limited life expectancy from the Vascular Access Type: Catheter ≥ 90 days clinical measure.

Response*:* We appreciate the commenters' suggestion to exclude patients with a limited life expectancy from the measure denominator and will consider whether this type of revision is

4 Ravani, J Am Soc Nephrol 24: 465–473, 2013.

feasible and appropriate for this measure.

Comment*:* Some commenters recommended that CMS consider making incentive payments to facilities meeting and/or exceeding benchmarks in the ESRD QIP in addition to penalizing facilities that do not meet or make progress toward the standards, because the current incentive program only withholds funding from the nation's kidney care infrastructure. One commenter recommended working to find ways, within the statutory authorities of the Act, to provide facilities with payment incentives for high performance in the ESRD QIP. The commenter stated that doing so is consistent with the principle that value-based purchasing programs should "redistribute to providers all of the funding that was set aside in accordance with their performance on the quality measures."

Response*:* We do not believe that we have the statutory authority to provide facilities with incentive payments for high performance on ESRD QIP measures.

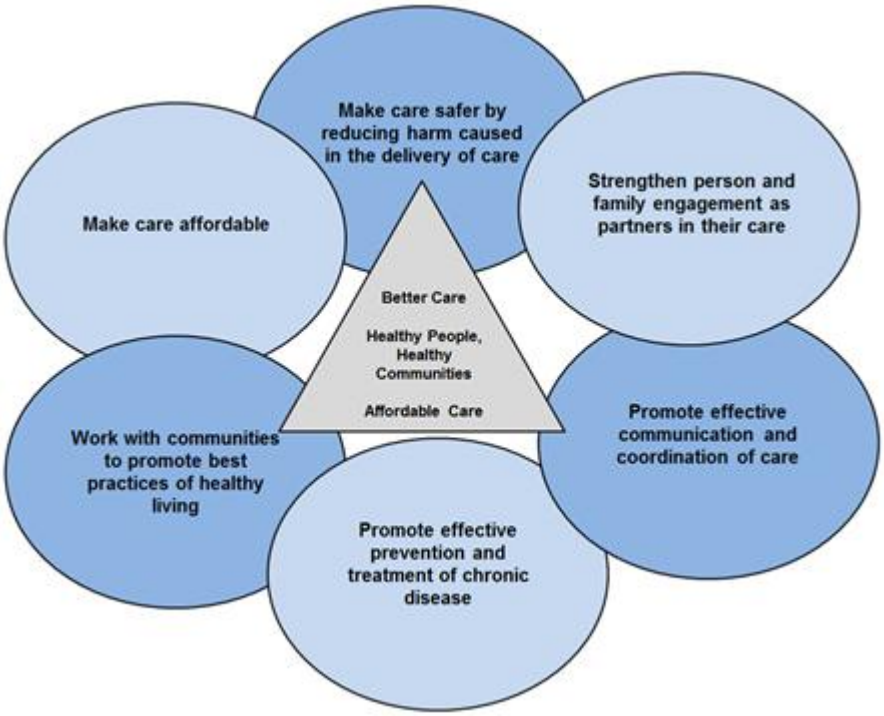
Comment*:* One commenter recommended that CMS revise the nomenclature it uses to categorize measures in the ESRD QIP because the current terminology is confusing and may contribute to a lack of patient understanding. The commenter stated that the use of the terms "clinical" and "reporting" do not align with the commonly accepted meaning of those words. The commenter recommended that CMS replace the term "clinical measures" with "accountability measures" and replace the term "reporting measures" with "required data submission."

Response*:* We disagree that the terms "clinical measure" and "reporting measure" are confusing. Specifically, the term "clinical" indicates that the clinical measures pertain to clinical care and aspects of the clinical environment that improve patient care. Furthermore, the term "reporting" indicates that reporting measures pertain to how well a facility meets requirements

for reporting data to CMS. Accordingly, we do not believe it is necessary to revise the nomenclature used to categorize measures in the ESRD QIP.

Comment*:* Some commenters were concerned that the ESRD QIP lacks a strategic vision and encouraged CMS to consult with the ESRD community to establish a clear set of principles and goals for the program. Commenter stated that the program currently seems to be focusing on adding new measures without considering whether each measure will drive improvements in dialysis care.

Response*:* The goals of the ESRD QIP closely align with the goals of the CMS Quality Strategy (the CMSQS). The CMSQS is designed to guide the activities of various components throughout the Agency and is aligned with the Department of Health and Human Services' (HHS') National Quality Strategy (the NQS). The six goals of the CMSQS are organized around NQS' three broad aims and drive and orient all of CCSQ's quality improvement programs, including the ESRD QIP, insofar as these aims align with the statutory goals of the program. The following figure illustrates the six goals of the CMSQS, which have been informed by extensive consultation with stakeholders across the country:



The strategic vision of the ESRD QIP is to adopt measures that address each of these goals. The following table illustrates the program's efforts to implement this strategic vision:

TABLE 18: ESRD QIP Alignment with CMSQS Quality Strategy Goals

CMSQS Goal	Measure	
Promote effective prevention and treatment of chronic disease		
	Kt/V Measure Topic	Hemodialysis
		Peritoneal Dialysis
		Pediatric Hemodialysis
		Pediatric Peritoneal Dialysis
	Vascular Access Type Measure Topic	Fistula
		Catheter for at Least 90 Days
	Mineral Metabolism Reporting	
	Anemia Management Reporting	
	Hypercalcemia	
	Standardized Transfusion Ratio	
	Screening for Depression and Follow Up reporting	
	Pain Assessment and Follow-Up reporting	
Strengthen person and family engagement as partners in their care	ICH CAHPS Reporting (**PY 2017**) and Clinical (**PY 2018**)	
Promote effective communication and coordination of care	Standardized Readmissions Ratio	

Make care safer by reducing harm caused in the delivery of care	NHSN Bloodstream Infection in Hemodialysis Outpatients
	NHSN Healthcare Personnel Influenza Vaccination reporting
Work with communities to promote best practices of healthy living	None.
Making care affordable	None.

As the table above illustrates, the ESRD QIP has not proposed or finalized measures for the following quality goals:

- Work with communities to promote the best practices of healthy living.
- Making care affordable.

We will evaluate these remaining goals, particularly the goal of making care affordable, to assess their appropriateness as policy goals for the ESRD QIP. In addition to evaluating the ESRD QIP measure set in terms of how well it addresses legislative mandates, NQS and CMSQS goals, we are also evaluating how well the measure set addresses policy priorities that stakeholders have brought to our attention. We continue to engage both external and internal stakeholders on a regular basis, to communicate the strategic vision of the program as well as to engage in dialogue useful to the development and implementation of policy that will effectively create improvements in the quality of care provided to ESRD beneficiaries.

Comment*:* Some commenters were concerned that CMS is proposing to adopt a number of measures that have not been reviewed or endorsed by NQF. One commenter stated that the Social Security Act authorizes the program to adopt measures that have not been endorsed by NQF, but the commenter recommended that this authority should only be exercised rarely.

Response*:* As described above, we may adopt non-NQF-endorsed measures under the ESRD QIP exception authority in section 1881(h)(2)(B)(ii) of the Act. This provision provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for

which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Although we proposed some measures that are not currently NQF-endorsed, they are pending NQF endorsement, and we are actively seeking this endorsement. We also considered other available measures that have been endorsed by the NQF and found no other feasible and practical measures. In addition, the MAP has supported or conditionally supported all of the measures proposed for the PY 2017 and PY 2018 ESRD QIP.

Comment*:* Some commenters were concerned about the process CMS uses to develop measures for ESRD. Commenters stated that the measure development process does not consider the day-to-day operations of a dialysis facility, appears to be pre-determined and closed to influence from the ESRD community, is insufficiently transparent, and is not focused on areas that are of concern to the ESRD community.

Response*:* Our development process makes use of the CMS Measures Management System Blueprint, which is publicly available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html. The CMS Blueprint guides measure development through all stages in order to prepare the measures for public comment, and submission to NQF. Development work begins with an extensive review of relevant literature, which is then presented to a panel of technical experts (members of which are selected after a public call for nominations) convened for the purpose of providing guidance to our quality measure development contractor. These panels typically include practicing nephrologists and nurses, ESRD researchers, and other experts who may meaningfully contribute to the content area under discussion. The results of their deliberations

are posted publicly on a CMS website, and any measures developed through this process undergo a 30-day public comment period prior to being considered for inclusion in the ESRD QIP. We have additionally submitted most of our measures to NQF for endorsement, and as part of that process, we must submit extensive documentation supporting the measure specifications, and the measure is scrutinized extensively by a steering committee to assess measure importance, scientific acceptability, feasibility, and usability. Furthermore, we propose the measures through our annual notice and comment rulemaking process to allow for public comments.

Comment*:* One commenter recommended CMS ensure the integrity of the data used to develop measures and score facilities on measures in the ESRD QIP. Other commenters did not support the use of multiple data sources in the ESRD QIP.

Response*:* We are continuing to work diligently to ensure the validity and reliability of data that is used to calculate facility scores and to develop measures for the ESRD QIP. We believe that our efforts to solicit stakeholder feedback through the CROWNWeb Users Group have dramatically accelerated our efforts on this, and we looking forward to the continued collaboration.

We believe that our measures are currently valid and reliable, and use a variety of tools to assess reliability and validity. We base our measure specifications on rigorous clinically peer-reviewed findings, convene technical expert panels of clinicians and statistical experts, run medical record reliability pilot tests, and submit measures to the Secretary's consensus-based endorsement entity and the Measures Application Partnership for review. We use these tools as appropriate and feasible to ensure validity and reliability.

We believe that it is appropriate to use more than one data source to collect ESRD QIP measure data because the use of multiple data sources ensures that measure scores are calculated

using the most reliable data source available, and that data from one source can be validated against data from another source.

Comment*:* A commenter recommended that CMS align measurement methodologies and reporting requirements across CMS ESRD quality programs. Commenter stated that current misalignments are creating confusion and are burdening facility staff.

Response*:* The ESRD QIP, Dialysis Facility Compare program, and the Dialysis Facility Reports program have different purposes, which in certain cases necessitates divergent measure specifications and scoring methodologies. We are currently in the process of reviewing measure specifications and scoring methodologies across the three programs, and we will continue to create alignments where appropriate.

Comment*:* A number of commenters recommended applying six exclusion criteria to all measures in the ESRD QIP unless there is a clinical or operational reason not to do so: 1) Beneficiaries who die within the applicable month; 2) Beneficiaries who receive fewer than 7 treatments in a month; 3) Beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented good faith effort to have them participate in such a visit during the applicable month; 4) Transient dialysis patients; 5) Pediatric patients (unless the measure is specific to pediatric patients); and 6) Kidney transplant recipients with a functioning graft. Commenter also recommended that patients should only be attributed to a facility after being assigned to the facility for 60 days, and that the dialysis adequacy measures should exclude patients with fewer than four eligible claim months.

Response*:* We considered applying these six global exclusion criteria in response to comments on the CY 2014 ESRD PPS proposed rule (78 FR 72192). We agree with commenters that exclusion criteria for the ESRD QIP measures should be consistent, where

feasible. We further believe, however, that exclusions also need to take into account the population to which a measure applies and the settings for which the measures were developed (for example, in-center hemodialysis as opposed to home hemodialysis). As stated in previous rules, we will continue to look for ways to align exclusion criteria for measures in the ESRD QIP, as long as there is evidence to support such consistency.

Comment*:* Commenter stated that measures in the ESRD QIP predominantly focus on in-center dialysis. Commenter recommended developing new measures, and modifying existing measures, to take greater account of peritoneal and home hemodialysis. Commenter further recommended that measure development activities should utilize data from patients on home dialysis, rather than extrapolating data from patients on in-center dialysis. Commenter stated that this is particularly important for measures of dialysis adequacy, because patients on home hemodialysis receive four to six treatments per week, while patients on in-center hemodialysis receive three treatments per week on average. Other commenters recommended that CMS increase home hemodialysis patients' representation in current ESRD QIP measures, particularly in measures directly assessing quality of care and patient experience, such as the ICH CAHPS survey. These commenters stated that home hemodialysis patients represent 10 percent of the ESRD population and are excluded from most measures currently used in the program.

Response*:* We appreciate commenters' interest in ensuring that home dialysis patients are appropriately included in the ESRD QIP. Because home hemodialysis patients currently comprise a small percentage of the ESRD population, we have confronted challenges in developing quality measures that can meaningfully distinguish facility performance in the quality of care furnished to these patients, and many of our existing measures specifically exclude home hemodialysis patients from the denominator for this reason. However, we remain interested in

exploring ways to capture these patients in the ESRD QIP, including developing measures that would assess their quality of care.

Comment*:* Some commenters recommended that CMS reevaluate the Dialysis Adequacy measure topic, because the measures assess the quantity and sufficiency of dialysis, but do not account for the patient's overall health. Commenters stated that this results in a focus on meeting the measure standard, rather than achieving the Kt/V level that is best for the individual patient.

Response*:* The current measure specifications are informed by the KDOQI clinical practice guidelines and the current body of evidence about respective clinical thresholds. These minimum standards do not specifically preclude individualization of care, but treatment should not fall below the minimum standards supported by evidence and guidelines.

Comment*:* One commenter was concerned that the ESRD QIP overemphasizes laboratory-based measures and stated that measures that assess a patient's quality of life are more meaningful.

Response*:* We recognize that the majority of the measures that we previously adopted for the ESRD QIP involve laboratory measurements (for example, the Hypercalcemia and Dialysis Adequacy clinical measures). However, we also note that we are finalizing many measures in this final rule that are not laboratory-based measures, such as the SRR, STrR, and ICH CAHPS clinical measures, as well as the Screening for Depression and Follow-Up and the Pain Assessment and Follow-Up reporting measures. These non-laboratory based measures are intended to address patients' quality of life by assessing patient and family engagement in their care, the clinical care patients receive, and conditions impacting patients' ability to participate in activities of daily living.

Comment*:* One commenter recommended CMS develop a "palliative care exclusion" to avoid unfairly penalizing facilities for tailoring a very ill patient's care to the patient's informed preferences. Another commenter stated that the ESRD QIP does not meet the needs of patients pursuing palliative care because it does not include measures that assess improvements in quality of life or whether care is consistent with patients' treatment goals. The commenter recommended that CMS develop measures that prioritize patient comfort and align the care furnished with patient preferences and goals. Commenter also recommended that CMS develop measures on reducing the social and psychological impact of ESRD, advanced care planning, facility documentation of surrogate decision-makers, facility assessment of patients' needs on first visit after hospitalization, and medication reconciliation.

Response*:* We recognize that some patients may seek palliative care, and that it is important to take this into account when developing robust clinical quality measures for patients with ESRD. Through our ongoing measure maintenance work, we will consider this and other potential exclusion criteria, and their role in measure specifications. We will also consider the commenter's recommendations as we establish priorities for future measure development.

Comment*:* One commenter recommended that CMS reinstate the Hemoglobin Less than 10 g/dL clinical measure, because it protects patients from anemia under-treatment. Commenter stated that since the removal of the Hemoglobin Less than 10 g/dL clinical measure, mean hemoglobin levels among dialysis patients have declined and transfusions have increased, indicating that facilities are not adequately addressing anemia in this population. Commenter further stated that a Hemoglobin Less than 10g/dL measure is consistent with FDA labeling of Erythropoiesis stimulating agents (ESAs) because ESA treatment should be initiated when patients reach a hemoglobin level of 10 g/dL. Commenter also states that the goal of

maintaining a hemoglobin level of at least 10 g/dL is appropriate because the risk of receiving a transfusion increases four-fold when hemoglobin levels fall below 10 g/dL.

Response*:* We appreciate commenter's recommendation to re-adopt the Hemoglobin < 10 g/dL clinical measure in the ESRD QIP. As discussed in the proposed rule, we share commenter's concerns about adequate maintenance of patients' hemoglobin levels. In addition, FDA guidance advises that treatment of anemia should minimize the occurrence of transfusions among ESRD dialysis patients, and we believe that the STrR is consistent with the guidance, and will serve to guard against underutilization of ESAs among patients. For this reason, we proposed to implement the STrR clinical measure in Payment Year 2018.

Comment*:* Some commenters stated that patient-months indicating a Kt/V value greater than 2.5 should not be excluded from the Hemodialysis measures, because patients on nocturnal dialysis may achieve such values, and they should be included in the measure.

Response*:* As stated in the CY 2013 ESRD PPS Final Rule, "We do not currently have the ability to identify patients who are receiving thrice weekly in-center nocturnal hemodialysis and do not have a measure specific to this population...Patients with HD spKt/V values greater than 2.5 are excluded from the measure calculation as these values are considered implausible for most hemodialysis patients" (77 FR 67488). As part of our measure re-evaluation process, we are considering alternatives to the 2.5 cut-off for spKt/V values, as well as avenues for identifying patients receiving in-center nocturnal hemodialysis. We will continue to pursue both avenues of inquiry in our ongoing effort to provide as comprehensive and accurate an assessment of dialysis adequacy in the QIP as is possible.

Comment*:* One commenter recommended that CMS use raw data to independently calculate Kt/V values for the Dialysis Adequacy clinical measure topic, because this will

improve the measures' accuracy.

Response*:* As stated in the CY 2013 ESRD PPS Final Rule, "We choose to collect reported Kt/V, rather than the data elements for Kt/V, due to the limitations of collecting data on Medicare claims and to minimize burden on facilities" (77 FR 67489). This is still true because the measure continues to be based on data reported on Medicare claims. We continue to believe that Medicare claims are a reliable data source for this purpose because instructions for submission of Kt/V on Medicare Claims are very specific in the requirement to report Kt/V calculated from either Daugirdas II or urea kinetic modeling, the two most reliable methods for determining Kt/V, consistent with the most recent NKF KDOQI consensus recommendations and supported by a recent Technical Expert Panel convened in 2013.

Comment*:* Commenter recommended converting the Hypercalcemia clinical measure to a reporting measure, because the ESRD PPS will not be including oral-only drugs until 2024. Commenter stated that this provision of the ESRD PPS will delay the economic incentives for facilities to underutilize oral-only drugs, so the hypercalcemia measure is not needed to protect patient safety.

Response*:* We believe it is important to retain Hypercalcemia as a clinical measure in the ESRD QIP because this measure is the only clinical outcome measure endorsed by NQF for bone mineral metabolism, and issues related to bone mineral metabolism are tremendously important for patients with ESRD. The anticipated addition of oral medications in the ESRD PPS may incentivize the use of less costly calcium-based phosphorus binders and less use of cinacalcet, which may lead to increased hypercalcemia in the ESRD dialysis population. We further note that the measure's clinical significance has already been accounted for in the scoring methodology that was finalized for the PY 2016 program and proposed for PY 2017-2018,

wherein the Hypercalcemia measure is given less weight than other measures.

Comment*:* Some commenters recommended that CMS work with the kidney community to develop a composite phosphorous/calcium/PTH measure, because a composite measure would be more likely to improve patient outcomes than a measure evaluating one of the individual components.

Response*:* We welcome an opportunity for collaboration on this and other projects. We note, however, that in 2010, a Technical Expert Panel discussed the possibility of developing measures for phosphorus, and was unable to come to a consensus regarding a phosphorus measure that assesses appropriate levels of phosphorus due to a lack of evidence supporting a clinical threshold. A reporting measure was developed and originally endorsed by the NQF in 2007, and forms the basis of the Mineral Metabolism reporting measure implemented in the ESRD QIP. In 2011, NQF reviewed two phosphorus measures, establishing one with an upper limit (hyperphosphatemia) and one with a lower limit (hypophosphatemia). NQF did not endorse either measure. A recent 2013 Technical Expert Panel recommended the development of a reporting measure for PTH, which we have specified, and are currently working to test prior to submitting it to NQF for endorsement. However, the panel concluded that there was insufficient evidence to develop a clinical measure. We are unaware of more recent evidence that makes it likely that consensus around such a clinical performance measure would be reached in new measure development efforts at this time, but we would be interested in discussing any such evidence with stakeholders.

Comment: One commenter recommended aligning the dates used for calculating patient censuses under the Vascular Access Type measure topic and NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure to reduce administrative burden. Commenter stated

that the Vascular Access Type measure topic is based on the last treatment of the month, while the NHSN census is based on the ESRD facility's first two working days of the month.

Response*:* We appreciate the recommendation. Because these measures serve different purposes, and because the methods used to calculate the measures have shown to be reliable, we do not believe there is sufficient technical rationale to justify aligning these administrative tasks at this time.

Comment*:* One commenter recommended that CMS consider coordinating occupational therapy with dialysis treatments.

Response*:* We thank the commenter for the input.

Comment*:* One commenter stated their concern that the ESRD QIP does not adequately account for the challenges faced by acute hospital-based programs that occasionally treat chronic patients. Commenter recommended that CMS reevaluate the exclusion criteria for ESRD QIP measures and exclude these facilities, because patients are already sicker when entering care at these facilities and will not remain there long enough for the patient's improvement to be attributed to the facility.

Response*:* We thank commenters for the recommendation. Some of our proposed measures, such as the SRR and STrR, do seek to address patient comorbidities through risk-adjustment. Other measures, such as the Dialysis Adequacy and Vascular Access Type measures, identify the types of patients who should be excluded as determined by available evidence. We welcome specific recommendations regarding new exclusion criteria for our measures, which we can address through our ongoing measure re-evaluation process.

Comment*:* One commenter recommended that when calculating all of the ESRD QIP measures, CMS should identify an alternative first ESRD service date for individuals who

resume dialysis.

Response*:* We thank commenters for the recommendation. All measures in the ESRD QIP only include patients on dialysis, so an alternate first service date for those resuming dialysis would only potentially affect measures that exclude patients for some initial period. The original 90-day rule following beginning of ESRD was implemented to allow time for patients to stabilize and to ensure that a patient is a chronic dialysis patient (that is, did not receive temporary dialysis therapy). Currently, we use the Medical Evidence Form 2728 to capture the date of first dialysis in order to help determine patient exclusions for the Dialysis Adequacy and Hypercalcemia clinical measures. For future payment years, we will explore the appropriateness of using the date of return to regular dialysis for those individuals who resume dialysis after transplant for the Dialysis Adequacy and hypercalcemia clinical measures.

For the STrR measure, time at risk begins at the start of the facility treatment period (starting with day 91 after onset of ESRD after a patient has been treated at the facility for 60 days) and continues until the earliest occurrence of the following: a Medicare claim indicating a diagnosis on the exclusions list, three days prior to a kidney transplant, death, end of facility treatment, or December 31 of the year. Upon discharge from a facility, the patient continues to be attributed to that facility for 60 days. Patients who resume dialysis after transplant resume time at risk once they have been back at a dialysis facility for 60 days. Therefore, we believe this recommendation may be of less concern for the STrR.

The SRR, the vascular access measures, the NHSN Bloodstream Infection measure, the ICH CAHPS measure, and the reporting measures in the ESRD QIP measure set do not have exclusion criteria related to the first ESRD service date and so are unaffected by the first ESRD service date.

Comment*:* Some commenters requested that CMS reevaluate the Hemodialysis Adequacy clinical measures' inclusion of patients who are treated at a facility at least twice in a month, because facilities experience difficulties in obtaining Kt/V measurements for patients receiving a small number of treatments during the time they are at the facility. Specifically, commenters recommended that instead of excluding patients seen at a facility two times or fewer in a month, the measure should exclude patients seen fewer than seven times. Commenter stated that it may not be possible for a facility to draw the blood needed to determine a Kt/V value if a patient is seen fewer than seven times in a month. Commenter further stated that 9.99 is reported on Medicare claims for patients receiving less than six treatments at a facility in a month, because patients receiving so few treatments may have changed modalities, received transplantation, or undergone long hospitalizations. Commenters also stated that it would be inappropriate for a facility to change a patient's hemodialysis prescription if the facility only treated the patient two times in a month. Commenter further stated that it is not possible to monitor patient conditions, modify treatment protocols, and evaluate the impact of such changes when patients are treated fewer than seven times in a month. Commenter recommended not including patient-months in the denominator if the Kt/V value reported on Medicare claims is 9.99, and that facilities should submit four months of claims for a patient before the patient is included in the measure.

Response*:* We disagree with commenters' assertion that that 9.99 is reported on claims for patients receiving six or fewer treatments per month. We note that this is inconsistent with the instructions in the Claims Processing Manual, which does not direct providers to use 9.99 for claims with fewer than seven treatments in the billing period, but instead provides the following guidance:

"Value Code D5 – Result of last Kt/V reading. For in-center hemodialysis patients this is the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis this may be before the current billing period but should be within 4 months of the claim date of service.

Hemodialysis: For in-center and home-hemodialysis patients prescribed for three or fewer treatments per week, the last Kt/V obtained during the month must be reported. Facilities must report single pool Kt/V using the preferred National Quality Forum (NQF) endorsed methods for deriving the single pool Kt/V value: Daugirdas II or Urea Kinetic Modeling (UKM). The reported Kt/V should not include residual renal function.

A value of 8.88 shall be entered on the claim if the situation exists that a patient is prescribed and receiving greater than three hemodialysis treatments per week for a medically justified and documented clinical need. The 8.88 value is not to be used for patients who are receiving "extra" treatments for a temporary clinical need (for example, fluid overload). A medical justification must be submitted for patients receiving greater than 13 treatments per month.

This code (D5) is effective and required on all ESRD claims with dates of service on or after July 1, 2010. In the event that no Kt/V reading was performed providers must report the D5 with a value of 9.99."

Despite the fact that Medicare claims do not require facilities to report a Kt/V value of 9.99 on claims with fewer than seven times, we agree with commenters who stated that it is difficult to alter patients' Kt/V values if they are seen infrequently during a month. We also agree with commenters who stated that it is inappropriate for a facility to change a patient's hemodialysis prescription if the patient is typically treated at a different facility. For these

reasons, beginning with the PY 2017 program, we will change the exclusion criteria of the Adult and Pediatric Hemodialysis Adequacy measures, such that patients treated at a facility fewer than seven times in a month are excluded from the measures for the month. This revision will appear in the finalized measure specifications for the PY 2017 and PY 2018 programs, available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

We also disagree that requiring that a patient be treated at a facility for four months before the patient is included in the measure is appropriate. As noted above, we are now requiring that a patient receive at least seven treatments at a facility during a month before being included in the Hemodialysis Adequacy measures for that month. We believe this modification sufficiently addresses commenters' concerns about facilities ability to impact patients' Kt/V levels when they only treat the patient a limited number of times.

C. Websites 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 were 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 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.

We did not receive any comments on this change.

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 can be adjusted towards the mean (that is, facilities with low exposure volume can be adjusted more than facilities with high exposure volume, and the performance rate can 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 can be based on the volume of exposure, facility scores can be adjusted more if there are fewer patient-months in the denominator, and facility scores can be adjusted less if there are many patient-months in the denominator.

We proposed 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.

We sought comments on this proposal. The comments and our responses are set forth below:

Comment*:* One commenter supported the proposal to calculate the NHSN Bloodstream Infection measure with the Adjusted Ranking Metric because this adjustment "will provide a more reliable SIR, and better reflect the differences in opportunity for HAI prevention in ESRD facilities." The commenter also recommended monitoring and ongoing assessment of this ranking.

Response*:* We thank the commenter for their support.

Comment*:* Some commenters did not support using the Adjusted Ranking Metric to calculate performance rates for the NHSN Bloodstream Infection measure because the public has not been provided with sufficient details about the adjustment's methodology to offer informed comments on the proposal, so the proposal does not meet the requirements of the Administrative Procedures Act. The commenter also stated that although NQF #1460 (the measure upon which the NHSN Bloodstream Infection measure is based) remains endorsed, even with the revised specifications to include the ARM adjustment, an NQF Steering Committee still has yet to review the revised specifications, and this has limited public scrutiny. Another commenter did

not support the use of the Adjusted Ranking Metric in the NHSN Bloodstream Infection measure, because the adjustment imposes a rank order on facilities that is not appropriate for quality improvement and is not mandated by the Act.

Response*:* We have reviewed the information we made publicly available regarding the ARM methodology for the CY 2015 ESRD PPS comment period, and we agree with commenters that greater detail would have allowed commenters to more meaningfully analyze and comment on the proposed revision to the NHSN Bloodstream Infection clinical measure. Therefore, we are not finalizing the proposal to adopt the ARM reliability adjustment for purposes of calculating facility performance on the NHSN Bloodstream Infection clinical measure. Instead, facility performance on this measure will be calculated as finalized in the CY 2014 ESRD PPS final rule, using the Standardized Infection Ratio (78 FR 72204 through 72207).

Comment*:* One commenter did not support the adoption of the NHSN Bloodstream Infection clinical measure in the ESRD QIP because apparent differences in performance are actually an artifact of reporting practices. Accordingly, facilities that diligently monitor and report infections receive lower scores than those that do not, and this creates a perverse incentive for facilities to not report dialysis events to NHSN. As an alternative to including the NHSN Bloodstream Infection measure as a clinical measure, another commenter recommended including it as a reporting measure.

Response*:* We understand commenter's concern regarding differences in performance as an artifact of reporting practices, and agree that reporting rates in the NHSN Bloodstream Infection measure are subject to detection bias. This is one of the concerns that prompted us to propose the NHSN data validation study for the NHSN Bloodstream Infection clinical measure in CY 2015. In addition, CDC is working to assist facilities and groups to evaluate the quality of

their submitted data, and we recognize that support for a more systematic means of assessing and ensuring data quality and completeness is needed. Because including a clinical measure on bloodstream infections will provide stronger incentives for facilities to monitor and reduce these infections, as compared to a reporting measure on the same topic, we continue to believe that it is essential to maintain the measure as a clinical measure.

Comment*:* Some commenters did not support the continuation of the NHSN Bloodstream Infection measure in the ESRD QIP, because sufficient information about how the measure is adjusted for access type is not available to the public.

Response*:* The specifications for the NHSN Bloodstream Infection in Hemodialysis Outpatients measure (NQF #1460) include the methodology used to stratify the NHSN Bloodstream Infection measure by vascular access type. These specifications include the following information about how the measure is adjusted for access type:

"Both the numerator and denominator are stratified by vascular access type since vascular access type is the single greatest risk factor for bloodstream infection in this population. The vascular access variables that are collected and included in this analysis are: arteriovenous (AV) fistula, AV graft, other access device, tunneled central line, and nontunneled central line. If more than one access type is present in a patient, the bloodstream infection event is attributed to the access type with the greatest risk (that is, AV fistula < AV graft < other access device < tunneled central line < nontunneled central line). During denominator collection, the user is asked to count each patient as having only 1 vascular access type, following the algorithm described. During numerator collection, all vascular access types present at the time of the bloodstream infection event are reported and the algorithm is applied during analysis of the data.

This information appears on the specifications, which were posted at

http://www.cdc.gov/nhsn/nqf/ on August 12, 2014, have been available through the NQF website since the measure was endorsed in August 2011.

Comment*:* One commenter recommended that CMS and CDC consider adjusting the patient counting methodology for the NHSN Bloodstream Infection clinical measure such that all patients treated in the facility in a month are included in the patient count for that month, rather than the current method, which includes only counts of patients that are in the unit on the first two treatment days of the month.

Response*:* CDC has conducted pilot validation work with a group of dialysis facilities and found that the census on the first two working days of the month was a satisfactory predictor of the entire month's patient treatment count. The alternative of counting denominator data on a daily basis has been required in inpatient settings, but was determined by CDC to be unacceptably burdensome for dialysis facilities conducting manual data collection.

Comment*:* Some commenters did not support the NSHN Bloodstream Infection measure as a clinical measure in PY 2016, because performance standards were not identified prior to the measure's expansion to a clinical measure.

Response*:* We appreciate the commenters' concerns about establishing values for the NHSN Bloodstream Infection clinical measure performance standards before the beginning of the PY 2016 performance period. However, we stated in the CY 2014 ESRD PPS Final Rule that we wanted to begin assessing facilities on the number of these events as soon as possible, rather than merely assessing whether facilities report these events, because of the abnormally large impact HAIs have upon patients and the healthcare industry. We believe these safety concerns justified the adoption of the NHSN Bloodstream Infection clinical measure before collecting all of the baseline data needed to apply the traditional achievement and improvement

scoring methodologies. We also note that, in recognition of the fact that we would not initially be able to award improvement points to facilities, we set the minimum TPS low enough that a facility can meet it even if it receives zero achievement points on the NHSN Bloodstream Infection clinical measure, as long as it meets or exceeds the performance standard for each of the other finalized clinical measures.

Comment*:* One commenter did not support the continuation of the NHSN Bloodstream Infection measure in the ESRD QIP, because determining whether a positive blood culture is a true bloodstream infection is a subjective exercise.

Response*:* As stated in the CY 2015 ESRD PPS final rule, "The NHSN Bloodstream Infection clinical measure is an objective measure based solely on the presence of a positive blood culture. Although NHSN collects information on access-relatedness to provide additional information that is of use for prevention purposes, the NHSN Bloodstream Infection clinical measure does not rely upon assessments of whether the bloodstream infection was access-related" (78 FR 72207).

Comment*:* One commenter recommended modifying the NHSN Bloodstream Infection measure to focus on event-specific indicators, beginning with access-related bloodstream infections. Commenter stated that focusing on specific indicators would help facilities develop prevention plans and would be a more appropriate benchmark for assessing dialysis-related infections.

Response*:* We thank the commenter for their recommendation. As discussed in the CY 2014 ESRD PPS Final Rule (78 FR 72205), NQF endorsed a bloodstream infection measure (that is, NQF #1460, the measure upon which the NHSN Bloodstream Infection clinical measure is based) because positive blood cultures (the reported event under the bloodstream infection

measure) can be objectively identified. Although the measure focuses on the presence of a positive blood culture, event-specific indicators (that is, counts and rates of access related bloodstream infections) are available in NHSN. Both CDC and CMS encourage facilities to review and utilize this data, together with overall bloodstream infection rates, for prevention purposes. As we continue to further develop and refine the measure, we may consider a greater focus on event-specific indicators (for example, access-relatedness) in the future.

Comment*:* Commenter recommended that CMS should require facilities to implement CDC's core interventions for dialysis bloodstream infection prevention, particularly interventions 7 and 8, which the commenter stated should be made into a clinical measure.

Response: We thank the commenter for their recommendation. As stated in the CY 2014 ESRD PPS final rule, "We continue to encourage facilities to adopt all of CDC's core prevention interventions. However, they are not required under the ESRD QIP because we do not believe it is feasible at this time to design a performance measure that would accurately evaluate facility compliance" (78 FR 72206).

For these reasons, we are not finalizing the proposal to adopt the ARM reliability adjustment for purposes of calculating facility performance on the NHSN Bloodstream Infection clinical measure. Instead, facility performance on this measure will be calculated as finalized in the CY 2014 ESRD PPS final rule, using the Standardized Infection Ratio (78 FR 72204-72207). The technical specifications for this finalized measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

E. Oral-Only Drug 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.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* One commenter supported CMS's interpretation of the requirements of the Protecting Access to Medicare Act of 2014 (PAMA) to delay the adoption of measures (preferably outcomes-based) related to conditions treated by oral-only drugs.

Response*:* We appreciate the commenter's support, but clarify that PAMA requires that for 2016 and subsequent years, the measures included in the ESRD QIP include measures that are specific to the conditions treated with oral-only drugs, and that such measures, to the extent feasible, be outcome-based.

Comment*:* Some commenters stated that the Hypercalcemia measure does not meet the Protecting Access to Medicare Act of 2014 (PAMA) requirement for the ESRD QIP to include a measure "specific to conditions treated with oral-only drugs." One commenter stated that it is not an effective measure for oral-only drugs because it is strongly influenced by parenteral vitamin D. Another commenter stated that current oral-only drugs are intended reduce elevated

levels of parathyroid hormone and phosphorus, and that the Hypercalcemia measure is not related to either condition. Commenters recommended that CMS adopt measures related to these conditions for adoption in the PY 2018 program, not the PY 2016 program, in accordance with the requirements of PAMA.

Response: While we do not agree with these comments, we recognize that we could, consistent with PAMA, adopt measures as late as for PY 2018 that are specific to the conditions treated with oral-only drugs. We will take these comments into account as we evaluate what measures, including the Hypercalcemia clinical measure, might satisfy this new statutory requirement in the future.

F. Requirements for the PY 2017 ESRD QIP

1. Revision to the Expanded ICH CAHPS Reporting Measure

For the ICH CAHPS reporting measure, we proposed 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 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 proposed 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 proposed 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 sought comments on this proposal. The comments and our responses are set forth below.

Comment: Many commenters did not support the requirement to conduct the ICH CAHPS survey on a semiannual basis, because it is an unfunded mandate and does not provide facilities with sufficient time to make changes to the facility environment based on survey responses. Commenters also requested further evidence that a semiannual survey administration improves patient outcomes. For these reasons, some commenters requested that CMS reduce the ICH CAHPS survey to one administration per year, until it can be determined that survey fatigue does not result in lower ICH CAHPS scores. Other commenters recommended allowing facilities to coordinate with the Networks, such that the facilities field the survey once during the performance period, and the Networks field the survey a second time.

Response*:* Several options were considered for the frequency of administering the survey. A Technical Expert Panel that we convened suggested that quarterly administration was too frequent due to the low turnover in facilities. Annual collections might result in outdated information for public reporting and quality monitoring purposes as well as a decrease in respondent recall. By surveying twice a year, we capture a diverse range of patients within their care cycle, some fairly new patients along with others with more longevity on dialysis. With semiannual administration, facilities will learn first-hand about issues concerning the care offered and where there may be gaps in providing care to this vulnerable population.

Semiannual administration of the survey improves reliability of results that will be useful for quality improvement interventions. These more reliable results will lead to quality improvement and improve the patient experience.

Comment: Some commenters did not support the adoption of the ICH CAHPS measure in the ESRD QIP because the survey instrument consists of 58 core questions, and this is burdensome for patients, particularly if facilities are required to have the survey administered on a semiannual basis. In order to reduce the burden on patients, these commenters recommended allowing venders to administer only one of the survey's three domains to each patient in the sample.

Response: While we understand that the ICH CAHPS survey may be time consuming for some patients, we believe its value as a tool for assessing the patient's experience of care outweighs this concern. In-center hemodialysis patients spend up to 12 hours a week in treatment, and are therefore the best source of information about the quality of care provided in the facility. Furthermore, the protocol for the ICH CAHPS survey allows patients to receive assistance on the survey from family members or a caregiver not associated with the dialysis

facility. In addition, we note that a patient need only answer 29 of the 58 core questions for the survey to be considered complete. Looking at results from the recent CMS Mode Experiment, less than 1 percent of the sampled patients submitted incomplete surveys. Anecdotally, we found that patients were eager to complete the survey, as evidenced by calls to the ICH CAHPS hotline upon receipt of the pre-notification letter regarding the survey administration.

Comment: Some commenters stated that the ICH CAHPS measure should not include homeless people, because vendors have trouble administering the survey to this population, and facilities are penalized for incomplete surveys.

Response*:* We are aware that it might be difficult to contact homeless persons to perform the ICH CAHPS survey; however, we are interested in ensuring that all patients, regardless of housing status, receive high quality care from the multidisciplinary team at their facility. We are particularly concerned about the needs of homeless patients because they may have different concerns than other patients that need to be addressed by the facility. We further note that under the ICH CAHPS survey administration and ESRD QIP scoring methodology, facilities are not penalized if they are either (1) unable to contact a patient for the survey administration, or (2) receive incomplete survey responses, provided that the survey vendor followed the administration protocol.

Comment*:* Some commenters stated that facilities should not be held accountable for low response rates when they do not have an opportunity to review patient contact information used by survey vendors. One commenter also recommended increasing the minimum number of qualifying patients because small and rural facilities often have high non-response rates.

Response*:* As noted above, facilities with high non-response rates, regardless of their location or population size, are not penalized on the basis of their survey response rate. Instead,

scores on the ICH CAHPS reporting measure are based on whether the facility administers the survey on a twice-yearly basis using a third-party, CMS-approved vendor and submits these survey results to CMS via that third-party vendor. We therefore disagree that high non-response rates for small and rural facilities justify increasing the minimum number of qualifying patients for this measure, and we note that doing so would effectively discount (for the purposes of the ESRD QIP) the experiences of a substantial number of patients. In addition, the ICH CAHPS survey administration specifications include methods of confirming that patient contact information is as up-to-date as possible. ICH CAHPS survey vendors are required to verify the contact information provided by the ICH CAHPS Coordination Team from CROWNWeb by using a commercial address update service. Survey vendors are permitted to ask facilities to provide updated addresses and telephone numbers for all patients they served during the sampling window. To maintain and protect the identity of the patients sampled, survey vendors cannot give the list of sample patients to the facility when they request updated patient addresses and contact information.

Comment*:* Some commenters stated that versions of the survey used for patients who do not speak English as their first language are mistranslated, particularly the Chinese version.

Response*:* We appreciate commenter's input regarding the translated versions of the ICH CAHPS survey. Recent corrections to the Chinese language versions of the ICH CAHPS survey have been made to reflect changes to the English version of the instrument. Our language specialists assure us that we are using translations which the majority of people speaking a given language will understand, but we are open to concerns and feedback about the translated versions of the ICH CAHPS survey. Please send any questions or comments to ichcahps@rti.org.

Comment*:* One commenter stated that the ICH CAHPS survey should be expanded to

include all patients with ESRD, such as those who dialyze at home, instead of being restricted to in-center hemodialysis patients.

Response*:* We appreciate the commenter's recommendation that we develop additional questions or surveys intended to capture a larger proportion of the ESRD population. While the current survey is specific to in-center hemodialysis patients, we will look into opportunities to capture other patients, such as home hemodialysis and peritoneal dialysis patients, in the future.

Comment*:* One commenter sought clarification as to how many times a patient must be treated at a facility before he or she becomes eligible for the ICH CAHPS measure.

Response*:* Patient eligibility for the ICH CAHPS measure is not determined on the basis of a set number of treatments, but rather on the amount of time a patient is treated at a facility. Nevertheless, assuming that a typical hemodialysis patient receives three treatments per week, and given that a patient must be seen at a facility for three months to be eligible for the ICH CAHPS survey, an average survey-eligible patient will receive 36 treatments before becoming eligible for the measure.

Comment*:* One commenter was concerned that the ICH CAHPS survey is of limited use in the ESRD population, because its administration excludes patients who die or are too sick to complete the survey, and the survey does not ask patients about advance care planning. Commenter recommended CMS continue to work on the ICH CAHPS survey so that it provides more actionable information about whether the care patients receive is consistent with patients' goals.

Response*:* We understand commenter's concerns about the ICH CAHPS survey excluding patients who are deceased or physically or mentally incapable of completing the survey. We believe that in a patient experience of care survey, patients are most qualified to

evaluate their experience. While we agree that those who are capable of completing the survey but require assistance to do so should receive the necessary assistance, we do not believe that a survey administered to a family member or proxy on behalf of a patient is a satisfactory substitute for patient input. Therefore, we do not believe it is appropriate to include patients who are deceased or are mentally or physically incapable of completing the survey in the ICH CAHPS survey at this time. We appreciate commenter's recommendation to modify or include new elements in the survey aimed at providing actionable information about whether a patient's care is consistent with the patient's goals for care, and will take this into consideration in the future.

For these reasons, we are finalizing the expanded ICH CAHPS reporting measure as proposed for the PY 2017 ESRD QIP and for future payment years. The technical specifications for this finalized measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

2. 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 19 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 proposed to remove one measure, Hemoglobin Greater than 12 g/dL, beginning with the PY 2017 measure set (see Table 20 below).

TABLE 19: 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 $\geq$ 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.
1454	Hypercalcemia Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
N/A[2]	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[3]	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 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.
[3] We note that this measure is based upon a current NQF-endorsed serum phosphorus measure (NQF #0255).

TABLE 20: 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. Policy for Determining when a Measure is "Topped-Out" in the ESRD QIP, and the Removal of 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 proposed 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 proposed 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 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 21.

TABLE 21: 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 21 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 proposed 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 did not propose to remove the Pediatric Hemodialysis Adequacy measure from the ESRD QIP because we 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 proposed that even if we determine that a clinical measure is topped out according to the statistical criteria we apply, we would 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 sought comments on these proposals. The comments and our responses are set forth below.

Comment*:* One commenter supported removal of the Hemoglobin Greater than 12 g/dL clinical measure, because there is little variation in facilities' performance. The commenter additionally supported this proposal "because under the PPS, facilities no longer have an incentive to overuse erythropoietin stimulating agents." Several commenters recommended continuing to publicly report facility scores to ensure that patients' hemoglobin levels are properly monitored.

Response*:* We thank the commenters for the support. We further note that the Dialysis Facility Compare program will continue to publically report facility scores on the Hemoglobin Greater than 12 g/dL measure, and that this will help ensure that patients' hemoglobin levels are properly monitored.

Comment*:* Some commenters did not support the proposal to remove the Hemoglobin > 12 g/dL clinical measure from the ESRD QIP, because the measure is clinically important, and removing this measure could lead to a lapse in anemia monitoring in this patient population. One commenter recommended that CMS keep the Hemoglobin > 12 g/dL clinical measure, but reduce its weight for QIP scoring purposes in order to maintain facilities' focus on anemia management while decreasing this measure's impact on facility scores.

Response*:* We agree that maintaining patients' hemoglobin levels below 12 g/dL is clinically important. For this reason, the Dialysis Facility Compare program will continue to publically report facility scores on the Hemoglobin Greater than 12 g/dL measure, and we believe that this will help ensure that patients' hemoglobin levels are properly monitored. Nevertheless, based on the statistical criteria for determining when a measure is topped out in the ESRD QIP, we have determined that performance on this measure is so high and unvarying that meaning distinctions in facility performance cannot be made. Accordingly, we do not believe it is appropriate to use the measure in a value-based purchasing program, such as the ESRD QIP, because the measure is not an effective tool for incentivizing facilities to further improve the quality of care provided to patients with ESRD.

Comment*:* One commenter recommended that CMS reevaluate the Hemoglobin > 12 g/dL clinical measure, because it does not account for the differences in "average" hemoglobin levels among dialysis patients of different ages, genders, and overall health. For example, the commenter stated that while a hemoglobin of 12-14 g/dL is "normal" for women, the range for men is 14-18 g/dL, and that male patients may be denied access to treatments that would raise their hemoglobin levels to "normal" because their facility is concerned about its score on the hemoglobin > 12 g/dL clinical measure.

Response*:* We appreciate the commenter's input and note that we are removing the Hemoglobin Greater than 12 g/dL clinical measure from the ESRD QIP beginning in the PY 2017 program. However, we will consider the commenter's recommendation as we continue to evaluate the use of the measure in other CMS ESRD quality programs, such as Dialysis Facility Compare.

Comment*:* One commenter sought clarification as to whether the Anemia Management reporting measure is sufficient to meet CMS's statutory requirements regarding measures on anemia management if CMS chooses to remove the Hemoglobin > 12 g/dL clinical measure from the ESRD QIP.

Response*:* Based on the FDA's evolving position on ESAs, we believe the Anemia Management reporting measure meets the statutory mandate to include such measures in the ESRD QIP. The FDA labeling for ESAs previously included a hemoglobin level target range of 10 to 12 g/dL for chronic kidney disease patients. In 2011, the FDA released a modified drug recommendation for the use of ESAs in chronic kidney disease patients, removing these hard cutoffs and replacing them with more generalized guidance to "individualize dosing and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions." We therefore believe the Anemia Management reporting measure's requirement that providers report ESA dosages, rather than prescribing a course of action, aligns with the current FDA labeling regarding ESA usage. Additionally, we note that the STrR clinical measure, finalized for the PY 2018 ESRD QIP, meets the statutory requirement for measures on anemia management.

Comment*:* One commenter did not support the proposal to remove the Hemoglobin > 12 g/dL clinical measure from the ESRD QIP, because its removal and the inclusion of the proposed Standardized Transfusion Ratio may lead facilities to revert to higher ESA doses in an effort to avoid transfusions.

Response*:* Evidence currently suggests that ESA doses have declined sharply since 2011, due in large part to the FDA label change for ESAs. Since that time, the Hemoglobin Greater than 12 g/dL clinical measure has become topped out as fewer patients have hemoglobin levels that exceed 12 g/dL, and we believe that current payment incentives (i.e., the inclusion of ESAs

in the ESRD PPS) will minimize the risk of excessive utilization of ESAs. However, we intend to continue monitoring hemoglobin levels through the Anemia Management reporting measure and the Dialysis Facility Compare program.

Comment*:* Many commenters supported the proposed statistical criteria for determining when a measure is topped-out in the ESRD QIP. However, one commenter recommended modifying the criteria used to determine when to remove a measure from the ESRD QIP, and further recommended that a measure should not be removed from the program if the measure uniquely "addresses the needs of a specific population within the ESRD program." Another commenter supported the statistical criteria, but also recommended that CMS should consider lowering the thresholds for determining when a measure is topped out.

Response*:* We agree with commenters that a measure should not be removed from the ESRD QIP if it uniquely addresses the needs of a specific population within the ESRD population. We are finalizing the proposed statistical criteria for determining that a measure is topped-out and should be removed from the ESRD QIP. However, for the reasons explained below, we are not finalizing our proposal to retain a clinical measure that is statistically topped-out 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. Instead, based on comments received, we are finalizing a policy that allows us to retain a topped-out clinical measure if it addresses the unique needs of a subset of the ESRD population, because we believe that this criterion is clearer and more transparent than the one proposed. Additionally, we agree with the commenter that statistically topped out measures should be retained in the ESRD QIP measure set if they address the unique needs of a subset of the ESRD population, because we believe that the drawbacks associated with scoring a topped out measure are less significant than the benefits of including as

many subsets of the ESRD population as possible.

Comment*:* One commenter sought clarification as to why CMS is not proposing to remove the Pediatric Hemodialysis Adequacy measure, despite the fact that it meets the statistical criteria for being a topped-out measure in the ESRD QIP.

Response*:* We originally proposed to retain the Pediatric Hemodialysis Adequacy clinical measure for two reasons: (1) there are few measures available that focus on the care furnished to pediatric patients; and (2) we believed that the small number of facilities that are eligible to receive a score on the measure should properly set a standard of care for all facilities treating pediatric hemodialysis patients, even if these other facilities are not eligible to a receive a score on the measure. As explained above, and based on public comments, we are not finalizing a policy that would allow us to retain a topped-out clinical measure on the basis that its continued inclusion in the ESRD QIP measure set will continue to set a high standard of care for dialysis facilities, because we agree with the commenter that this standard may be difficult to apply.

Comment*:* Commenter did not support the use of the first statistical criterion for determining when a measure is topped out in the ESRD QIP, because in a sample size of roughly 5600 facilities, measure scores will appear to be statistically indistinguishable, even though the truncated coefficient of variation is less than 0.1.

Response*:* The two proposed statistical criteria were selected to create alignments between the ESRD QIP and other CMS quality-reporting and VBP programs, such as the Hospital Inpatient Quality Reporting program, the Hospital VBP program, and the Hospital Outpatient Quality Reporting program. We recognize that using both of the statistical criteria instead of just the second (that is, truncated coefficient of variation is less than 0.1) raises the threshold a measure must reach before it is considered topped out. Nevertheless, we believe that

this elevated threshold appropriately differentiates topped-out measures from measures that reliably distinguish facility performance, whereas the use of only the second criterion would inaccurately classify reliable measures as being topped out.

Comment*:* Commenter stated that there is little room for facilities to improve on the dialysis adequacy measures. For this reason, commenter recommended that the adequacy measures should be removed from the ESRD QIP, and that performance on these measures should be monitored through other means.

Response*:* As illustrated in Table 21 above, the Adult Hemodialysis and the Adult Peritoneal Adequacy measures do not meet the statistical criteria for being a topped out measure in the ESRD QIP. Although performance rates are high overall, there is still room for facility improvement on the measures, and we therefore do not think it is appropriate to remove the measures from the ESRD QIP. As explained above, even though the Pediatric Hemodialysis Adequacy measure meets the statistical criteria for being a topped out measure in the ESRD QIP, we have decided not to remove it because it addresses the unique needs of a specific subset of the ESRD population.

For these reasons, we are finalizing the removal of the Hemoglobin Greater than 12 g/dL measure from the ESRD QIP, beginning with the PY 2017 program. We are also finalizing as proposed the statistical criteria for determining when a measure is topped out in the ESRD QIP. We are not finalizing our proposal to retain a clinical measure that is statistically topped-out 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. Instead, we are finalizing that we will not remove a statistically topped-out measure if the measure addresses the unique needs of a specific subset of the ESRD population.

c. New Measures 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 proposed to adopt one new clinical measure that addresses care coordination (see Table 22).

TABLE 22: 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. 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.[5] 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

[5] 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.

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%.[6] 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 proposed 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

6 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.

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 did not believe it was 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 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 proposed 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 (for example, 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_TechnicalSpecifications.html. We proposed 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_TechnicalSpecifications.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_TechnicalSpecifications.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 infraction 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 infraction 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_TechnicalSpecifications.html.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* One commenter supported the proposal to adopt the Standardized

Readmission Ratio clinical measure, because "hospital readmissions may be an indicator of poor access to follow-up primary care or missed opportunities for inpatient and ambulatory care providers to better coordinate care."

Response*:* We thank the commenter for the support.

Comment*:* Some commenters did not support the proposal to adopt the SRR measure because it could harm patients. Specifically, commenters stated that the measure could lead facilities to deny care to high-risk populations, particularly in urban settings where patients have more than one option for dialysis treatment. One commenter further stated that the measure's risk-adjustment methodology will not completely remove this incentive to "cherry-pick" patients, which would be detrimental to patient health and waste healthcare resources. Commenter was also concerned that facilities may delay needed hospital admissions if the SRR measure were to be adopted in the ESRD QIP.

Response*:* We agree that the concern for unintended consequences is a serious one with outcome measures. Access to care is particularly important and we continue to seek ways to ensure that access is unabated. This is part of the reason we proposed to adopt the SRR measure, which incorporates a risk-adjustment methodology that levels the playing field for facilities with different case-mixes and counters the incentive for cherry-picking patients. We also have the capacity to monitor and evaluate for some types of unintended consequences. For example, we currently assess rates of mortality at the facility level in the Dialysis Facility Compare program. This is an approach similar to that used on Hospital Compare, which publicly reports both mortality and readmissions rates for hospitals. In general, we note that mortality and readmission rates are positively correlated among dialysis facilities and in other settings, suggesting that reducing readmissions does not create increased risk to patients through "cherry-

picking". We also note that similar measures have been implemented in other post-acute care settings for quality reporting and value-based purchasing, including long-term care hospitals, inpatient rehabilitation facilities, and nursing homes. The SRR risk adjustment is consistent with these measures. We intend to monitor whether the implementation of this measure leads to unintended consequences.

Comment*:* Many commenters did not support the proposal to adopt the SRR measure because it is not a fair way to evaluate facility performance. Specifically, commenters stated that unplanned readmissions are beyond the control of dialysis facilities, and that cultural factors can make patients noncompliant with treatment protocols, leading to hospital admissions.

Response*:* We disagree with assertion that unplanned readmissions are beyond the control of dialysis facilities. While the causes of readmissions are multifactorial, our analyses support that the facility exerts an influence on readmissions roughly equivalent to that exerted by the discharging acute care hospital. We believe that coordination of care requires interaction between multiple providers, including those discharging the patient, and those continuing patient care following discharge. While cultural factors and patient noncompliance can lead to hospital admissions, this is no less true for the acute care hospitals, long-term care hospitals, inpatient rehabilitation facilities, nursing homes, and home health agencies, and it does not negate the deleterious consequences readmissions can have for those patients.

Comment*:* Some commenters stated that facilities are typically not notified when a patient is discharged from a hospital, that many patients are discharged from and readmitted to a hospital before they return to their dialysis facility. Commenters also stated that facilities cannot compel nephrologists to see patient immediately after the patients are discharged from a hospital. Commenters recommended that patients with a readmission within one to five days of an index

discharge should be excluded from the measure, because facilities typically do not have a chance to see these patients before they are readmitted to a hospital, and 17 percent of hospitalized patients with ESRD are readmitted to a hospital within three days of the index discharge.

Response*:* We recognize that a disproportionate number of readmissions may occur during the days immediately following discharge. We believe this reflects an important opportunity for quality improvement that may be missed if these readmissions are excluded from the readmission measure. While it is true that several days may pass between discharge and a patient's first regularly scheduled appointment at a dialysis facility, we submit that if this pattern of practice results in excessive levels of readmissions, then it represents a failure to successfully manage a patient's care from the acute to non-acute setting. Additionally, under the Conditions for Coverage, a dialysis facility must have a medical director whose responsibilities include a quality assessment and improvement program (CfC §494.150). Therefore, facilities can compel nephrologists to see a patient immediately after the patients are discharged from the hospital, because improving on quality issues, such as care coordination, is part of the medical director's responsibilities.

Comment*:* Many commenters stated that facilities should not be placed in the position of managing comorbid conditions that typically accompany ESRD, and commenters preferred a measure that was limited to readmissions that are related to ESRD and dialysis. Commenters stated that the measure should be limited to readmissions associated with ESRD (as opposed to focusing on all readmissions, irrespective of cause), because the majority of readmissions for patients with ESRD are not attributable to diagnoses related to ESRD and dialysis, and this could penalize facilities for readmissions beyond their scope of control. One commenter stated it may be difficult to distinguish readmissions related to dialysis and ESRD from those that are not, so

the commenter recommended addressing this issue with further adjustments to the measure's statistical models, and by adding additional adjustments for case mix.

Response*:* A Technical Expert Panel (TEP) that we convened for the purpose of developing this measure considered the issue of whether dialysis facility readmission measures should be all-cause, or limited to a specific set of readmissions related to ESRD and dialysis. The TEP concluded that an all-cause measure was appropriate for the SRR because it could not come to a consensus of what specific causes for readmissions did or did not fall within the control of dialysis facilities or could be considered to be related to ESRD and dialysis. This approach is consistent with readmission measures implemented for other quality programs, and is augmented using a planned readmissions algorithm that excludes readmissions identified as having been planned, with the rationale that such readmissions do not reflect poor quality of care. This algorithm was originally developed for hospital readmissions measures, and has been adapted for use in the dialysis facility setting, as well as nursing homes, home health agencies, inpatient rehabilitation facilities, and long-term care hospitals.

Comment*:* Many commenters expressed a number of technical concerns with the specifications for the SRR measure. Specifically, commenters stated that using the 2728 form as the data source for determining patient comorbidities is inappropriate because the form is not used to track comorbidities that develop after the initiation of ESRD; commenters therefore recommend obtaining a reliable data source for comorbidities before adopting the measure. Commenters further stated that the measure relies on too many data sources to be specific to ESRD, and that facilities do not have ready access to hospital data, which they could use to design quality improvement programs.

Response*:* Although we do incorporate some information from the 2728 form in the risk

adjustment model, the comorbidities are identified using Medicare Claims data. We use many data sources to construct our quality measures, but the data are derived from ESRD dialysis patients, and are therefore relevant to the care of this patient population. We recognize that dialysis facilities do not have access to hospital claims data, and that they believe they could benefit from such access in developing quality improvement programs. Providing such data is fraught with difficulty, such as logistical delays in the availability of the data, concerns about patient privacy across providers, and the lack of an effective delivery system for such data. While we continue to consider how such data may be provided in a way that is meaningful and as actionable as possible, we believe implementing a quality measure based on claims data is appropriate and consistent with the implementation of readmission measures in other settings. Additionally, we have implemented measures in the LTCH, IRF, and Home Health quality reporting programs even though hospital and other claims data are not currently available to these providers. Even if we could find a feasible way to make the hospital data available, there would be a substantial delay between the time we receive it and the time we could make it available to facilities. It is therefore not feasible for us to provide facilities hospital data in a short timeframe.

Comment*:* Some commenters stated that sickle cell trait, angiodysplasia, myelodysplasia, diverticular bleeding, asthma and nursing home/rehab status should be included as risk-factors in the measure calculations. Some commenters did not support the proposal to adopt the SRR measure, because it does not risk-adjust for patients' socioeconomic status. Commenters recommended that CMS incorporate this risk adjustment into the SRR measure, because otherwise facilities serving a high percentage of low-income patients may be subject to unnecessary and inappropriate payment reductions. One commenter further recommended that

the SRR measure adjust for patient race, language, life circumstances, and environmental factors, because these factors have an impact on health outcomes and are beyond the control of the facility. One commenter also recommended that CMS institute a peer-grouping system in order to compare dialysis facilities that are similarly situated and treat similar patient populations before incorporating any further outcome measures into the ESRD QIP.

Response*:* The SRR already includes risk adjustment for the prior-year comorbidities as supported by a TEP and analysis of data. The suggested comorbidities were not included in the risk adjustment model following input from the TEP and a 30-day public comment period. We are aware that there are differing opinions regarding our current approach in risk-adjusting measures in the QIP for socioeconomic status (SES). We note that risk-adjusted outcome measures aim to reveal differences related to the quality of care provided. We believe that quality of care received by patients of lower SES contributes at least in part to the observed association between SES status and the readmissions rate. We continue to have concerns about holding dialysis facilities to different standards for the outcomes of their patients of low SES—we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations.

Concerns that facilities treating large numbers of low socioeconomic status patients are disproportionately penalized by quality measure performance may be addressed through risk adjustment, but other alternatives exist that would first need to be considered, such as peer grouping stratification. Peer group stratification involves stratifying hospitals by the hospital's proportion of low-SES patients, as a method to correlate readmission rates and penalties with patient income. We may consider incorporating such a peer-grouping stratification or an

alternate method of addressing socioeconomic status in the future, as we continue to revise and refine the SRR clinical measure.

Comment*:* Some commenters stated that the measure's specifications are inappropriate because the denominator is defined in terms of index discharges, as opposed to the number of eligible patients at a facility. Commenters recommended using the latter method because under the proposed method a facility's score could be disproportionately reduced if one or two patients had high readmission rates, even if the facility had a low readmission rate overall.

Response*:* The same issue was discussed by the TEP in the course of their evaluation of the SRR. As a consequence of those deliberations, we have structured the SRR measure to account for frequently hospitalized patients in two ways: first, it excludes all hospitalizations following a patient's 12th admission (note that 1 percent of all patients are admitted more than six times in a calendar year) and, second, the model that defines the expectation of readmission adjusts for hospitalizations that involve high risk diagnoses that are rare but very likely to result in a 30-day readmission (for example, sickle-cell anemia, HIV/AIDS).

The measure is focused on the process of readmission following a hospital discharge, and for this purpose the denominator is appropriate. Each hospital discharge is an opportunity for success or failure in managing the transition of a patient's care from the acute care facility to the dialysis facility. Allowing for risk-adjustment, the SRR assesses the rate of success at a given dialysis facility, and compares it to the rate of success at other facilities. It is true that a facility that has relatively fewer hospitalizations will have a smaller denominator, but what portion of those hospitalizations are followed by a readmission within 30 days is still a valid indicator of the successful management of care transitions. If one took as the denominator the set of all patients at the facility, we might be led to conclude that this facility with relatively few hospital

discharges had a reasonable rate of readmissions even though, for the condition of the patient being discharged, we would have expected significantly fewer readmissions.

Furthermore, we proposed in the CY 2015 ESRD PPS Proposed Rule to account for variability in small facilities' SRR scores by excluding facilities with fewer than 11 discharges, and by applying a small facility adjustor (which "gives facilities the benefit of the doubt when measure scores can be unduly influenced by a few outlier patients") for facilities with 11 to 41 index discharges. We believe that this aspect of the ESRD QIP scoring methodology will mitigate the impact of one or two outlier patients on a small facility's SRR score.

Comment*:* Some commenters sought clarification as to why the proposed SRR measure is not limited to patients on chronic dialysis for 90 days, when this exclusion is included in the Standardized Mortality Ratio and Standardized Hospitalization Ratio measures. One commenter stated that this specification should align across the three measures.

Response*:* The original 90-day exclusion following the start of ESRD dialysis was implemented to allow time for patients to stabilize; as a result, hospitalizations and deaths in this period did not count against the dialysis facility when computing the SHR and the SMR. The SRR diverges on this point because the readmissions function differently. The SRR measure addresses the question as to how well the patient is managed once discharged from an acute-care hospital and assesses the outcome of the discharge. The start of dialysis defines the point in time when patients begin to be at risk for hospitalization or death while in the care of a dialysis facility (for the purposes of calculating the SMR and SHR measures). By contrast, risk for readmission begins upon discharge from an acute care hospital when calculating the SRR measure. As SRR is a measure of care coordination, there is no expected need for a stabilization period. Applying one would limit the measure's efficacy at assessing coordination of care for

the discharged patient.

Comment*:* Some commenters were concerned that the proposal to exclude index hospitalizations that occur after a patient's 12th readmission in a calendar year will unduly impact small facilities, because these facilities' scores are disproportionately impacted by outliers. Commenters sought clarification as to why this criterion was raised from 6 readmissions to 12 readmissions.

Response*:* We initially considered allowing a maximum of six readmissions per patient-year (95th percentile of the 2009 test population). We made the change since we were concerned that there might be seasonal exclusions--that is, that this exclusion might disproportionately exclude hospitalizations occurring later in the reporting period and that these hospitalizations might, in some way, be different from hospitalizations occurring earlier in the reporting period (that is, in the calendar year).Variants of the measure that include either the cap of 6 or 12 readmissions are highly correlated (97.8 percent). Since increasing the exclusion criteria to 12 admissions made only a small difference, we felt comfortable applying this criterion in the hope of reducing the likelihood of bias.

Comment*:* Some commenters stated that the Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio measure (NQF #1789) excludes patients who have an incomplete claims history from the past year. Commenters sought clarification as to why this criterion was not included in the proposed SRR measure.

Response*:* We considered adopting this exclusion for the SRR measure but decided against doing so because it would exclude approximately one-third of ESRD dialysis patients who are discharged from the hospital during their first year of ESRD treatment. Many ESRD beneficiaries are not Medicare eligible at the initiation of dialysis but may still be likely to

experience a hospitalization within the first year of dialysis treatment. As a consequence, the exclusion criterion would effectively eliminate accountability for readmissions within the first year of dialysis for patients who were not Medicare eligible prior to being diagnosed with ESRD, and we believe that the measure should assess all eligible unplanned readmissions of ESRD dialysis patients.

Comment*:* Some commenters stated that risk-adjusting for the discharging hospital does not sufficiently account for geographic variability in admission and readmission rates. Commenters also recommended risk-adjusting for the admitting physician because physicians decide when to admit and re-admit patients to a hospital.

Response*:* We decided not to propose a physician adjustment for three reasons—our general goal of encouraging the facility's coordination with its physicians; harmonization with readmission measures implemented in quality programs for other settings; and issues with attribution of discharges and readmissions to specific nephrologists or other care providers.

Variations in practice patterns may result in undesirable practices that this and other ESRD measures are seeking to improve. In view of the concept of shared accountability, adjusting for physician practice also removes a potential role for the dialysis facility in modifying physician practice.

Under our regulations (42 CFR 494.150(c)(2)(i)), dialysis facilities are responsible for overseeing the provision of care by a multi-disciplinary team, including the nephrologist treating the patient. Oversight of individual staff nephrologist care, including, ensuring adherence to facility policies and Medicare regulations, is primarily the responsibility of the site Medical Director, a paid employee of the dialysis facility, and, additionally, the responsibility of the facility governing body. Risk adjusting for physician would place CMS in the position of

suggesting that a dialysis facility is not responsible for health consequences experienced by patients as the result of business or policy decisions by the facility administration.

We designed the SRR measure to be aligned as closely as possible with the existing Hospital-Wide Readmission Measure (NQF# 1789). Adjusting for physician effects in this measure would be inconsistent with similar readmission measures in other care settings where we assume that like dialysis facilities, the physicians treating the patients fall under the facility's responsibility.

Risk-adjusting for the nephrologist would also create issues with attribution. First, ESRD patients are often under the care of multiple physicians and attribution to a particular physician would be difficult. Second, it is not clear whether it is more appropriate to hold responsible the nephrologist seeing the patient immediately before the index admission, or the nephrologist seeing the patient immediately after the discharge, or both.

We do not adjust our readmission measures to account for regional hospitalization practices. We believe that regional variation in hospital utilization that is related to that hospital's case mix does not justify differences in dialysis facility readmission rates because this variation is modifiable by provider behavior.

Comment*:* One commenter was concerned that the double random effects model used in stage 1 of the proposed SRR measure is biased against rural facilities, because these facilities are likely to be the only major ones available, and they are likely to be served by one major hospital. Commenter requested data on the measure's differential impact before adopting the measure. Commenter also recommended adjusting the measure to account for the distance patients travel from their homes to their dialysis facility and to the admitting hospital, because this could influence patient choices to utilize health care resources.

Response*:* The risk adjustment methodology uses a mixed model, with fixed effects estimated for the dialysis facilities' contribution to readmissions, and random effects estimated for the hospitals' contribution to risk for readmissions. In the event that a rural facility is paired only with a single hospital, the associated (random) hospital effect is estimated by borrowing information from all the other hospitals nationwide. There is no reason to believe that rural facilities (or any facilities) would be penalized with this approach. As in the case of care coordination measures for other settings, responsibility for outcomes is shared between the facility and the hospital.

Comment*:* Commenter stated that using a fixed effects model in the proposed SRR measure is inconsistent with the use of a random effects model in the NHSN Bloodstream Infection's Adjusted Ranking Metric. Commenter stated that the random effects model is more appropriate for the dialysis facility setting.

Response*:* Using random effects and fixed effects requires different statistical assumptions when estimating the contribution of a risk factor to patient outcomes of care. While we recognize that using fixed effects, along with random effects, in the risk-adjustment methodology for the SRR measure is different than the model we use to risk-adjust the Bloodstream Infection measure, our risk-adjustment methodology for the SRR measure is consistent with the use of fixed effects models developed for the SMR and SHR. We also note that the NQF has endorsed both approaches to risk-adjustment. The SRR measure incorporates both fixed and random effects in its adjustment model for particular purposes. When there is only one hospital and one dialysis facility serving a community, the random effects approach basically assumes that the hospital is drawn at random from the population of hospitals, as is the underlying assumption in a random effects model. Thus, the adjustment for the hospital in that

case would be essentially that of a randomly selected hospital. In other instances, where the same hospital is paired with two or more dialysis facilities, the overall rate of readmissions is used in the model to determine the hospital adjustment. In either case, the random variation due to the hospital contributes to the standard error of the estimated facility response. There are no additional assumptions in the fixed effects for facilities, as opposed to the additional statistical assumptions required of a random effect.

Comment*:* One commenter stated that the validity of the SRR measure is called into question by the high number of risk-adjustments included. Specifically, commenter stated that risk-adjusting for BMI at incidence of chronic dialysis is inappropriate because the recorded values may have been incorrectly documented, and because a patient's BMI is likely to change significantly between the initiation of chronic dialysis and an index hospitalization.

Response*:* Our risk adjustment is intended to fairly compare a given facility to the national level of performance after properly adjusting for the case-mix in that facility. Thus, the adjustments were chosen to reflect important comorbidities and characteristics of patients in a given facility, and were assessed with respect to their association with the readmission outcome. We have, however, avoided risk-adjusting for facility practices that reflect choices in care provided and that may result in better or worse outcomes. We did this to avoid adjusting away care choices made by providers that may account for important differences in facility outcomes. We are not aware of a particular standard defining the number of risk adjustors in a model that would call its validity into question, but we carefully consider the risk model's parsimony during its development, evaluating components for redundancy, and removing those that are either redundant or do not contribute to the model. We continuously re-evaluate our quality measures for appropriateness, and our analyses indicate that incident BMI is a significant and appropriate

predictor of health outcomes in the ESRD dialysis population. *Comment:* One commenter stated that claims codes used in a non-ESRD population should not be used to determine planned readmissions in the ESRD population, as it the case for the proposed SRR measure.

Response*:* The list of acute diagnoses and planned procedures—both of which were initially developed for the Hospital-Wide Readmission Measure (NQF #1789)—were reviewed by a nephrologist, by members of the Technical Expert Panel convened in April 2012, and by stakeholders during the CMS public comment period in May 2013 for the purpose of determining whether they were appropriate for the SRR measure. This process resulted in the planned readmissions algorithm as it is currently specified for the SRR. We believe the systematically excluded claims codes identify readmissions that are planned, and therefore do not reflect a failure in the transition of care for the ESRD population. These codes are applicable to the ESRD population insofar as they are submitted by hospitals for ESRD and non-ESRD patients alike, and are therefore appropriate for exclusion from the SRR.

Comment*:* One commenter stated that claims data is not sufficient to reliably estimate actual and expected readmission rates. Commenter recommended that the proposed SRR measure should use data from facilities' electronic medical records.

Response*:* A key advantage for claims-based risk-adjustment is the availability of standardized data elements for all Medicare beneficiaries. There is currently no set standard of medical record compatibility and no national electronic medical record system across dialysis provider organizations.

Comment*:* Some commenters did not support the adoption of the proposed SRR measure, because the measure only has a "moderate" degree of reliability.

Response*:* We believe that the SRR clinical measure captures important quality data for

the purposes of the ESRD QIP program. We believe the SRR is sufficiently reliable for inclusion in the ESRD QIP because it meets the NQF's moderate degree of reliability standard, and particularly in light of our policies to set the case minimum for this measure at 11 index discharges and apply the small-facility adjuster to facilities with between 11 and 41 index discharges. We provide detailed analysis of the reliability of the SRR at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/AnalysisoftheReliabilityoftheProposedSRRandSTrRMeasures.pdf. From 2009 through 2012, the SRR has an inter-unit reliability ranging from 0.49 to 0.54, which indicates a moderate degree of reliability. For context, the standard of an acceptable level of reliability is 0.40 or higher.

Comment*:* One commenter sought clarification as to how the proposed SRR measure will count hospital stays less than 24 hours, observation days, and same-day surgical procedures.

Response*:* The SRR measure assesses the risk of readmission to an acute care hospital within 30 days of discharge from an acute care hospital. Patients who are not admitted to an acute care hospital within 30 days of discharge are not included in the measure. Patients who are admitted will be included in the measure, even in cases (such as same-day surgical procedures) where admission and discharge occur within a 24-hour period. Such instances account for 1.3 percent of hospitalizations eligible to serve as index discharges in the SRR in 2012.

Comment*:* One commenter sought clarification on how the proposed SRR measure will address unsuccessful kidney transplants in the six months following the transplant. Commenter recommended that the measure exclude these transplant failures.

Response*:* As specified, the measure does not exclude patients who are hospitalized after a failed kidney transplant. We realize that this detail was not clear in the measure methodology

report and we will edit the report to ensure clarity. As part of our ongoing quality measure re-evaluation process, we will examine this issue and consider how best to explicitly account for failed transplants in the SRR.

Comment*:* One commenter sought clarification on whether "poisoning by nonmedical substances" encompasses chronic substance abuse.

Response*:* We clarify that "poisoning by non-medicinal substances" does not include ICD-9 codes for ongoing alcohol or drug abuse. Please refer to the breakdown of this CCS group on AHRQ's website: http://www.hcup-us.ahrq.gov/toolssoftware/ccs/AppendixASingleDX.txt.

Comment*:* Some commenters stated that adopting the SRR measure would penalize two facilities for the same readmission: hospitals through the Hospital Readmissions Reduction Program and dialysis facilities through the ESRD QIP. Other commenters stated that readmissions measures are not an effective way to increase care coordination because different types of facilities (for example, dialysis facilities and hospitals) are paid separately.

Response*:* We agree that it is possible that a hospital and a dialysis facility could be penalized simultaneously for the same readmission event. We believe that both the hospital and the facility should be held accountable for ensuring that ESRD patients transition successfully from the hospital to post-acute care in the facility. Although different types of facilities are paid separately, we believe that all providers involved in the transition of care from acute to non-acute settings share responsibility for avoiding excessive rates of unplanned readmissions.

Comment*:* One commenter stated that facilities will experience difficulty in explaining facility scores on the SRR clinical measure to patients, and that doing so may be "politically challenging" when the dialysis facility is affiliated with the admitting hospital system.

Response*:* The CY 2015 ESRD PPS Proposed rule includes a link to a measure

methodology report (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html) which provides an extensive discussion of how to interpret scores on the SRR measure. Simply put, a readmission ratio of greater than 1.0 reflects that a facility's patients are at higher risk for readmissions than they would be at an average facility. A score below 1.0 reflects that a facility's patients are at lower risk for readmissions than they would be at an average facility. A lower ratio is preferable because it indicates that a facility is doing a better job of managing patient transitions from a hospital back to the dialysis facility.

Comment*:* Some commenters recommended that CMS should delay the adoption of this measure until it provides facilities with reports documenting their performance with patient-level data, so that facilities can identify root causes and implement improvement plans. Commenters also recommended delaying the adoption of the proposed SRR measure until it has been endorsed by NQF.

Response*:* From March through April 2014, we conducted a dry run of the SRR, in which facilities were given the opportunity to view a quality report that provided their readmission measure results. At facility request, we also made patient-level data available for their review and entertained facility comments regarding the measure and the reporting process. We acknowledge the desire to delay implementation until after endorsement by NQF, and the reasoning behind such a suggestion. However, we believe that readmissions represent an important outcome of care for dialysis patients, given the population has a readmission rate of around 36 percent, which is twice that of the Medicare population.

Comment*:* One commenter recommended that CMS continue to exclude pediatric patients from the proposed SRR measure and any future readmission measures, because the

pediatric population is so small that a single readmission can skew the unit's results and may incentivize facilities to deny admission to pediatric patients.

Response*:* We thank the commenter for the recommendation and will take it into account in future measure development work.

Comment*:* One commenter stated that the SRR measure should exclude planned readmissions.

Response*:* We appreciate the commenter's support for the SRR's exclusion of planned readmissions. This is an approach we have incorporated into measures of readmissions across multiple settings, and we agree that it is appropriate for this measure because planned readmissions do not reflect failures in care transitions and if not excluded, could bias SRR results for facilities that treat patients who receive certain kinds of in-patient hospital care.

Comment*:* One commenter recommended that CMS require hospitals to provide facilities with data concerning a patient's dry weight, dialysis prescription changes, and continuing antibiotics on the day a patient is discharged. Commenter stated that CMS could require hospitals to provide this data using the hospital Conditions for Coverage or the Hospital Value-Based Purchasing Program, and that this information is crucial for facilities to identify problems that lead to unplanned readmissions.

Response*:* We thank commenters for the suggestions, which capture an important issue of care coordination. We believe all providers should communicate and coordinate the care of patients transitioning from one setting of care to another. We agree that effective communication of clinically relevant data is an important goal. We are exploring means by which to encourage the transfer of relevant information between providers.

For these reasons, we are finalizing the SRR clinical measure as proposed for the PY

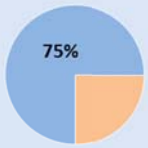
2017 ESRD QIP and for future payment years. The technical specifications for this finalized measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

Summary of Finalized PY 2017 Measure Set

★ New measure for PY 2017

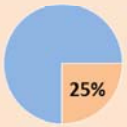
Clinical Measures – 75% of Total Performance Score (TPS)

1. Vascular Access Type Measure Topic – AVF
2. Vascular Access Type Measure Topic – Catheter ≥ 90 days
3. Kt/V Dialysis Adequacy Measure Topic – Adult Hemodialysis
4. Kt/V Dialysis Adequacy Measure Topic – Adult Peritoneal Dialysis
5. Kt/V Dialysis Adequacy Measure Topic – Pediatric Hemodialysis
6. Hypercalcemia
7. NHSN Bloodstream Infection in Hemodialysis Outpatients
8. ★ Standardized Readmission Ratio



Reporting Measures – 25% of TPS

1. ICH CAHPS Patient Experience of Care Survey
2. Mineral Metabolism
3. Anemia Management



3. 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 proposed to establish CY 2015 as the performance period for PY 2017 ESRD QIP.

We sought comments on this proposal. We did not receive any comments and are finalizing it as proposed.

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

We proposed 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. 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 proposed 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 would 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 proposed 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 sought comments on these proposals. The comments and our responses are set forth below.

Comment*:* One commenter supported CMS's use of benchmarks to drive quality improvement in the ESRD QIP, and the scoring methodology proposed for the PY 2017 program, because it aligns with the methodology used in the Hospital Value-Based Purchasing program.

Response*:* We thank the commenter for the support.

Comment*:* One commenter was concerned with the proposed benchmarks for PY 2017, stating that these benchmarks are "unrealistic" because the increasingly high thresholds for achievement are making it harder for facilities to score well, even though they may be delivering high-quality care to patients. Commenter stated that for some measures, circumstances beyond a facility's control, such patient eligibility for a fistula and patient choice, will impact facility scores.

Response*:* We disagree that the proposed benchmarks for PY 2017 are unrealistic or unachievable. Benchmarks for clinical measures are pegged to national performance rates, such that 15 percent of facilities met the benchmarks two years before the performance period.

Accordingly, the benchmarks represent a high level of achievement, but they are not unrealistic because they have been met by 15 percent of facilities nationwide, and because they represent past (and typically lower) standards of practice.

Comment: One commenter supported the use of benchmarks to drive quality improvement in the ESRD facility setting, but stated that pegging benchmarks to national performance rates creates a "continually moving target." The commenter further stated that without an adjustment for facility location, population, or demographics, these benchmarks may penalize a facility that is performing well in comparison to its peers. The commenter recommended that CMS determine standards for each individual measure using evidence-based practices and provide these standards to facilities. Another commenter recommended CMS carefully evaluate established benchmarks to ensure that the high standards established do not create an incentive for facilities to deny care to sicker patients.

Response*:* We thank the commenter for the support. We recognize that pegging benchmarks to national performance rates creates a continually moving target for facilities, because facility performance on clinical quality metrics typically improves over time. We believe it is appropriate for benchmarks to increase, in line with improvements in national performance rates, because not increasing the benchmarks would hold facilities to a lower standard of care and would diminish incentives for improvement. We discussed above the possibility of using a peer group stratification system for dialysis facilities as a feasible approach to risk adjustment. We welcome input on how such a system might function, and will consider its utility for future years of the ESRD QIP.

Comment*:* One commenter stated that it is inappropriate for the ESRD QIP to base payment reductions on retroactive performance, and recommended that CMS should finalize

measures and performance standards in a timely manner, in order to ensure facilities are made aware of appropriate standards.

Response*:* The current achievement scoring methodology generally compares facility performance in the performance period to national performance two years before the performance period, except in cases where there is a compelling patient safety reason to accelerate the adoption of a clinical measures (for example, the NHSN measure in the PY 2016 ESRD QIP). If facility performance during the performance period were to be compared to national performance during the performance period, this would place facilities on a "forced curve" and ensure that fifty percent of facilities fell below the performance standard. Additionally, we appreciate that facilities want to learn as soon as possible what the ESRD QIP measure set will be for a given CY. For this reason, we are finalizing measures the PY 2018 program in this final rule, 14 months before the beginning of the performance period for those measures. Finally we publish numerical values for performance standards as soon as data reflecting current national facility performance become available.

Comment*:* Commenter stated that facilities should not be scored on a forced normal curve. Commenter stated that this practice is not mandated by the Act, that it has been dismissed as invalid in quality improvement initiatives used in other professions, and that this penalizes facilities for providing patient-centered care when it is inconsistent with measure goals and targets.

Response*:* We appreciate commenter's concerns; however, the ESRD QIP does not use a normal curve to score facilities, nor have we proposed to adopt such a methodology in the proposed rule.

For these reasons, we are finalizing the performance standards for the PY 2017 ESRD

QIP as proposed.

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

Upon the publication of the CY 2015 ESRD PPS Proposed Rule, we did not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks for the clinical measures, because we did not yet have complete data from CY 2013. Since that time, we have collected the data needed to calculate finalized performance standards for the PY 2017 ESRD QIP. For all of the clinical measures, including the SRR clinical measure, this data comes from the period of January through December 2013. Table 23 lists the finalized numerical values for all of the finalized PY 2017 ESRD QIP clinical measures except the NHSN Bloodstream Infection clinical measure.

TABLE 23: 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	64.46	52.42	78.56
%Catheter	9.92	18.36	3.23
Kt/V			
Adult Hemodialysis	96.89	91.08	99.35
Adult Peritoneal Dialysis	87.10	70.19	95.20
Pediatric Hemodialysis	94.44	84.15	99.06
Hypercalcemia	1.30	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	1.325	0.555

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 proposed to substitute the PY 2016 performance standard, achievement threshold, and/or benchmark for that measure.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* One commenter supported the proposal to use performance standards from the previous year if the current year's standards are lower.

Response*:* We thank the commenter for the support. For this reason, we will finalize our proposal to utilize previous years' performance standards if they are higher than those of the next year. The performance standards for the measures used in previous years of the ESRD QIP have not declined. Therefore, for PY 2017, we will use the performance standards in the above table.

c. 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 proposed to continue to use these performance standards for these measures in the PY 2017 ESRD QIP. We sought comments on this proposal. We did not receive any comments on this proposal.

5. 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 proposed 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 proposed 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 proposed 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.

We sought comments on this proposal. We did not receive any comments and are finalizing it as proposed.

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 therefore did not propose 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 did not propose any changes to the policy that facilities

must be eligible to receive a score on at least one reporting measure and at least one clinical measure to be eligible to receive a TPS, or the policy that a facility's TPS will be rounded to the nearest integer, with half of an integer being rounded up.

7. Minimum Data for Scoring Measures for the PY 2017 ESRD QIP and Changing the 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 proposed 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 did not propose any changes to this policy.

However, with respect to the proposed SRR measure, we proposed 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 proposed 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 proposed 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 proposed 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 did not propose any further changes to the 30 survey-eligible case minimum for this measure. We proposed 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 sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* Many commenters did not support the proposed data minimum requirements for the reporting measures because the commenters stated that the requirements unfairly penalize facilities that may not be able to legitimately report data for a few patients. As an alternative, the commenters recommended applying a consistent case minimum of 26 for all measures in the ESRD QIP.

Response*:* We agree with commenters that requiring facilities with small patient populations to report data for all but one eligible patient may unfairly penalize small facilities, because failing to report data for two or more patients will have a greater impact on small facility than on larger facilities. However, we disagree that it is appropriate to set the case minimum at 26 for these reporting measures, because doing so would not allow CMS to collect baseline data for a large percentage of patients. We believe that setting the case minimum at 11 for the Anemia Management and Mineral Metabolism reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly penalize small facilities that are unable, for legitimate reasons, to report data on all but one patient. We further believe that setting the case minimum at 11 is appropriate, because this would align with the case minimum policy for the clinical measures in the ESRD QIP. Therefore, we are finalizing a case minimum policy of 11 for the Anemia Management and Mineral Metabolism reporting measures.

Comment*:* One commenter did not support the proposed minimum data requirements for the ICH CAHPS measure, because small facilities will have difficulty obtaining 30 completed surveys. Commenter recommended CMS use actual response rates from the CY 2014 survey to

determine eligibility criteria for this measure in PY 2017 and PY 2018.

Response*:* Under the minimum data requirements proposed for the ICH CAHPS reporting measure for PY 2017, a facility that (1) treats fewer than 30 survey-eligible patients during the eligibility period (that is., CY 2014); or (2) receives fewer than 30 completed surveys during the performance period (that is., CY 2015) is not eligible to receive a score on the ICH CAHPS measure. We are finalizing below that these data minimum requirements also apply to the ICH CAHPS clinical measure for PY 2018. Therefore, if a small facility treats more than 30 ICH CAHPS eligible patients during the eligibility period but receives fewer than 30 completed surveys total from the two survey administrations for the performance period, that facility will receive an "N/A" on the ICH CAHPS measure for that Payment Year. We disagree with commenter's recommendation to use CY 2014 response rates to determine survey eligibility criteria for the ICH CAHPS measure because actual response rates are susceptible to a number of biases, including facility case-mix, response propensity, and the mode of survey administration. We believe the current minimum data requirement avoids the possibility of unfairly penalizing facilities based on these response biases by relying solely on the number of patients treated and the number of surveys completed to determine ICH CAHPS scoring eligibility.

Comment*:* One commenter did not support calculating clinical measure performance rates for facilities with between 11 and 25 eligible patients, and then applying the small facility adjuster to these facilities' scores. One commenter stated that including facilities with small numbers of eligible patients, and compensating (via the small facility adjuster) for the random effects that inevitably appear, is not consistent with the NQS goal of applying consistent approaches to quality measurement.

Response*:* We recognize that measures using a patient-minimum of 11 are somewhat less

reliable than measures using a patient-minimum of 26. Despite this modest decline in the measures' reliability, we continue to believe that it is essential to score facilities with between 11 to 25 eligible patients on the clinical measures. Based on data from CY 2013, we have determined that applying a 26-patient-minimum to all of the clinical measures (as compared with continuing the current 11-patient-minimum) would result in the exclusion of an additional 562 facilities from the ESRD QIP, or 9.2 percent of facilities overall. Given the inherent tradeoff between a modest decline in measure reliability and including these 562 facilities in the ESRD QIP, we believe that on balance it is more important to include these facilities. Additionally, we recognize that the small facility adjuster is an imperfect mechanism for accounting for the possibility that a small number of outlier patients will disproportionately diminish a facility's score on a clinical measure. Nevertheless, given the program's commitment to the 11-patient minimum, using the adjuster is preferable to not using any adjustment, because the adjuster gives small facilities the benefit of the doubt. We further believe that this methodology is consistent with the NQS goal of a consistent approach to quality measurement because it is applied to all clinical measures in the ESRD QIP.

Comment*:* One commenter did not support the use of the small facility adjuster in the ESRD QIP, because adjustments are haphazardly applied to facilities with similar numbers of eligible patients and patient-months in the numerator. For example, and with respect to the Peritoneal Dialysis Adequacy clinical measure, a facility with 18 eligible patients that misses the threshold for 3 patients would not receive an adjustment, whereas a facility with 17 eligible patients that misses the threshold for 3 patients would, as would a facility with 19 eligible patients that misses the threshold for 3 patients. If the small facility adjuster remains in the ESRD QIP, commenter recommended rounding the measure score after applying the adjustment,

as opposed to beforehand, which the commenter states is the current practice.

Response*:* The small facility adjustment is applied consistently to facilities' performance rates (for example, 87.5 percent for the Adult Peritoneal Dialysis clinical measure), such that facilities with fewer eligible patients receive more of an adjustment than facilities with more eligible patients. With respect to the example provided by the commenter, we recognize that the impact of the small facility adjustment on measure scores can be different for facilities with the same or similar numbers of eligible patients for each facility. This variable impact on facility measure scores is attributable to the achievement and improvement scoring methodologies used in the ESRD QIP. Scores on the clinical measures are determined by selecting the higher of the facility's achievement and improvement scores. The achievement score is determined by comparing the adjusted performance rate to the achievement threshold and benchmark, and the facility's improvement score is determined by comparing the adjusted performance rate to the facility's baseline rate. Accordingly, the impact of the small facility adjustment on a measure score (as opposed to a performance rate) will depend upon whether a measure is scored on the basis of achievement or improvement, as well as the facility's improvement threshold. Therefore, the variable impact of the small facility adjustment is not inherent to the small facility adjuster, but rather an intentional artifact of the ESRD QIP scoring methodology. Finally, we note that the small facility adjustment is applied to the measure performance rate (as opposed to the measure score), with rounding performed at the 6th decimal place. Rounding to the nearest integer already occurs after the small facility adjustment is applied, and this is consistent with the commenters recommendation on this finalized policy. The following summarizes the rounding algorithm that is currently applied to the performance score calculation for facilities with 11-25 eligible patients:

- Calculate the measure performance rate (x_i=(#patient-months numerator/#patient-months denominator)*100), round to 6th decimal place
- Calculate the facility weight (w_i=1-n_i/26), round to 6th decimal place
- Calculate the Standard Error (SE(x_i)), round to 6th decimal place
- Calculate adjusted measure performance rate ($t_i = x_i + w_i * SE(x_i)$), round to nearest integer.

For these reasons, we are finalizing the minimum data policies as proposed, with the exception of the patient minimum policies for the Anemia Management and Mineral Metabolism reporting measures. We are finalizing that a facility must treat at least 11 qualifying patients to receive a score on the Anemia Management and Mineral Metabolism reporting measures.

We proposed 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 also proposed 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 sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

Table 24 displays the finalized 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 24: 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
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)	11 qualifying patients	Before July 1, 2015	N/A
Mineral Metabolism (Reporting)	11 qualifying patients	Before July 1, 2015	N/A

8. 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 proposed 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 performance period for PY 2017 (that is., 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 proposed 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 (that is, 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 sought comments on this proposal. We did not receive any comments and are finalizing it as proposed.

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 did not propose any changes to this policy.

Based on the finalized performance standards listed above, we have determined that a facility must meet or exceed a minimum TPS of 60 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 determining this minimum TPS, because we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the PY 2017 performance period. We proposed 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 25 below.

TABLE 25: Payment Reduction Scale for PY 2017 based on the Most Recently Available Data from CY 2013

Total Performance Score	**Reduction**
100-60	0%
59-50	0.5%
49-40	1.0%
39-30	1.5%
29-0	2.0%

9. 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 proposed 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 proposed to deduct 10 points from the facility's TPS. Once we have developed and adopted a methodology for validating the CROWNWeb data, we intend to consider whether payment reductions under the ESRD QIP should be based, in part, on whether a facility has met our standards for data validation.

We also proposed 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 proposed 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 proposed 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 proposed 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 sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* Some commenters supported the proposal to validate data submitted for the NHSN Bloodstream Infection measure, and stated that asking facilities to provide blood culture reports on a quarterly basis is appropriate. However, one commenter also recommended that the proposed feasibility study be more robust. In particular, the commenter stated that previous validation studies of NHSN data revealed that facilities were underreporting dialysis events, and that facilities did not understand when to report that an infection was a "dialysis event." The commenter recommended that these findings should be incorporated into the proposed feasibility study. Commenters also recommended expanding the number of facilities undergoing validation beyond 9, because the "proposed nine-facility feasibility study is not robust enough to evaluate true validation concerns." Commenters recommended auditing the NHSN data of 10 percent of facilities, because this would create a strong incentive for facilities to accurately report dialysis events. Another commenter stated that the validation study should be expanded to NHSN data that is used directly used to score the NHSN Bloodstream Infection measure.

Response*:* We thank the commenters for their support. We initially considered

expanding the scope of the feasibility study to include more than nine facilities. We decided not to do so because we thought it was important to demonstrate the study's feasibility, and to further develop the study's methodology, before expanding the study to include more facilities. Expanding the study to include more facilities before demonstrating its feasibility and validity could lead to a waste of agency resources. Furthermore, we are aware of existing studies that call into question the validity of data entered into the NHSN system. The existence of these studies is one of the reasons why we proposed to conduct the feasibility study, and results from previous studies will be taken into account when developing the methodology for the feasibility study. Additionally, we appreciate the recommendation to use a validation study of NHSN data to audit ten percent of facilities, and we agree that such a process could improve the validity of NHSN data overall. We will consider expanding the scope of the study once we have reviewed the results of the feasibility study.

Comment*:* Some commenters stated that the CROWNWeb validation pilot is actually an audit of facility data, and is not focused on testing a new payment or delivery model. Commenters were concerned that the pilot places facilities at risk for incurring a 2 percent payment reduction and recommended "intermediate penalties" as an alternative. Commenters further recommended that CMS ensure that facilities have some means to dispute CMS claims that they reported invalid data.

Response*:* We agree that one of the purposes of the validation pilot is to identify instances in which facilities reporting invalid data to CROWNWeb. However, we do not believe it is appropriate to designate the validation pilot as an "audit" of facility data, because the ultimate objective of the study is to improve the validity of data reported to CROWNWeb, rather than to penalize facilities for reporting invalid data. We further note that we did not propose to

penalize facilities for reporting invalid data; if and when we propose to do so in future rulemaking, we will consider implementing an appeal process facilities can use to contest CMS determinations that invalid data was reported to CROWNWeb. Finally, we recognize that facility non-compliance with the requirements of the CROWNWeb validation pilot may result in payment reductions that would not otherwise be imposed. We believe this is warranted, because facility compliance is essential to the success of the validation pilot, and we wish to provide a strong incentive for facilities to transmit the requested medical records needed to validate CROWNWeb data.

Comment*:* One commenter stated that CROWNWeb should be fully functional before assessing penalties for assessing penalties for submitting invalid data.

Response*:* We agree that is it essential to improve the functionality of CROWNWeb, and we believe that the pilot validation study will assist in identifying systematic issues with CROWNWeb that diminish the system's functionality. We did not propose to impose penalties on facilities for reporting invalid data, and we will consider the functionality of CROWNWeb if we decide to propose to impose such penalties in future rulemaking.

Comment*:* One commenter recommended that CMS should make the methodology for the proposed NHSN validation feasibility study transparent and seek input from nephrologists and dialysis professionals when developing the methodology.

Response*:* We agree that it is important to make the methodology of the feasibility study transparent. We will make the methodology publically available on a CMS web site and notify the public of its availability via a CROWN Memo or similar mode of formal communication. Additionally, we confirm that the CMS contractor conducting the validation feasibility study will consult nephrologists and dialysis professionals when developing the study's methodology.

Comment*:* Some commenters did not support the proposal to validate data used to calculate the NHSN Bloodstream Infection measure because the commenter stated that the measure should have been validated before it would adopted in the ESRD QIP.

Response: NHSN provides detailed trainings, protocols, and guidance for users to follow to ensure that data are reported in a standardized manner and according to requirements. A small validation study was conducted prior to the adoption of the measure in the ESRD QIP. Information from this study is described in the measure specifications. We recognize that continuous internal and external evaluation and quality checks of the reported data are important for accuracy and reliability. We further note that one of the purposes of the feasibility study is to improve the validity of data reported to NHSN, and we continue to believe that one of the outcomes of the study will be to improve the validity of the NHSN Bloodstream Infection measure.

Comment*:* Some commenters did not support the proposal to impose a 10-point reduction on facilities that fail to send medical records to CMS within the 60-day timeframe, because the 60-day time frame is too short, and the penalty discriminates against facilities selected to participate in the validation studies, particularly small facilities. Commenters also stated that the ESRD CfCs already require facilities to comply with such requests. Commenter further stated that CMS has not demonstrated that facilities do not comply with these requests, and therefore did not support a penalty for non-compliance until the problem has been demonstrated. One commenter also questioned whether the Act authorizes CMS to deduct points from a facility's TPS if it does not comply with the requirements of data validation studies.

Response*:* We disagree that the 60-day time frame is too short for facilities to respond to requests to validate medical records, because facilities should have these records on hand, and

sampled facilities will only be required to submit a small number of medical records the CROWNWeb and NHSN Bloodstream Infection studies. We recognize that the ESRD CfCs already require facilities to comply with these requests for medical records, and we are not aware of any evidence suggesting that they are not already doing so. Nevertheless, we continue to believe that assessing penalties on a facility's TPS is the surest way to ensure that facilities provide the medical records needed to complete the studies. This is because facilities are typically not surveyed for compliance with the ESRD CfCs on any given year, so deducting points from a facility's TPS provides a more certain process for penalizing noncompliance with the requirements of the validation studies. Our proposal to deduct points from a facility's TPS is consistent with section 1881(h)(3)(A)(i) of the Act, because it is part of our 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. The main purpose of these studies is to assess whether facilities are reporting accurate data, and we have determined that review of medical records is integral to that determination.

For these reasons, we are finalizing, as proposed, CROWNWeb pilot data-validation program and the feasibility study for validating data reported to CDC's NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure.

10. Monitoring 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.

Because we proposed to adopt the SRR clinical measure for the PY 2017 program, and also proposed to adopt the STrR clinical measure for the PY 2018 program, we proposed 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 sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* Some commenters supported the proposed access study because monitoring and remediating cases of cherry-picking are important for ensuring that patients receive high quality care.

Response*:* We thank commenters for their support.

Comment*:* One commenter requested more information from CMS regarding its proposal

to monitor dialysis facility admission and discharge practices, because this proposal may lead to additional reporting (and burden) for facilities.

Response*:* We are still in the process of finalizing the methodology for the proposed access study. Once we have developed the methodology, we will make it publically available on a CMS web site and notify the public of its availability via a CROWN Memo or similar mode of formal communication. We clarify, however, that the study will make use of existing data and will not impose any additional burden on facilities.

Comment*:* One commenter recommended that, instead of performing the proposed monitoring access study, CMS focus its efforts on developing a more comprehensive set of comorbidities for use in adjusting the standardized outcome measures.

Response*:* We appreciate the recommendation to further develop the risk-adjustment methodologies associated with the SRR and STrR measures, and we will continue to do so as part of our ongoing measure re-evaluation process. However, we disagree that efforts to develop risk-adjustment methodologies should be pursued in lieu of the proposed access study. We believe both activities are important, and we intend to pursue them at the same time

For these reasons, and because we are finalizing the SRR clinical measure for PY 2017 (as discussed in more detail above), and the STrR measure for PY 2018 (as discussed in more detail below), we are finalizing that we will conduct a study to determine the impact of adopting the SRR and STrR measures on access to care. Further details about the study and its methodology will be made available on a CMS web site, and facilities will be notified via a CROWN Memo when this information is available.

11. 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 therefore proposed 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 proposed 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 proposed 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.

We stated that this policy would 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 made the determination to grant an exception to facilities in a region or locale, then we proposed 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 sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* Some commenters supported the proposal to add an Extraordinary Circumstances Exception to the ESRD QIP, because facilities should not be required to meet the program's requirements when they are forced to close.

Response*:* We thank commenters for their support.

Comment*:* Some commenters supported the proposal to add an Extraordinary Circumstance Exception but sought clarification as to what constitutes an "extraordinary circumstance." Commenters recommended that events such as fires and explosions, which are not typically considered "natural disasters" should be considered "extraordinary circumstances." Commenters also recommended granting exceptions for facilities that temporarily close for renovation or relocate.

Response*:* The Extraordinary Circumstances Exception is intended to address facility closures beyond the control of the facility, and is not limited to natural disasters. We note that

eligibility determinations for this exception will be made on a case-by-case basis and based entirely on evidence and documentation that facilities present.

Comment*:* One commenter recommended that camps and short-term dialysis units should have an opportunity to take advantage of the extraordinary circumstances exception, because they operate under unique circumstances that do not apply to most facilities.

Response*:* We appreciate that camps and short-term dialysis units operate under unique circumstances. However, these circumstances are categorically different than the types of circumstances covered by the Extraordinary Circumstances Exception, because their closure is within the facility's control and is generally planned in advance. Accordingly, operating for a short period of time will not be grounds for granting an Extraordinary Circumstances Exception.

For these reasons, we are finalizing the proposal to adopt an Extraordinary Circumstance Exception in the ESRD QIP, beginning with the PY 2017 program.

F. Requirements for the PY 2018 ESRD QIP

1. Modification of 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 proposed 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 clarified that we were not proposing any other changes to the measure specifications for the Mineral Metabolism

reporting measure.

We sought comments on this proposal. The comments and responses are set forth below.

Comment*:* One commenter supported the proposal to allow facilities to report both plasma and serum phosphorous under the Mineral Metabolism reporting measure, beginning in PY 2018.

Response*:* We thank the commenter for the support.

Comment*:* Many commenters supported the proposal to modify that Mineral Metabolism reporting measure, but sought clarification as to why it is not feasible to do so starting in PY 2017, and urged CMS to adopt the change for PY 2017.

Response*:* We thank commenters for their support. We have already begun working to incorporate this modification into the CROWNWeb system. However, we do not expect to be able to fully implement the modification by January 1, 2015 (that is, the beginning of the PY 2017 performance period), so it is not possible to collect plasma phosphorus data for the PY 2017 program.

For these reasons, we are finalizing the proposed modifications to the Mineral Metabolism reporting measure, beginning with the PY 2018 program. The technical specifications for this finalized measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

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

For the PY 2018 ESRD QIP, we proposed 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 proposed to convert to a clinical measure. We also proposed 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 26).

TABLE 26: 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. 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 proposed 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 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 also proposed 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 was 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 proposed 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 proposed 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 sought comments on this proposal to adopt the proposed STrR clinical measure. The comments and our responses are set forth below.

Comment*:* Some commenters supported the proposal to adopt the Standardized Transfusion Ratio clinical measure because the measure "assesses the poor outcomes related to anemia in the ESRD QIP."

Response*:* We thank commenters for their support.

Comment*:* Many commenters did not support the proposal to adopt the STrR measure because it is not a fair way to evaluate facility performance. Specifically, commenters stated that transfusion events are beyond the control of facilities, that physicians outside of the facility may order a transfusion (which would unduly detriment the facility's score on the measure) or fail to continue a patient's ESA doses during the patient's hospitalization, and that hospital physicians' misunderstanding about hemoglobin levels is often the source of unnecessary transfusions. One

commenter recommended stratifying the STrR measure according to patient comorbidities to capture only blood transfusions that could be prevented by the dialysis facility. Commenters further stated that the measure does not reliably differentiate facility performance because a transfusion event could be attributed to a chronic condition or an acute problem during hospitalization, as opposed to poor anemia management on the part of facilities.

Response*:* We recognize that most transfusions occur outside the dialysis facility. We further recognize that blood transfusions are often ordered in response to acute events, such as gastrointestinal bleeding or other trauma, that happen during the hospitalization. However, peer-reviewed research identifies a strong association between achieved hemoglobin and subsequent transfusion events.[7] Our analysis of patient and facility level risk-adjusted models supports the literature. These observational analyses are consistent with the findings of an earlier randomized controlled trial that identified marked differences in rates of transfusion related to targeted hemoglobin.[8] Because dialysis facilities have a direct role in determining achieved hemoglobin as a result of their anemia management practices, we believe there is a shared responsibility in subsequent transfusion events. The attribution of responsibility to the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) as measured by the STrR is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication. These exclusion co-morbidities are

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7 Collins et al., "Effect of Facility-Level Hemoglobin Concentration on Dialysis Patient Risk of Transfusion", Am J Kidney Dis. 2014;63(6):997-1006; Hirth RA, Turenne T, Wheeler JRC et al., (November 2012) "Did the dialysis Prospective Payment System result in more patients receiving transfusions?" Poster presentation at ASN Renal Week in San Diego, CA; Sibbel S, Bond C, Wilfehrt H et al.(2013 April) "Decreased Population Hemoglobin (HB) Levels and Increased Transfusion (TFN) Rates Under New ESA Guidelines in Patients (PTS) with ESRD at a Large Dialysis Organization (LDO). Poster to be presented at the National Kidney Foundation (NKF) Spring Clinical Meeting in Orlando, FL. Abstract retrieved from http://ww3.aievolution.com/nkf1301/index.cfm?do=abs.pubSearchAbstracts; Hirth, et al. 2014

8 (Foley 2008)

obtained from Medicare Claims, based on recommendations of the Anemia Technical Expert Panel convened in 2012, as well as recent peer reviewed publications evaluating transfusions.[9] We believe that the salient quality issue is not that a clinical decision to order a transfusion was made, but that the management of a patient's anemia resulted in circumstances that necessitated such a transfusion.

We also believe that the discontinuation of a patient's ESA dose during an acute hospitalization is very unlikely to affect the patient's hemoglobin levels unless the hospitalization is of very long duration, given the several weeks long half-life of red blood cells in the patient's circulation after being release from the bone marrow. Therefore, ESA dosing and achieved hemoglobin present on admission, which are the responsibility of the dialysis facility, are much stronger drivers of the need for transfusion than whether or not an ESA is given during an average length hospitalization for any given admission diagnosis.

Further, we are not aware of peer-reviewed evidence that would support a concern that hospital-based physicians do not understand the significance of hemoglobin levels and, therefore, order unnecessary transfusions. Although transfusion decisions are individualized based on a patient's clinical condition, many acute care hospitals use national guidelines to determine when a blood transfusion is appropriate. The guidelines that we are aware of do not differentiate between chronic dialysis patients and the general population. Additionally, if this type of misunderstanding does exist, we believe that proper communication and coordination of care between the dialysis facility and hospital physicians could help reduce the possibility that an unnecessary transfusion is ordered.

Comment*:* Many commenters expressed a number of technical concerns with the

[9] Ibrahim HN, Ishani A, Foley RN et al. "Temporal Trends in red blood transfusion among US dialysis patients, 1992-2005". American Journal of Kidney Disease. 2008; 52: 1115

specifications for the STrR measure. Specifically, commenters stated that using the 2728 form as the data source for determining patient comorbidities is inappropriate because the form is not used to track comorbidities that develop after the initiation of ESRD, the form is often filled out incorrectly, and the form systematically underestimates the number of patient comorbidities. Commenter therefore recommends obtaining a reliable data source (such as the Common Working File) for comorbidities before adopting the measure. Commenters further stated that facilities do not have ready access to transfusion data, which they could use to design quality improvement programs.

Response*:* The STrR uses both Form 2728-derived incident comorbidities and patient demographics as well as Medicare Claims derived prevalent comorbidities for its risk-adjustment and exclusions. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication, and may develop after initiation of dialysis. It is important, however, that we be circumspect in risk-adjusting for conditions that appear after the initiation of dialysis, to avoid adjusting for conditions that resulted from the care decisions made by the provider. These exclusion co-morbidities are obtained from Medicare Claims, based on recommendations of the Anemia Technical Expert Panel convened in 2012, as well as recent peer reviewed publications evaluating transfusions.[10]

Comment*:* Some commenters were concerned about validity of claims data used to identify qualifying transfusion events, because hospital coding for transfusions is inconsistent, and sometimes codes do not distinguish between preparing for a transfusion and the transfusion

10 Ibrahim HN, Ishani A, Foley RN et al. "Temporal Trends in red blood transfusion among US dialysis patients, 1992-2005". American Journal of Kidney Disease. 2008; 52: 1115

itself. Commenters also stated that the claims data used to score the measure is incapable of differentiating among the various reasons for a blood transfusion. As such, the measure does not accurately predict or identify when a patient actually receives a transfusion.

Response*:* Prior research has supported the validity of billing codes for identifying red blood cell transfusions.[11] Additionally, other recent articles accepted and published in peer reviewed journals support the review and acceptance of this method of identification of transfusions from administrative data.[12] Specifically, we used multiple sources (procedure codes, revenue center codes, and value codes) to improve the ability to detect actual transfusion events during a hospitalization. Red blood cell transfusions are identified by in-patient records with revenue center codes in (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) or value code = 37 or procedure code in (9903, 9904) and with out-patient records with revenue center codes in (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) and HCPCS code in (P9010, P9011, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9058, 36430). The measure does not attempt to address the particular reason for a transfusion event, only that one occurred. One "transfusion event" is counted per inpatient claim if one or more transfusion-related revenue center or value codes are present. This is the way most inpatient transfusion events are reported on claims (that is, using revenue center or value codes, not procedure codes). We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center and value codes reported so that the number of discrete events counted is the same whether the claim indicates 1 unit of blood or multiple units of blood.

Comment*:* Some commenters did not support the proposed STrR measure because it has

11 Segal JB1, Ness PM, Powe NR. Validating billing data for RBC transfusions: a brief report. Transfusion. 2001 Apr;41(4):530-3.
12 Collins et al., "Effect of Facility-Level Hemoglobin Concentration on Dialysis Patient Risk of Transfusion", Am J Kidney Dis. 2014;63(6):997-1006; and Hirth et al, Blood Transfusion Practices in Dialysis Patients in a Dynamic Regulatory Environment, Am J Kidney Dis. 2014 (in-press).

not been endorsed by NQF, and one commenter was concerned about the measure's validity and reliability. Commenter recommended delaying the adoption of the measure until it has been endorsed by NQF.

Response*:* The STrR measure has undergone rigorous review by a TEP and the CMS measure development contractor, and for the reasons detailed in the proposed rule and this final rule, we believe that the measure reliably assesses facility performance. Because unexpected transfusions in the ESRD population are responsible for considerable and unnecessary morbidities and healthcare costs, and because no NQF-endorsed measures of anemia management are currently available for use in the ESRD QIP, we believe that the benefits of adopting the measure for the PY 2018 ESRD QIP outweigh the costs of waiting to adopt the measure until it has been endorsed by NQF.

Comment*:* One commenter recommended that CMS develop a hemoglobin-adjusted STrR rather than the STrR proposed in the proposed rule. Commenter stated that facilities should only be held responsible for transfusions related to chronically low hemoglobin levels, and that this adjustment would better differentiate between patients with chronically and acutely low hemoglobin levels.

Response*:* We thank commenters for the recommendation. We agree that achieved hemoglobin is a significant facility-associated component of transfusion risk. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, there is a shared responsibility in subsequent transfusion events. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased

transfusion risk, and increased risk of ESA complication. Applying a hemoglobin target would not be consistent with the FDA label, which does not support hemoglobin targets.

Comment*:* One commenter recommended that CMS use calendar year (CY) 2010 to set permanent performance standards for the STrR measure. Because transfusion rates have increased since CY 2010, commenter stated that the proposed performance standard would set an inappropriately low threshold for expected transfusion events.

Response*:* We do not believe it would be appropriate to use CY 2010 to set permanent performance standards for the STrR measure. The measure was designed to assess relative rates of transfusion, not to hold facilities accountable to a historical rate of transfusion. Furthermore, setting the performance standard at CY 2010 rates would not allow us to respond to fluctuations in transfusion rates in the future, and we believe it is appropriate to do so, particularly in the event that future national transfusion rates fall below levels achieved in CY 2010.

Comment*:* Some commenters stated that the risk-adjustment methodology for the proposed STrR measure should not be based on the risk-adjustment methodology for the Standardized Hospitalization measure, because hospitalizations and transfusions involve different types of risk factors. Commenters stated that adjusting for risks that are more proximately associated with transfusions would require the use of claims data for determining patient comorbidities.

Response*:* We agree with commenters' assertion that more proximate claims-based risk factors are appropriate for use in the risk adjustment strategy for STrR. We also believe that this has already been accomplished using our measure methodology. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions

that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication. By excluding transfusions not associated with anemia management, we are able to assess the rate of transfusions most subject to influence by the quality of care provided by dialysis facilities. Exclusion comorbidities must have occurred within the last year, and have a similar, but stronger impact for the measure, than risk-adjustment. As a consequence, transfusions that are occurring are not attributable to these non-anemia management-based causes. These exclusion co-morbidities are obtained from Medicare Claims, based on recommendations of the Anemia TEP convened in 2012, as well as recent peer reviewed publications evaluating transfusions.[13]

Comment*:* One commenter recommended that CMS limit the number of transfusion events that a single patient can contribute to this measure, because very frequent transfusions may be required due to conditions that the dialysis facility cannot control, such as chemotherapy treatment, presence of bone marrow malignancies, or sickle cell anemia, which may not be captured in the past year on Medicare claims.

Response*:* We thank commenters for the recommendation. Because of the way transfusion information is reported in claims, there are different rules for counting transfusion events depending on whether or not they occur in inpatient or (less commonly) in outpatient settings.

For the STrR, transfusion events are counted differently depending on whether they are identified based on a procedure code, a revenue center code, or a value code. The transfusion procedure may only be billed only once per day per visit. For the STrR, unique "transfusion events" are counted for each transfusion procedure code listed on an inpatient claim, with one

13 Ibrahim HN, Ishani A, Foley RN et al. "Temporal Trends in red blood transfusion among US dialysis patients, 1992-2005". American Journal of Kidney Disease. 2008; 52: 1115

event counted for any of those codes on a given day. Additionally, one "transfusion event" is counted per inpatient claim if one or more transfusion-related revenue center or value code is present. The vast majority of inpatient claims we identify as having evidence of a transfusion (92 percent) do not include a transfusion related procedure code. Therefore, most inpatient transfusion events are identified based on revenue center or value codes. As noted above, we count a single transfusion event for the inpatient claim regardless of the number of transfusion revenue center and value codes reported on the claim, resulting in a very conservative estimate of blood transfusions from inpatient claims. In all cases, the number of events counted is the same whether the claim indicates 1 unit of blood or multiple units of blood, again favoring a conservative estimate of number of transfusion events from inpatient claims.

Transfusion events are not common in outpatient settings, but similar rules apply. Multiple HCPCS codes reported for the same Revenue Center Date are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, three pints of blood reported with the same Revenue Center Date would be counted as a single transfusion event.

Therefore, the algorithm for identifying blood transfusion events described here results in a very conservative estimate of transfusion rates, limiting the impact of individual patients who receive multiple units of blood or multiple transfusions during any one episode of care. We agree that there are many conditions, including acute malignancy diagnoses and hereditary anemias (for example, sickle cell anemia) that influence transfusion risk. The STrR uses Form 2728-derived incident comorbidities and patient demographics as well as Medicare Claims derived prevalent comorbidities in the risk-adjustment strategy for STrR. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved

hemoglobin) is strengthened by applying an extensive list of exclusions described in the technical report at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication. These exclusion co-morbidities are obtained from Medicare Claims, based on recommendations of the Anemia Technical Expert Panel convened in 2012, as well as recent peer reviewed publications evaluating transfusions.[14] The list of comorbid exclusions includes acute cancer diagnoses and Sickle Cell Anemia, as well as other conditions that are associated with increased transfusion risk beyond the dialysis facilities' control.

Comment*:* Some commenters stated that transfusions related to "non-actionable conditions," such as chronic gastrointestinal bleeding, motor vehicle accidents, and transfusions related to surgical procedures, should be excluded from the measure. Accordingly, commenters recommended that CMS should develop a comprehensive list of exclusions before adopting the measure.

Response*:* The STrR incorporates a list of exclusions based on patient conditions identified through claims data. These exclusions help to ensure that transfusions for which the facility may not reasonably be held accountable are not incorporated in the measure numerator. A full list of exclusions may be read at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html. However, for any given admission diagnosis such as a motor vehicle accident, or a hospital event such as a surgical procedure, the achieved hemoglobin present on admission, which is a function of ESA dosing and the responsibility of the dialysis facility, is a strong predictor of a transfusion event

14 Ibrahim HN, Ishani A, Foley RN et al. "Temporal Trends in red blood transfusion among US dialysis patients, 1992-2005". American Journal of Kidney Disease. 2008; 52: 1115.

during the hospitalization.

Comment*:* One commenter sought clarification on how transfusions will be attributed to facilities, particularly when a patient receives a transfusion and temporarily relocates to a new facility before returning to their home facility.

Response*:* The STrR Methodology Report, which was published concomitantly with the CY 2015 ESRD PPS Proposed Rule, provides the detailed algorithm used by the STrR measure to attribute patients to a facility. Briefly, if a patient undergoes a transfusion event, the facility to which this patient is assigned at the time is responsible for it irrespective of where the event takes place or whether the patient is temporarily receiving dialysis at another facility.

Comment*:* One commenter did not support the STrR measure as proposed, because it is not sufficient on its own right to discourage under-treatment of anemia. Commenter also recommended that the measure should be stratified to capture only those transfusions that could have been prevented by the dialysis facility.

Response*:* The STrR is intended to monitor facility-level, risk-adjusted blood transfusion use, which is one important consequence of under-treatment of anemia in chronic dialysis patients, and it is the most appropriate measure of which we are aware that is available for this purpose.

Comment*:* One commenter stated that facilities will experience difficulty in explaining facility scores on the STrR clinical measure to patients, and that doing so may be "politically challenging" when the dialysis facility is affiliated with the admitting hospital system.

Response*:* We have produced a technical report that describes the measure methodology and provided a web link in the proposed rule (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html). A transfusion

ratio of greater than 1.0 reflects that a facility's patients are at higher risk for transfusions than they would be at an average facility. A score below 1.0 reflects that a facility's patients are at lower risk for transfusions than they would be at an average facility. A lower ratio is preferable because it indicates that a facility is doing a better job of managing patient anemia, as assessed through the occurrence of transfusions.

For these reasons, we are finalizing the STrR measure as proposed for the PY 2018 program and future payment years. The technical specifications for this finalized measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

b. Adoption of the Pediatric Peritoneal Dialysis Adequacy Clinical Measure in 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 proposed to add a new measure of pediatric peritoneal dialysis adequacy to the Dialysis Adequacy measure topic. We stated that 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.[15] Although recent studies suggest improvement in mortality rates among pediatric patients

15 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.

receiving maintenance dialysis over time, mortality in this patient population remains high.[16] 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,[17] 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 pediatric peritoneal dialysis adequacy currently exist, we proposed 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

16 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.

17 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.

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 proposed 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_TechnicalSpecifications.html.

We sought comments on this proposal to adopt the Pediatric Peritoneal Dialysis Adequacy measure. The comments and our responses are set forth below.

Comment*:* Many commenters supported the adoption of the Pediatric Peritoneal Dialysis Adequacy measure, because it is important to ensure that this patient population is adequately dialyzed.

Response*:* We thank the commenters for their support.

Comment*:* One commenter supported adoption of the Pediatric Peritoneal Dialysis Adequacy clinical measure, but recommended CMS change the Kt/V target to a range, because it

is harder to reach the proposed threshold for a pediatric patient than it is to reach the threshold for adult patients.

Response*:* The proposed minimum target of Kt/V-1.8 is consistent with clinical guidelines and also the recommendations of a TEP which we convened for this purpose. The TEP recommended using a target of 1.8 while recognizing that although limited evidence in the pediatric population exists, clinical practice guidelines and clinical opinion support the recommendation that target clearance in pediatric patients should meet or exceed adult standards. Studies of adult peritoneal dialysis patients identified better survival at Kt/V 1.8/week, and not 1.7 (Paniagua 2002, JASN 2002, Lo, KI 2005). We also believe that a target range could have the effect of substituting the current target with the lower boundary of any specified range.

Comment*:* One commenter did not support the adoption of the Pediatric Peritoneal Dialysis Adequacy clinical measure because it exposes pediatric patients to unnecessary risk. Commenter stated that "residual" Kt/V requires 24-hour urine collection, and that young children who are not toilet trained would need to be hospitalized and have a Foley catheter placed, which would put them at risk for infections and illness.

Response*:* We appreciate commenters' concerns for the safety of pediatric patients, and for the opportunity to clarify this point. The commenters statement about the potential difficulties inherent in collecting a 24 hour urine on young children on peritoneal dialysis have been previously addressed in both the KDOQI recommendations as well as the recommendations of the TEP. Both KDOQI and the TEP members recommend addition of 24 hour urine if available. They acknowledge that the 24 hour urine is usually not available for use in the Kt/V calculation for very young PD patients. In that case, they recommend that the Kt/V collection be based solely on the dialysate collection. The commenter's concern that patients would have to

be hospitalized to complete a 24 hour collection in order to perform the calculation is not consistent with the clinical guidelines upon which the measure was based.

For these reasons, we are finalizing the Pediatric Peritoneal Dialysis Adequacy measure as proposed for the PY 2018 program and future payment years and adding this measure to the Dialysis Adequacy Measure Topic. The technical specifications for this finalized measure can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

c. 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 facilities 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 proposed 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 did not propose 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_TechnicalSpecifications.html.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* Some commenters supported the proposal to convert the ICH CAHPS reporting measure into a clinical measure, because a clinical measure would hold facilities responsible for their ability to provide patients with a positive experience of care, adopting the clinical measure would strengthen the significance of patient input in the ESRD QIP, and facilities have had sufficient experience with the survey instrument for them to be reliably scored

on the measure. One commenter stated that, in the hospital setting, scoring CAHPS survey results has led to positive changes in the treatment environment.

Response*:* We thank commenters for their support.

Comment*:* One commenter did not support the adoption of an ICH CAHPS clinical measure because the measure would be based on patient perceptions (as opposed to clinical data). Commenter further stated that the ICH CAHPS clinical measure unfairly penalizes facilities, because providers have to contend with a number of obstacles (including reductions in payments under the ESRD PPS) and clinical variables, of which patients may not be aware. Commenter also stated that the "efficacy of the survey administration" may impact results, so the proposed clinical measure would evaluate facilities, in part, based on the competencies of survey vendors.

Response*:* We understand commenters' concerns about the ICH CAHPS measure and its patient-centered assessment of care. We further understand that patients may not be aware of the multiple influences on facilities, such as the ESRD PPS bundle and other clinical variables. However, we believe that patients are qualified to assess their perceptions of their individual care, because the quality of care provided to patients should not be impacted by reimbursement rates or the severity of a patient's illness. The ICH CAHPS survey provides patients with an opportunity to assess the care they receive as in-center hemodialysis patients, and the results from this survey will give facilities the opportunity to develop plans for quality improvement on this aspect of care. All ICH CAHPS survey vendors must be approved by CMS to ensure that the survey is administered consistently across facilities, and vendors are required to undergo annual training sessions and submit a Quality Assurance Plan to us. Furthermore, the ICH CAHPS Coordination Team intends to carry out oversight activities, including site cities and data

reviews for anomalies, to ensure that the survey is being administered according to the ICH CAHPS survey protocol. We note that, ultimately, the choice of survey vendor is within the control of the facility. If a facility believes its vendor is not properly administering the survey, then the facility should report to this to CMS and seek the services of another qualified survey vendor.

Comment*:* Some commenters did not support the proposal to convert the ICH CAHPS reporting measure into a clinical measure, because the clinical measure includes questions pertaining to nephrologists' care in the ICH CAHPS survey. Commenters stated that most dialysis facilities have little to no control over the nephrologists who are working in facilities, as well as over physicians seen outside the facility, and that both types of physicians are implicated in the survey question used to determine facility scores on the global rating for Nephrologists' Communication and Caring. Commenter further stated that this limits the facility's opportunity improve patient experience in this area.

Response*:* We disagree that facilities should not be held accountable for the quality of care provided by nephrologists treating patients at their facility. Dialysis facilities are required under our regulations (42 CFR 494.150(c)(2)(i)), to oversee the provision of care by a multi-disciplinary team, including the nephrologist treating the patient. Oversight of individual staff nephrologist care, ensuring adherence to facility policies and Medicare regulations, is primarily the responsibility of the site Medical Director, a paid employee of the dialysis facility, and, additionally, the responsibility of the facility governing body. We understand and agree that facilities should not make or unduly influence treatment decisions made by a patient and his or her nephrologist. However, the facility can ensure that the treatment environment is one in which patients feel empowered and informed enough to participate in their care by enacting

policies regarding patient engagement, and selecting medical professionals whose behavior aligns with these principles. As a result, we believe facilities are capable of improving patients' experiences with their nephrologists and may share information received with physicians outside of the facility.

Comment*:* Some commenters did not support the adoption of the proposed ICH CAHPS clinical measure because patients typically dialyze at the same facility for long periods of time, and it is difficult for facilities and nephrologists to always meet patients' expectations. As an alternative to basing measure scores on "top-box" responses, one commenter recommended that facilities should receive credit for responses that indicate satisfactory (as opposed to exemplary) experience.

Response*:* While we understand commenters' concerns about being able to consistently meet patients' expectations regarding their care, we believe that patient satisfaction and involvement in their treatment is a key element of successful ESRD treatment. The scoring methodology does not require facilities to get 100 percent on a particular measure, but it evaluates overall how the facility does.

Comment*:* Some commenters did not support the proposal to convert the ICH CAHPS reporting measure into a clinical measure. Commenters stated that the ICH CAHPS survey was originally developed for hospitals, and that transitioning the survey to the dialysis facility setting may encourage facilities to provide substandard care (for example, inappropriately shortening the length of dialysis sessions) in order to please patients. Commenters further stated that it is often impossible for facilities to meet patient expectations when treating a chronic condition such as ESRD, and that patients might inappropriately direct their frustrations towards facilities and their staff.

Response*:* We understand that facilities are concerned about a potential conflict between "pleasing patients" and providing clinically adequate care. The ICH CAHPS survey was developed through literature reviews; focus groups of in-center hemodialysis patients and their families, nephrologists and facility staff; a review of existing surveys for ESRD patients; and a Technical Expert Panel. We therefore believe the survey adequately accounts for many perspectives of dialysis care and will allow patients to provide their opinions of the care they receive without fear of retribution. At this point, we lack any evidence to substantiate concerns that facilities will provide substandard care "in order to please patients" or that "it is often impossible for facilities to meet patient expectations when treating a chronic condition"; should such evidence arise, we will reevaluate the use of the ICH CAHPS survey in the ESRD QIP for future payment years.

Comment*:* One commenter stated that the ICH CAHPS survey instrument is unreliable, because only 53 percent of patients with ESRD are able to complete forms for patient-reported outcomes, and basing facility scores on responses from the remaining patients cannot be generalized to reflect the true experience of all patients at a facility.

Response*:* We acknowledge commenter's concern regarding the overall response rate, but note that a 53 percent response rate is considered better than average, particularly for a vulnerable, chronically ill patient population. However, response rates are not a measure of reliability because response rates are subject to a variety of factors. As part of the process of submitting NQF #0258 to NQF for re-endorsement, we conducted reliability testing for the measure. Specifically, we found that the item total correlations for Kidney Doctor Communication were all above 0.40. Nineteen of the 22 item-total correlations for Dialysis Facility Care and Operations were above 0.40. Six of 11 item-total correlations for Patient

Empowerment were above 0.40. Internal consistency reliabilities for the three scales ranged from 0.75 to 0.93. We believe the measure is reliable because the item total correlations for the measure's three composite measures all exceeded 0.40, which indicates a moderate level of reliability.

Comment*:* Some commenters did not support the expansion of the ICH CAHPS reporting measure into a clinical measure, because published research demonstrates that several items on the survey are unreliable.

Response*:* We are aware of some studies that have questioned the reliability of the ICH CAHPS survey questions. However, a recent study in which we have been involved found that psychometric analyses strongly support the internal consistency, reliability, and validity of the ICH CAHPS survey scales.[18] This study further showed that these scales can be used to discriminate variation in quality of care among dialysis facilities, and that scale scores were strongly related to patients' global ratings of nephrologists, dialysis center, and dialysis center staff. We therefore believe that the survey questions are reliable.

For reasons, we are finalizing the ICH CAHPS clinical measure as proposed for the PY 2018 program and future payment years. Technical specifications for the ICH CAHPS clinical measure can be found at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

d. 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

18 Weidmer BA, Cleary PD, Keller S, Evensen C, Hurtado MP, Kosiak B, Gallagher PM, Levine R, Hays RD (2014). Development and Evaluation of the CAHPS (Consumer Assessment of Healthcare Providers and Systems) Survey for In-Center Hemodialysis Patients. *Am J Kidney Diseases*. [Epub ahead of print].

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.[19] Studies have also shown that depression and anxiety are the most common comorbid illnesses in patients with ESRD.[20] 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.[21] Nevertheless, depression and anxiety remain under-recognized and under-treated, despite the availability of reliable screening instruments.[22] 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 proposed 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 proposed to adopt a reporting measure based on this NQF-endorsed measure so that we can collect data that

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19 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.

20 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.

21 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.

22 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.

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 proposed 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 proposed 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_TechnicalSpecifications.html.

We sought comments on these proposals. The comments and our responses are set forth below.

Comment*:* Some commenters supported the Screening for Clinical Depression and Follow-Up reporting measure, and recommended that CMS either require facilities to use the same screening for depression, or require facilities to report the methodology used. Commenters

also recommended that CMS require facilities to provide documentation of referral for treatment of depression beyond the abilities of the renal social worker.

Response*:* We appreciate commenters' support, and will consider incorporating these recommendations in future rulemaking.

Comment*:* Many commenters did not support adoption of the Screening for Clinical Depression and Follow-Up reporting measure. Commenters stated that the Screening for Clinical Depression and Follow-Up reporting measure is outside the dialysis facility's scope of practice, and that staff social workers are not qualified to provide treatment for depression. Commenters also stated that a measure on depression screening and follow-up is not covered within the statutory authorities of the ESRD QIP, since Section 1881 (h)(1)(A) of the Act limits the program to "renal dialysis services." Commenters also stated that while facilities can do depression screenings, they are not equipped to provide psychotherapy services, and that requiring facilities to conduct the assessment is a disservice to patients, who would be better served by pyschotherapists. Comments further stated that depression unrelated to dialysis should not fall under the purview of the dialysis facility, and that conducting the annual assessment is unduly burdensome (particularly with respect to hiring staff to provide the assessment and training staff to enter data correctly). Commenters further stated that a future clinical version of this measure would require dialysis facilities to provide these services. Commenter stated that the measure would be more appropriate for the Comprehensive ESRD Care Initiative, because that initiative includes physicians as well as dialysis facilities.

Response*:* We appreciate commenters' input on this measure. First, we disagree that screening patients for clinical depression is outside the scope of practice for dialysis facilities. Patient assessments, including screenings for clinical depression, are a critical aspect of renal

dialysis services, because they enable facilities to assess whether a patient needs additional care. We further note that the ESRD CfCs requires that facilities perform a "comprehensive assessment [for each patient that] must include, but is not limited to . . . [an] evaluation of psychosocial needs by a social worker" (42 CFR 494.80(a)(7)). We maintain that performing depression assessments is covered by this section (and, by extension, fall within the scope of work for dialysis facilities), because screening for clinical depression is an evaluation of the patient's psychosocial needs. We further disagree that requiring facilities to report whether they screen patients for clinical depression is unduly burdensome because depression screening is a type of a psychosocial evaluation, which, as stated above, facilities are already required to perform as a condition for coverage under the Medicare program. We also note that this measure does not, and will not, require facilities to provide psychotherapy services to patients. We believe that this measure will incentivize facilities to perform a clinical depression screening for each qualifying patient and develop a follow-up plan in order to ensure that the patient receives appropriate treatment. Although we agree that facilities are not equipped to actually treat the depression, we believe that the screenings can be performed by the individuals already in the multidisciplinary care team, such as a staff social worker. We appreciate that the Comprehensive ESRD Care model seeks to directly address coordination of care issues in the dialysis facility setting, but do not believe this precludes us from adopting a measure on this issue for the ESRD QIP, and we believe that information gained as a result of this measure can be used to better inform policy decisions in both the ESRD QIP and the CEC model.

Comment*:* Some commenters did not support the proposal to adopt the Screening for Clinical Depression and Follow-Up reporting measure because facilities are already performing these screenings, and because screening for depression overlaps with the Medicare Conditions

for Coverage for ESRD facilities. One commenter recommended CMS instead consider using a measure such as the Standardized Hospitalization Ratio to capture the effective management of the dialysis patient.

Response*:* We appreciate that some facilities may already be performing these screenings. However, we do not believe that all facilities are doing so, and we believe that the Screening for Clinical Depression and Follow-Up reporting measure will incentivize all facilities to conduct depression screening and initiate follow-up plans when necessary. We also recognize that some facilities that are already screening patients for depression in order to meet the requirements of the ESRD CfCs will experience significant additional burdens associated with reporting data for the reporting measure. Nevertheless, depression is a highly prevalent condition in patients with ESRD, which impacts many aspects of a patient's life and is associated with higher rates of mortality in the ESRD population. We therefore believe the benefits of incentivizing facilities that are not already doing so to regularly screen their patients for depression outweigh the data reporting burdens for facilities that are already conducting these screening to meet the requirements of the ESRD CfCs.

Comment*:* Some commenters sought clarification as to what characteristics a screening instrument must have to qualify as an "age appropriate tool" and what constitutes a "follow-up plan" in the context of the proposed Clinical Depression and Follow-Up reporting measure. The commenters also sought clarification as to whether facilities are required to screen all patients for depression, or whether only patients "identified as potentially having a problem" should be screened. Commenters sought clarification as to whether the facility would be required to perform the screening, or whether another provider would be required to do so.

Response*:* The measure does not require facilities to select any particular screening tool

because we believe that each facility should be able to select the tool that is most appropriate for each of their patients. However, examples of screening tools that we would consider to be age-appropriate include, but are not limited to:

Adolescent Screening Tools (12-17 years): Patient Health Questionnaire for Adolescents (PHQ-A), Beck Depression Inventory-Primary Care Version (BDI-PC), Mood Feeling Questionnaire (MFQ), Center for Epidemiologic Studies Depression Scale (CES-D), and PRIME MD-PHQ2

Adult Screening Tools (18 years and older): Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI or BDI-II), Center for Epidemiologic Studies Depression Scale (CES-D), Depression Scale (DEPS), Duke Anxiety-Depression Scale (DADS), Geriatric Depression Scale (GDS), Cornell Scale Screening, and PRIME MD-PHQ2

We further note that we would consider an appropriate follow-up plan to be one that outlines a proposed course of action, including at least one of the following: (1) additional evaluation for depression; (2) suicide risk assessment; (3) referral to a practitioner who is qualified to diagnose and treat depression; (4) pharmacological interventions; and/or (4) other interventions or follow-up for the diagnosis or treatment of depression.

Under this measure, facilities are required to report whether they screened qualifying patients for depression, and whether they developed a follow-up plan.

Comment*:* One commenter recommended increasing the minimum age for qualifying patients from 12 to 18, because pediatric patients present unique challenges for depression assessment.

Response*:* Although we recognize that patients between the ages of 12 and 17 present unique challenges for depression assessment, we believe it is critically important to include these patients because adolescent-onset depression is associated with multiple negative health

outcomes, including an increased sick of death by suicide, suicide attempts, and recurrence of depression in young adulthood. In addition, the measure specifications for NQF #0418, the measure upon which this reporting measure is based, provides that the measure is appropriate for patients ages 12 to 17, and we agree with NQF's assessment because there are age-appropriate screening tools for this population, and requiring facilities to report data on whether these depression screenings were provided could prevent the negative outcomes listed above.

Comment*:* Some commenters did not support the proposal to adopt the Depression Screening and Follow-Up reporting measure, because the measure upon which it is based (NQF #0418) is specified for physicians, not dialysis facilities. Because the follow-up component of the measure requires a physician referral, commenter stated that the measure is not appropriate for dialysis facilities.

Response*:* We recognize that the NQF-endorsed version of this measure is specified for physicians, but we continue to believe that it is an appropriate measure for the dialysis facility setting. Dialysis facilities see patients with ESRD far more frequently than nephrologists and primary care physicians. Accordingly, dialysis facilities are in a better position to detect when their patients are in need of treatment for depression. Furthermore, under the ESRD CfCs, the nephrologist is considered part of the multidisciplinary team that provides dialysis treatment. As a result, we believe nephrologists should be capable of referring patients in need of further treatment.

Comment*:* Some commenters did not support the adoption of the Depression Screening and Follow-Up reporting measure because it is a "check-box" measure (that is, facilities receive credit on the basis of attestations), there is no depression screening tool specific to patients with ESRD, and there is limited data on the effectiveness of pharmacotherapies for depression in

ESRD patients. One commenter was concerned that adopting the measure could lead to increased utilization of pharmacotherapies without a concomitant decline in rates of depression, because this effect has been seen in studies of the general population. One commenter also recommended that CMS develop alternative measures on depression that would be more valid for the dialysis setting.

Response*:* We recognize that scores on this measure are based on whether the facility reported one of six conditions for each qualifying patient. Depression is a significant concern for patients with ESRD, but it remains underdiagnosed and undertreated. We believe that facilities will more vigilantly monitor and screen for depression because the measure requires facilities to report whether they performed the screening. Additionally, we appreciate commenters' concerns that this measure could lead to an overutilization of pharmacotherapies for depression in patients with ESRD. However, we are not aware of any evidence indicating pharmacotherapies are overused in the ESRD population; absent such evidence, we do not believe that this concern is sufficient to delay adoption of this measure. Finally, we appreciate commenters' recommendation that we develop a measure specific to depression in the dialysis setting. We will continue to evaluate the measure's specifications, and if we conclude that modifications are needed, we intend to propose to adopt them in the future.

Comment*:* One commenter did not support the adoption of the Screening for Depression and Follow-Up reporting measure because patients risk being denied transplants if they are diagnosed with depression. Commenter was also concerned that adopting the measure may result in an over-reliance on pharmacotherapies without encouraging the types of emotional and social support that are needed to treat patients suffering from depression and ESRD.

Response*:* We appreciate commenters' concerns regarding the impact of depression on

transplant eligibility and the possibility that this measure may result in increased use of pharmacotherapies the treatment of depression. However, absent evidence of transplant denials resulting from depression treatment or overuse of pharmacotherapies to treat patients' depression, we do not believe these concerns are sufficient to support delating adoption of the Clinical Depression Screening and Follow-Up reporting measure. We believe that a patient's psychosocial wellbeing is a critical aspect of an ESRD patient's overall health and quality of life.

Comment*:* One commenter did not support the Depression Screening and Follow-Up measure because a patient's status can change considerably during the year, and the commenter recommended requiring more frequent assessments.

Response*:* We agree that patients' depression status may change over the course of a year, and we encourage facilities to conduct more frequent screenings. Nevertheless, because PY 2018 will be the first time this measure will be included in the ESRD QIP, we think it is appropriate to ask facilities to report whether they performed the screening at least once per performance period. We may consider revising this requirement in future years as we learn more information, based on the data we receive.

Comment*:* One commenter did not support the Depression Screening and Follow-Up measure because it does not require facilities to assess the underlying psychosocial causes of depression, and because the measure does not require facilities to ensure that patients are engaged in their care, including the setting of patient-centric goals for treatment.

Response*:* This measure is intended to ensure ESRD patients who may be experiencing depression are identified and referred, if necessary, for follow-up treatment. It does not require the dialysis facility to diagnose the nature and causes of depression because these tasks are not suitable for a dialysis facility. Rather, we recognize that treatment for clinical depression should

be furnished by appropriately trained practitioners and other mental health professionals, and it is our hope that these professionals will evaluate psychosocial causes and engage patients in the selection of treatment goals.

Comment*:* Some commenters did not support the Screening for Clinical Depression and Follow-Up reporting measure, because there is a lack of concrete information about the causes of depression and optimal screening methods and referral practices in the ESRD population. One commenter also stated that applying the principles underlying this measure to both adult and pediatric patients is not valid, because adult and pediatric present the different symptoms of depression and require different types of follow-up treatment.

Response*:* The measure specifications for NQF #0418 (the measure upon which this reporting measure is based) provide guidance about what constitutes screening and follow-up within the context of the measure. Furthermore, the NQF-endorsed specifications do not include an exclusion for patients with ESRD, and we are not aware of any studies demonstrating that the particular causes of depression for patients with ESRD invalidate the measure's prescriptions for screening and follow-up. We therefore believe that the Screening for Clinical Depression and Follow-Up reporting measure is appropriate for patients with ESRD. Finally, as stated above, we note that NQF #0418 was specified for patients aged 12 and older, and we agree with NQF that it is appropriate to include pediatric patients who are 12 years or older.

Comment*:* Some commenters did not support the proposal to adopt the Depression Screening and Follow-Up measure, because meeting the requirements of the measure will create costs for the facility that will not be covered by comparable increases in payments under the ESRD PPS. Another commenter stated that Medicare fee-for-service does not allow or reimburse facilities for taking actions to address depression.

Response*:* We recognize that depression screenings are not specifically reimbursed under the ESRD PPS. However, psychosocial evaluations are included in the ESRD CfCs and are required for Medicare participation, and depression screening is a type of psychosocial evaluation. Although we understand facilities may incur additional costs for complying with the measure's requirements (because facilities cannot bill Medicare separately for these assessments and referrals), on balance we believe that these costs are outweighed by potential improvements for patients' well-being.

For these reasons, we are finalizing the Clinical Depression Screening and Follow-Up reporting measure as proposed. Technical specifications for the measure can be found at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html

e. Pain Assessment and Follow-Up Reporting Measure

Pain is one of the most common symptoms in patients with ESRD.[23] 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.[24] 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.[25] 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.[26] Patients

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23 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.

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

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

26 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

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.[27] Therefore, a measure that assesses whether facilities regularly assess their patients' pain, and develop follow-up plans as necessary, offers the possibility of improving the health and well-being of patients with ESRD.

We proposed 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 proposed 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.

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and emotional symptoms in chronic hemodialysis patients. (2005) *Journal of the American Society of Nephrology*; 16(8):2487-2494.

27 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.

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 proposed 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 proposed 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 age 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 proposed 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 proposed 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 proposed that conditions covering the first 6 months of the performance period must be reported in CROWNWeb before August 1 of the performance period, and that conditions covering the second 6 months of the performance period must be reported in CROWNWeb before February 1 of the year directly following the performance period. We believe this reporting schedule will ensure regular monitoring and follow-up of patients' pain without imposing an undue burden on facilities. Third, we proposed 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 sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* One commenter supported adoption of the Pain Assessment and Follow-Up reporting measure because the measure can help reduce the pain associated with dialysis needles, and also encourage facility staff to undergo training in pain management and cannulation techniques. Commenters also supported the measure because pain is an underdiagnosed and

undertreated condition in patients with ESRD that can inhibit individual function and change the ability of patients to fulfill their desired and required roles in life.

Response*:* We thank the commenters for the support.

Comment*:* Some commenters supported adopting the proposed Pain Assessment and Follow-Up reporting measure, because pain is an important concern among the ESRD population. Commenters recommended that CMS also require facilities to use the same screening tool, or collect information from facilities about the validated pain assessment tool used.

Response*:* We thank commenters for their support. We did not propose to collect information about the pain assessment tool used or to require facilities to use the same tool. However, we will take these recommendations into consideration as we reevaluate the measure for future payment years.

Comment*:* Many commenters did not support adoption of the Pain Assessment and Follow-Up reporting measure. Commenters stated that the Pain Assessment and Follow-Up reporting measure is outside the dialysis facility's scope of practice. Commenters also noted that while facilities can do pain screenings, they are not equipped to provide pain treatment services, and that requiring facilities to conduct the assessment is a disservice for patients, who would be better served by pain centers. Comments further stated that pain unrelated to dialysis should not fall under the purview of the dialysis facility, and that conducting the semiannual assessment is unduly burdensome. Commenters further stated that a future clinical version of this measure would require dialysis facilities to provide these services. Commenter stated that the measure would be more appropriate for the Coordinated ESRD Care model, because that initiative includes physicians as well as dialysis facilities.

Response*:* We appreciate commenters' input on this measure. First, we disagree that screening patients for pain is outside the scope of work for dialysis facilities. Patient assessments are a critical aspect of renal dialysis services because they enable facilities to provide care that is directly responsive to patient needs. The ESRD CfCs require that facilities perform a "comprehensive assessment [for each patient that] must include, but is not limited to . . . [an] evaluation of current health status and medical condition, including co-morbid conditions" (42 CFR 494.80(a)(7)). Because screening for pain is an assessment of patients' current health status, this screening falls within the ESRD CfCs and, by extension, the scope of work for dialysis facilities. We further disagree that the requirement for twice annual pain assessments is unduly burdensome because facilities are already required to perform an assessment of their patients' current health status, and pain assessments are an example of such as assessment. We also note that this measure does not, and will not, require facilities to provide chronic pain treatment services to patients. This measure requires facilities to report whether or not they performed a pain assessment for each qualifying patient, including whether or not they documented a follow-up plan. Although we agree that facilities are not the appropriate parties to actually treat pain, we do think the assessment can be performed by members of the multidisciplinary care team, such as a staff nurse. We recognize that the Coordinated ESRD Care model seeks to directly address coordination of care issues in the dialysis facility setting, but do not believe this precludes us from adopting a measure on the same issue for the ESRD QIP, and we believe that information collected as a result of this measure can be used to better inform policy decisions in the ESRD QIP and the CEC model.

Comment*:* Some commenters did not support adoption of the Pain Assessment and Follow-Up reporting measure because facilities are already performing these screenings,

screening for pain overlaps with the Medicare Conditions for Coverage for ESRD facilities, and the ICH CAHPS survey already asks patients about the presence of pain. One commenter recommended CMS instead consider using a measure such as the Standardized Hospitalization Ratio to capture the effective management of the dialysis patient. Another commenter also stated that uremia is typically responsible for pain in patients with ESRD, and recommended delaying the adoption of the measure until research identifies an effective way to relieve pain associated with uremia.

Response*:* We appreciate that some facilities may already be performing these screenings. However, we do not believe that all facilities are doing so, and we believe that the Pain Assessment and Follow-Up reporting measure will incentivize all facilities to conduct pain assessments and initiate follow-up plans when necessary. Additionally, one of the reasons we believe this measure is appropriate for dialysis facilities is that the actions required to comply with the reporting requirements are covered, as discussed above, by the ESRD CfCs.

Comment*:* One commenter recommended increasing the number of pain assessments patients receive each year beyond two and notes that the Joint Commission recommends assessing pain on an on-going basis.

Response: We agree that patients' pain status may change over the course of a year, and we encourage facilities to conduct more frequent assessments. Nevertheless, because PY 2018 will be the first time this measure is adopted in the ESRD QIP, we think it is appropriate to require facilities to report whether or not they performed a pain assessment once every six months. We may consider asking facilities to report more frequently in future years, after we have had an opportunity to evaluate the data that facilities report on this measure.

Comment*:* One commenter sought clarification as to whether facilities are required to

screen all patients for pain, or whether only patients “identified as potentially having a problem" should be screened.

Response*:* Under this measure, facilities are required to report whether they performed pain assessments for qualifying patients, and whether they developed a follow-up plan based on that assessment. As stated in the CY 2015 ESRD PPS Proposed Rule, qualifying patients for this measure are patients aged 18 years or older who have been treated at the facility for 90 days or longer (79 FR 40261).

Comment*:* Commenter did not support the proposal to adopt the Pain Assessment and Follow-Up reporting measure, because the measure upon which it is based (NQF #0420) is specified for physicians, not dialysis facilities. Because the follow-up component of the measure requires a physician referral, commenter stated that the measure is not appropriate for dialysis facilities.

Response*:* We recognize that the NQF-endorsed version of this measure is specified for physicians, but we continue to believe that it is an appropriate measure for the dialysis facility setting. Dialysis facilities see patients with ESRD far more frequently than nephrologists and primary care physicians. Accordingly, dialysis facilities are in a better position to detect when their patients are in need of treatment for pain. Furthermore, under the ESRD CfCs, the nephrologist is considered part of the multidisciplinary team that provides dialysis treatment. We therefore believe that nephrologists should be capable of referring patients for follow-up care following an initial pain assessment, if necessary.

Comment*:* One commenter did not support the adoption of the Pain Assessment and Follow-Up reporting measure because it focuses on chronic, not acute, pain, and chronic pain is best managed by physicians, not dialysis facilities. Commenter also stated that the measure is

not appropriate because significant pain is not typically associated with dialysis, and facilities are already addressing acute pain associated with dialysis, when it occurs.

Response*:* The purpose of this measure is to incentivize facilities to assess both chronic and acute pain. Although some facilities may already have in place robust processes to address acute pain, we believe there is still considerable room for improvement in the assessment and management of acute pain. Although chronic pain is best treated by a qualified physician, dialysis facilities see patients far more frequently than nephrologists or other physicians, so dialysis facilities are in the best position to conduct regular assessments and refer patients to appropriate practitioners as needed. We further note that the reporting measure does not require facilities to treat chronic pain, or to report whether they have done so.

Comment*:* One commenter did not support adoption of the Pain Assessment and Follow-Up reporting measure, because it is unclear whether the measure seeks to assess acute or chronic pain, and the commenter does not understand how this measure will improve patient care. For example, a pain assessment performed at one point in time may not be relevant to the patient's experience of pain at a different time.

Response*:* As stated above, this measure is intended to assess overall pain – both acute and chronic. We further believe that this measure will improve patients' quality of life because it will increase the likelihood that patients who suffer from pain will be identified and referred to an appropriate practitioner. Finally, as stated above, we agree that patients' pain status may change over the course of a year, and we encourage facilities to conduct more frequent assessments.

Comment*:* Some commenters did not support the adoption of the Pain Assessment and Follow-Up reporting measure because it is a "check-box" measure (that is., facilities receive

credit on the basis of attestations), and because there is no pain assessment tool specific for patients with ESRD.

Response*:* We recognize that scores on this measure are based on whether a facility reports one of six conditions for each qualifying patient once every six months. However, we disagree that the measure will not make an impact on patients' quality of life. Pain—both chronic and acute—is a significant concern for patients with ESRD, but it remains underdiagnosed and undertreated. We believe this measure will incentivize facilities to more vigilantly monitor and address patients' pain, and that as a result patients with pain issues will be identified more quickly and receive the follow-up care necessary to improve and maintain their quality of life.

We understand that there is no firm consensus on what pain assessment tool is best for patients with ESRD; however, there are a number of standardized tools available. We believe that facilities are in the best position to choose an appropriate screening tool for use with their patients. Examples of standardized assessment tools that we believe would be appropriate include but are not limited to the following: the Brief Pain Inventory (BPI); Faces Pain Scale (FPS); McGill Pain Questionnaire (MPQ); Multidimensional Pain Inventory (MPI); Neuropathic Pain Scale (NPS); Numeric Rating Scale (NRS); Oswestry Disability Index (ODI); Roland Morris Disability Questionnaire (RMDQ); Verbal Descriptor Scale (VDS); Verbal Numeric Rating Scale (VNRS); and Visual Analog Scale (VAS).

Comment*:* One commenter did not support the proposal to adopt the Pain Assessment and Follow-Up measure because the commenter is concerned that facilities will simply conduct a straightforward assessment (for example, a numerical pain scale) and prescribe analgesics. Commenter stated that it would be preferable to identify the underlying causes of chronic and

acute pain, and to develop care plans that address these causes.

Response*:* As stated above, we believe that facilities have many options when selecting an appropriate pain assessment tool, and we believe that facilities should be able to select the tool that is most appropriate for their patients. We further believe that decisions to prescribe analgesics are best left to the prescribing clinician, though it is our hope that clinicians will take into account the underlying causes of pain, as well as patients' treatment goals, when prescribing therapies.

Comment*:* One commenter did not support the proposal to adopt the Pain Assessment and Follow-Up measure, because meeting the requirements of the measure will create costs for the facility that will not be covered by comparable increases in payments under the ESRD PPS. Another commenter stated that Medicare fee-for-service does not allow or reimburse facilities for taking actions to address pain management.

Response*:* We recognize that pain assessments are not covered under the ESRD PPS. However, evaluations of current health status and medical condition are included in the ESRD CfCs and required for participation in the Medicare program, and pain assessment is an example of such an evaluation. Although we understand that facilities may incur additional costs for complying with the measure's requirements, on balance we believe that these costs are outweighed by potential improvements in patients' quality of life.

Comment*:* One commenter did not support the proposed Pain Assessment and Follow-Up reporting measure, because adopting the measure may lead to prescription of narcotics and other pain medications, which can cause iatrogenic effects.

Response*:* We understand the commenter's concern that a measure assessing pain may lead to prescription of narcotics and other pain medications, which can carry the risk of negative

side effects when used or prescribed inappropriately. However, absent evidence indicating that pain medication utilization rates among ESRD patients are unnecessarily high, we do not believe this concern is sufficient to delay adoption of the Pain Assessment and Follow-Up reporting measure because of the prevalence and severity of pain-related health issues in the ESRD population.

For these reasons, we are finalizing the Pain Assessment and Follow-Up reporting measure as proposed. Technical specifications for the measure can be found at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html

f. NHSN Healthcare Personnel Influenza Vaccination Reporting Measure

Infection is the second most common cause of death in patients with ESRD, following cardiovascular causes,[28] and influenza accounts for significant morbidity and mortality in patients receiving hemodialysis.[29] 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.[30] Vaccination is an effective preventive measure against influenza that can prevent many illnesses, deaths, and losses in productivity.[31] 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

[28] 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.
[29] 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.
[30] 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.
[31] 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.

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.[32] We therefore proposed to adopt an NHSN HCP Influenza Vaccination reporting measure for PY 2018 and future payment years.

We proposed 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 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 proposed 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

[32] 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.

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 proposed 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 proposed 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 proposed 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_TechnicalSpecifications.html.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment*:* Some commenters supported the proposal to adopt the NHSN HCP Influenza Vaccination reporting measure because HCP can expose patients to influenza if they have not been vaccinated, and because the measure will help improve patient safety.

Response*:* We thank the commenters for their support.

Comment*:* One commenter did not support the adoption of the NHSN HCP Influenza Vaccination reporting measure, because its definition of HCP is overly inclusive and reporting vaccination status for short-term HCP is overly burdensome. Commenter was concerned about facilities' ability to comply with the requirement to provide written documentation of each HCP's vaccination during the influenza season, and that if this measure is expanded to a clinical measure in the future it may limit access to temporary workers (including students and volunteers) due to the requirement that HCPs are included in the measure even if they only work at the facility for a single day.

Response*:* We disagree that the definition of "qualified healthcare personnel" is overly inclusive. The NHSN HCP Influenza vaccination measure was pilot-tested at over 300 healthcare facilities in the United States; based on the results of this pilot test, CDC restricted the types of non-employee healthcare personnel included in the measure in order to balance inclusiveness and feasibility of reporting for healthcare facilities. It is important to measure

influenza vaccination among non-employee healthcare personnel as many of these personnel provide care to or interact directly with patients and employee healthcare personnel, placing them at risk of acquiring or transmitting influenza. We therefore believe the inclusion of non-employee healthcare personnel in this measure is appropriate. We also note that this measure does not require facilities to report documentation regarding HCP immunization status when vaccinations are obtained within their own healthcare facility. Under the NHSN HCP Influenza Vaccination reporting measure and associated NHSN module, facilities should obtain written documentation of influenza vaccinations obtained outside of the healthcare facility, but need only report the total number of those vaccinations received outside of the healthcare facility.

Comment*:* One commenter supported CMS's effort to ensure HCPs are vaccinated, but was concerned about the administrative aspects of the proposed NHSN HCP Influenza Vaccination reporting measure. The commenter specifically sought clarification as to whether written documentation would be required to establish an HCP's vaccination status, and whether vaccinations received before October 1 would qualify under this proposed measure.

Response*:* Written documentation of an HCP's vaccination status is only required for HCP receiving the influenza vaccination outside of the healthcare facility. Acceptable forms of documentation of influenza vaccination received outside of the healthcare facility include a signed statement or form, or an electronic form or e-mail from the healthcare worker indicating when and where he/she has received the influenza vaccine, or a note, receipt, vaccination card, or similar form of documentation from the outside vaccinating entity stating that the healthcare worker received the influenza vaccine at that location. Facilities should maintain this documentation for their own record; however, only summary count of number reported within this category should be reported.

Under the NHSN HCP Influenza Vaccination reporting measure, the performance period for the denominator (the number of healthcare personnel working in a facility) is from October 1 through March 31. However, the numerator measurement (vaccination status) includes vaccines obtained "as soon as vaccine is available." As a result, an HCP working at the facility as of October 1 who was vaccinated in September would be considered vaccinated for the performance period under this measure.

Comment*:* One commenter supported the NHSN HCP Influenza reporting measure, but stated that the NQF-endorsed measure "only includes personnel working at a facility for 30 days or more." Commenter recommended that CMS exclude HCP working at a facility for less than 30 days from this measure.

Response*:* The NHSN HCP Influenza Vaccination module's requirement to include only healthcare personnel working in the healthcare facility for 30 days or more was in place during the 2012-2013 influenza season. Beginning with the 2013-2014 influenza season, facilities are required to report healthcare personnel working in the facility for one day or more from October 1 through March 31, because this more accurately captures healthcare personnel in the facility at risk of acquiring or transmitting influenza virus. The National Quality Forum (NQF) accepted CDC's proposal to make the change to one day or more in May 2013, and the current NQF-endorsed measure available at http://www.qualityforum.org/QPS/0431 reflects this revised specification.

Comment*:* Some commenters did not support the proposal to adopt the NHSN HCP Influenza Vaccination reporting measure because influenza vaccination is already a requirement for employment in dialysis facilities, and that adopting this measure will dilute the scores of other measures in the ESRD QIP.

Response*:* Although influenza vaccinations for healthcare professionals may be a condition of employment for some facilities, this is not a condition for all facilities, and some facilities do not require volunteers or short-term employees to have current influenza vaccinations. Accordingly, we believe that potential improvements to patients' health warrant the adoption of the measure. We further clarify that adopting this measure in the ESRD QIP will not dilute the weights of the clinical measures in the program. The scoring methodology we are adopting for PY 2018 weights the reporting measure scores equally to comprise 10 percent of a facility's TPS. Although this methodology reduces the significance of the other reporting measures it does not impact weight of the clinical measures, and it allows us to collect the baseline data needed to expand the NHSN HCP measure into a clinical measure in the future. We therefore believe that the benefits of adopting this measure outweigh the drawbacks of diluting the weight of the other reporting measures in the ESRD QIP measure set.

Comment*:* Some commenters did not support the proposal to adopt the NHSN HCP Influenza Vaccination measure, because meeting the requirements of the measure will create costs for the facility that will not be covered by comparable increases in payments under the ESRD PPS.

Response*:* We understand that this measure may result in additional cost to dialysis facilities from having to compile and report the vaccination status of their health care professionals; however, we believe that these costs are outweighed by improvements in community health resulting from an immunized workforce.

Comment*:* Some commenters stated that reporting data to NHSN HCP Influenza Module for dialysis facilities within a hospital will result in duplicative reporting because these entities are already included in the hospital's reporting. One commenter recommended that facilities

receive full credit on the measure if they indicate their hospital submitted the data on their behalf.

Response*:* Dialysis facility reporting will be completely separate from acute care reporting regardless of whether a dialysis facility is affiliated with acute care. It is important that all eligible healthcare personnel be counted by each facility where they work so that each facility's reporting to NHSN under this measure presents an accurate picture of the vaccination coverage among healthcare personnel at that specific facility or location. The concerns regarding duplicative reporting are unfounded, because reporting for the same individual's vaccination status will only occur in instances where that individual worked in both facilities during the reporting period. In these cases, it is appropriate to include the HCP in both facilities' counts because they meet the eligibility criteria for both facilities' reporting.

Comment*:* One commenter recommended that CMS consider collecting data for the NHSN HCP Influenza Vaccination reporting measure as actual numbers of HCPs vaccinated rather than percentages, because small facilities may appear to be noncompliant based on a small number of HCP not receiving a vaccination. The commenter further recommended that this information be reported annually rather than monthly, because this is consistent with the way data is entered into CROWNWeb.

Response*:* Under the proposed NHSN HCP Influenza Vaccination reporting measure, facilities are required to report the number of HCP working in the facility (denominator data) and the number of those individuals with a certain vaccination status (numerator data). Accordingly, in the process of calculating the percentage of HCPs who receive an influenza vaccination, the measure collects data on the actual number of HCPs vaccinated. We also note that for the PY 2018 program NHSN HCP Influenza Vaccination is a reporting measure, meaning that facilities

will receive a score on this measure based on the successful reporting of data, not on the values actually reported. In addition, monthly reporting is not required of facilities under this measure. Instead, facilities are required to submit a single summary report of final HCP influenza vaccination data for the specified influenza season by the annual reporting deadline.

For these reasons, we are finalizing the NHSN HCP Influenza Vaccination measure as proposed. Technical specifications for the measure can be found at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html

Figure 2: Summary of Finalized PY 2018 Measures

★ New measure for PY 2018

Clinical Measures

1. Vascular Access Type Measure Topic – AVF
2. Vascular Access Type Measure Topic – Catheter ≥ 90 days
3. Kt/V Dialysis Adequacy Measure Topic – Adult Hemodialysis
4. Kt/V Dialysis Adequacy Measure Topic – Adult Peritoneal Dialysis
5. Kt/V Dialysis Adequacy Measure Topic – Pediatric Hemodialysis
6. ★ Kt/V Dialysis Adequacy Measure Topic – Pediatric Peritoneal Dialysis
7. Hypercalcemia
8. NHSN Bloodstream Infection in Hemodialysis Outpatients
9. Standardized Readmission Ratio
10. ★ Standardized Transfusion Ratio
11. ★ ICH CAHPS Patient Experience of Care Survey

Reporting Measures

1. Mineral Metabolism
2. Anemia Management
3. ★ Clinical Depression Screening and Follow-Up
4. ★ Pain Assessment and Follow-Up
5. ★ NHSN Healthcare Personnel Influenza Vaccination

2. 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 proposed 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 proposed 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 sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

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

a. 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 proposed 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 proposed 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 sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures for the PY 2018 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the 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. 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 did not propose 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 proposed 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 proposed 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 proposed to set the performance standard as successfully submitting the HCP Influenza Vaccination Summary Form to CDC's NHSN system by May 15, 2017.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

4. 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 proposed 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.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

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 proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. Under this methodology, facilities receive points along an improvement range, defined

as a scale running between the improvement threshold and the benchmark. We proposed to define the improvement threshold as the facility's performance on the measure during CY 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.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

c. Scoring the ICH CAHPS Clinical Measure

For PY 2018 and future payment years, we proposed the following scoring methodology for the ICH CAHPS clinical measure. We proposed 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 (that is., 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 proposed 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 proposed to base the score on where a facility's performance rate falls relative to the achievement threshold and the benchmark for that measure. We proposed 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 proposed that the improvement threshold will be defined as facility performance in CY 2015, and further proposed to base the score on where a facility's performance rate falls relative to the improvement threshold and the benchmark for that measure. We proposed 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 proposed 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 proposed 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 proposed 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 sought comments on these proposals to score the ICH CAHPS clinical measure. The comment and our response are set forth below.

Comment*:* One commenter sought clarification as to how multiple administrations of the ICH CAHPS survey in a single performance period will factor into facilities' ICH CAHPS clinical measure scores if the ICH CAHPS clinical measure proposal is finalized.

Response*:* We clarify that survey responses from the two survey administrations will be compiled together into a single dataset, which will then be used to calculate facility scores on the ICH CAHPS clinical measure. In other words, responses to the first and second survey administrations will be combined to produce a facility's ICH CAHPS score. Each of the three composite measures consists of six or more questions from the survey that are reported as one composite score. Scores are created by first determining the proportion of answers to each

response option for all questions in the composite. The final composite score averages the proportion of those responding to each answer choice in all questions. Only questions that are answered by survey respondents will be included in the calculation of composite scores.

For these reasons, we are finalizing the scoring methodology for the ICH CAHPS clinical measure as proposed for the PY 2018 program and future payment years.

d. 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 did not propose 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 proposed 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 proposed 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 sought comments on these proposals. The comments and our responses are set forth below.

Comment*:* One commenter did not support the proposal to allocate zero points on the proposed Pain Assessment and Follow-Up measure if a facility does not report one of the six specified conditions for each patient. Commenter recommended using a scoring system that awards partial points for partial compliance.

Response*:* We agree with the commenter that an all-or-nothing methodology will not incentivize facilities to provide pain assessments and follow-ups if they are unable meet the requirements of the Pain Assessment and Follow-Up measure for a single qualifying patient. We also believe that this same concern applies equally to the Screening for Clinical Depression and Follow-Up reporting measure, because the proposed scoring methodology for both reporting measures is identical. In order to respond to the commenter's recommendation to award partial points, we finalize that the two measures will be scored as follows:

Pain Assessment and Follow-Up:

$$\left\{\frac{\text{Number of patients for whom facility reports one of six conditions during the first six months}}{\text{Number of eligible patients in the first six months}} + \frac{\text{Number of patients for whom facility reports one of six conditions during the second six months}}{\text{Number of eligible patients in the second six months}}\right\} \div 2$$

Screening for Clinical Depression and Follow-Up:

$$\frac{\text{Number of patients for whom facility reports one of six conditions during the performance period}}{\text{Number of eligible patients during the performance period}}$$

We selected the above scoring methodology for the Screening for Clinical Depression and Follow-Up reporting measure because it evaluates the percentage of eligible patients for whom a facility reports the data required for the measure. In contrast to the proposed scoring methodology, which would have assigned zero points on the measure if a facility failed to report data for a single patient, this methodology allows facilities to receive a high score on the measure even if they fail to report data for a small number of patients. We selected the above scoring methodology for the Pain Assessment and Follow-Up measure for the same reasons. However,

in this case we calculated separate percentages for first and second six months and averaged the two percentages together. We did this because the Pain Assessment and Follow-Up measure requires facilities to report data on a semiannual basis, and we believe that taking the average of the two percentages provides a fair way to evaluate facilities' overall performance during the performance period.

For these reasons, we are finalizing that we will calculate facility performance on the Screening for Clinical Depression and Follow-Up, Pain Assessment and Follow-Up, and NHSN HCP Influenza Vaccination reporting measures as described above.

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

With the following exceptions discussed below, we did not propose to change the minimum data policies for the PY 2018 ESRD QIP from those proposed above for the PY 2017 ESRD QIP. We also proposed 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 proposed that 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 proposed 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 proposed 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 did not propose 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 proposed to modify the case minimum requirements for the Anemia Management and Mineral Metabolism reporting measures beginning with the PY 2017 ESRD QIP. We did not propose 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 proposed 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 did not propose 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 proposed that all facilities, regardless of patient population size, will be scored on the influenza vaccination measure.

We sought comments on this proposal. The comments and our responses are set forth below:

Comment*:* Some commenters supported the proposal to determine facility eligibility for

scoring on the ICH CAHPS reporting measure based on the number of patients treated in the eligibility period, because it will allow providers to better anticipate their eligibility in a given year.

Response*:* We thank commenters for their support.

Comment*:* Many commenters did not support the proposed data minimum requirements for the reporting measures because the commenters stated that the requirements unfairly penalize facilities that may not be able to legitimately report data for a few patients. As an alternative, the commenters recommended applying a consistent case minimum of 26 for all measures in the ESRD QIP.

Response*:* We agree with commenters that setting the patient minimum for the Screening for Clinical Depression and Follow-Up, and Pain Assessment and Follow-Up reporting measures at one qualifying patient may unfairly penalize small facilities, because a failing to report data for two or more patients will have a greater impact on small facility than on larger facilities. However, we disagree that it is appropriate to set the case minimum at 26 for these reporting measures, because doing so would not allow CMS to collect baseline data for a large percentage of patients. We believe that setting the case minimum at 11 for the Screening for Depression and Follow-Up and Pain Assessment and Follow-Up reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly penalize small facilities that are unable, for legitimate reasons, to report data on all but one patient. We further believe that setting the case minimum at 11 is appropriate, because this would align with the case minimum policy for the clinical measures in the ESRD QIP. Therefore, we are finalizing a case minimum policy of 11 for the Screening for Clinical Depression and Follow-Up and Pain Assessment and Follow-Up reporting measures.

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 proposed to apply this finalized policy to the Screening for Clinical Depression and Follow-Up and the Pain Assessment and Follow-Up reporting measures. We further proposed 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 proposed 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 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 sought comments on these proposals but did not receive any comments.

For these reasons, we are finalizing the minimum data policies for the PY 2018 program as proposed, with the exception of the patient minimum policies for the Screening for Clinical Depression and Follow-Up and Pain Assessment and Follow-Up reporting measures. For the reasons discussed above, we are finalizing the policy that a facility must treat at least 11 qualifying patients during the performance period to receive a score on the Screening for Clinical Depression and Follow-Up and Pain Assessment and Follow-Up reporting measures.

Table 27 displays the finalized patient minimum requirements for each of the 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 27: 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)	11 qualifying patients	Before July 1, 2016	N/A
Mineral Metabolism (Reporting)	11 qualifying patients	Before July 1, 2016	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before July 1, 2016	N/A
Pain Assessment and Follow-	11 qualifying patients	Before July 1, 2016	N/A

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
Up (Reporting)			
NHSN HCP Influenza Vaccination (Reporting)	N/A	Before January 1, 2016	N/A

6. 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to include the following measures in the following subdomains of the proposed clinical measure domain (see Table 28):

TABLE 28: 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 sought 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 proposed 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 proposed to include a larger number of measures in the Patient and Family Engagement/Care Coordination subdomain. We proposed 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 proposed 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%

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 proposed to assign the entire subdomain weight to that measure. We additionally noted that improving patient safety and reducing bloodstream infections in patients with ESRD are two 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 proposed to give the proposed ICH CAHPS measure twice as much weight as the

proposed SRR measure. Additionally, we noted 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 proposed 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 proposed 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 proposed 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 sought comments on this proposal for weighting individual measures within the Clinical Measure Domain. The comments and our responses are set forth below.

Comment*:* One commenter supported the proposal to create a Clinical Measure Domain, and the weightings applied therein, because the proposed domain appropriately prioritizes outcome measures, and compared to process measures, outcome measures provide a better indication of quality care.

Response*:* We thank the commenter for the support.

Comment*:* One commenter supported ICH CAHPS clinical measure's proposed weight in the Clinical Measure Domain and recommended that CMS consider giving the measure greater weight in the future, because CAHPS is weighted slightly higher in other value-based purchasing programs.

Response*:* We thank the commenter for the support and we will consider increasing the weight of the ICH CAHPS clinical measure in future payment years.

Comment*:* Commenter supported placing the NHSN Bloodstream Infection measure alone in the Safety subdomain because reducing bloodstream infections is one of the highest priorities for patients with ESRD.

Response*:* We thank the commenter for the support.

Comment*:* One commenter did not support the proposed weighting for the subdomains within the clinical measure domain. Commenter stated that the proposed weighting places too much emphasis on the Patient and Family Engagement/Care Coordination subdomain which contains clinical measures over which the facility has the least control, and places too little emphasis on safety. Commenter recommended that CMS revise the weights of the subdomains to weight the Safety and Clinical Care subdomains equally, and assign less weight to the Patient and Family Engagement/Care Coordination subdomain.

Response*:* We disagree with the commenter that the proposed subdomain weighting

places too much emphasis on Patient and Family Engagement/Care Coordination, as compared to the Safety subdomain. As discussed in the CY 2015 ESRD PPS Proposed Rule (79 FR 40267), we proposed to assign the Patient and Family Engagement/Care Coordination subdomain slightly more weight than the Safety subdomain, because the former subdomain includes two measures and the latter subdomain only includes one measure. We continue to believe that these weights are appropriate for the PY 2018 ESRD QIP measure set, but we will reconsider the weighting system in its entirety, in light of the three criteria listed above (that is., the number of measures and measure topics in a proposed subdomain; how much experience facilities have had with the measures and measure topics in a proposed subdomain; and how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD) in future rulemaking.

Comment*:* One commenter recommended reducing the weight of the ICH CAHPS clinical measure in the Clinical Measure Domain "to avoid penalizing dialysis units that provide safe, high quality care" but do not score as highly on the ICH CAHPS measure.

Response*:* We agree that safety is a paramount concern in dialysis treatment, but also believe that patient experience is a crucial element of the overall care provided by the dialysis facility. As stated in the CY 2015 ESRD PPS Proposed Rule, we based decisions about subdomain and measure weighting on three criteria, and we continue to believe that the weight of the ICH CAHPS clinical measure is consistent with these criteria. We further note that it is possible for a facility that does not perform well on the ICH CAHPS clinical measure to avoid a payment reduction if it performs well on the other clinical measures.

Comment*:* One commenter did not support weighting the ICH CAHPS clinical measure at 20 percent of a facility's TPS, because small facilities will have trouble meeting the eligibility

requirements for this measure, which will result in a 20 percent reduction in their TPS.

Response*:* If a facility does not meet the eligibility requirements for the ICH CAHPS clinical measure, the facility will not be scored on the measure and the corresponding measure weight will be reallocated equally across the clinical measures for which the facility received a score.

Comment*:* Some commenters recommended lowering the weight of the ICH CAHPS clinical measure, because no studies have demonstrated a positive association between scores on the measure and positive patient outcomes.

Response*:* While it is premature to know for certain in this provider setting, measuring patient experience can lead to quality improvement. In other settings, better patient experience can lead to better outcomes. Patient experience and clinical measures may be related, but they are distinct measures of quality. ICH CAHPS supports the National Quality Forum's strategy priorities of Effective Communication and Care Coordination and Person and Family-centered Care as well as the Institute of Medicine's six specific aims for improvement.

Comment*:* One commenter did not support the proposed weighting for the Safety subdomain because there is only one measure in the domain. Commenter recommended that CMS not include subdomains with only one measure, or in the alternative, reduce that subdomain's weight so that the one measure is weighted similar to measures in the other subdomains.

Response*:* As stated in the proposed rule, we decided how to weight the Clinical Measure Domain subdomains and individual measures using three criteria: "(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" (79 FR 40267). We further stated that facilities have more experience with the NHSN Bloodstream Infection clinical measure than they do with the measures in the Patient and Family Engagement/Care Coordination subdomain, and 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" (79 FR 40268). We continue to believe that the weight assigned to the Safety subdomain and the NHSN Bloodstream Infection clinical measure is appropriate for these reasons.

Comment*:* Some commenters recommended lowering the weight of the NHSN Bloodstream Infection measure, because facilities do not reliably report the data used to calculate performance rates on the measure.

Response*:* NHSN provides detailed trainings, protocols, and guidance for users to follow to ensure that data are reported in a standardized manner and according to requirements. We recognize that continuous internal and external evaluation and quality checks of the reported data are important for accuracy and reliability. We further note that one of the purposes of the feasibility study is to improve the validity of data reported to NHSN, and we continue to believe that one of the outcomes of the study will be to improve the validity and reliability of the NHSN Bloodstream Infection measure. For this reason, and the reasons stated in the CY 2015 ESRD PPS Proposed Rule, we continue to believe that the NHSN Bloodstream Infection measure is weighted appropriately.

Comment*:* Some commenters recommended increasing the weight of the Vascular Access Type measure topic, because high scores on the measure topic are strongly associated

with positive patient outcomes.

Response*:* We agree that the Vascular Access Type measures are strongly associated with positive patient outcomes. For this reason, and for the reasons described in the CY 2015 ESRD PPS Proposed Rule, the Vascular Access Type received the second highest weighting (that is, 18 percent) in the Clinical Measure Domain, lower only than the ICH CAHPS clinical measure (20 percent) and the NHSN Bloodstream Infection measure (20 percent). Accordingly, we believe that the Vascular Access Type measure topic is weighted appropriately.

Comment*:* One commenter supported CMS's inclusion of a Patient and Family Engagement/Care Coordination subdomain, but feels the measures within this domain are not meaningful to patients because the ICH CAHPS clinical measure excludes home dialysis patients, and the Standardized Readmission Ratio does not assess patients' quality of life.

Response*:* We disagree that the measures in the Patient and Family Engagement/Care Coordination subdomain are not meaningful to patients. We are continuing to investigate the possibility of expanding the ICH CAHPS survey to include a greater proportion of the ESRD population. Nevertheless, the measure as it is currently specified assesses the experience of care for the majority of patients with ESRD. In addition, we believe the Standardized Readmission Ratio does assess patients' quality of life because preventing unplanned hospital readmissions significantly improves patients' quality of life.

Comment*:* One commenter did not think facilities' experience with a clinical measure should affect the weight assigned to the measure. For example, the proposed weight for the STrR clinical measure was reduced because facilities have not had a large amount of experience with this measure.

Response*:* We consider facility experience with a clinical measure in how we weight that

measure in order to give facilities time to become familiar with the reporting requirements and put into place the necessary tools to maximize their potential to score highly. We therefore believe it is appropriate to increase a measure's weight as facilities gain familiarity with the measure.

Comment*:* Some commenters supported the proposed criteria for assigning weights to measures and subdomains, but commenters recommended adding three additional criteria when assigning weights. Specifically, the commenters recommended the following three criteria: 1) Strength of evidence; 2) Opportunity for improvement; and 3) Clinical significance.

Response*:* We agree with commenters that these criteria encompass important considerations for evaluating measures. We clarify that these are criteria that are taken into account when making decisions about whether to adopt a measure in the ESRD QIP, because it would be inappropriate to adopt a measure that did not meet these criteria. For this reason, we do not believe it would be appropriate to also factor these criteria into decisions about how much weight to give measures in a facility's Clinical Domain score.

Comment*:* One commenter stated that the Clinical Domain scoring methodology does not provide more flexibility than the current scoring methodology because the current scoring methodology makes it possible to redistribute weights between clinical and reporting measures, and to distribute weights for individual measures within the two categories.

Response*:* We recognize that under the current scoring methodology it is possible to assign weights to individual measures without grouping them in subdomains, as proposed for the new scoring methodology. We nevertheless believe that assigning weights to subdomains (as opposed to just the measures contained therein) simplifies the process of prioritizing quality improvement goals as the program evolves, and in light of the NQS. We further believe that

assigning weights to subdomains provides for greater transparency, because it directly communicates CMS's priorities for measure areas. For these reasons, we believe that the merits of grouping measures into subdomains, and explicitly articulating weights for the various subdomains, outweighs the merits of continuing to weight measures individually.

Comment*:* One commenter was concerned that some measures span multiple subdomains. For example, SRR could be attributed to Patient and Family Engagement/Care Coordination subdomain as well as the Clinical Care subdomain.

Response*:* We recognize that some measures could reasonably be placed in multiple subdomains. In such cases, we need to make a judgment regarding which subdomain we think will be most appropriate. In the case of SRR, we believe that it is appropriate to place the measure in the Patient and Family Engagement/Care Coordination subdomain because the measure is primarily intended to evaluate care coordination, not the quality of clinical care provided by facilities.

For these reasons, we are finalizing that we will calculate facilities' Clinical Measure Domain scores beginning in PY 2018 as proposed.

7. Calculating the Reporting Measure Domain Score 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 proposed 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 proposed to establish a new Reporting Measure Domain. We further proposed 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 proposed 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 proposed to use the following general formula to determine a facility's RMA, based on its reporting measure domain score:

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

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 proposed 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 proposed 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 proposed to calculate a facility's TPS by subtracting the facility's RMA from its Clinical Measure Domain score. Additionally, we proposed 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 29.

TABLE 29: 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 29, we expect that 4.3 percent more facilities (222 overall) would receive a two percent 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 sought 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 also sought 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.

We sought public comments on these proposals. The comments and our responses are set

forth below.

Comment*:* One commenter supported the proposed scoring methodology for PY 2018, because it appropriately balances the importance of reporting and clinical measures in a facility's TPS. Another commenter recommended that CMS consider reallocating measure weights within the domains if a facility does not meet minimum data requirements for a measure.

Response*:* We thank the commenters for their support and recommendations.

Comment*:* Some commenters did not support the proposed RMA methodology for the ESRD QIP, because it is too complex and likely difficult to explain to patients. Commenters stated that the ESRD QIP should maintain a consistent scoring methodology from year to year. Commenters also stated that using more complicated scoring formulas makes the ESRD QIP less transparent, and limits facilities' ability to participate. Commenters recommended that CMS delay finalizing any change in scoring methodology to allow for more time to analyze the proposed changes and how facilities would perform under the new scoring system. Commenters recommended that CMS continue to use the current weighting system, because it assigns greater weight to the clinical measures, as compared to the reporting measures. Another commenter stated that the weight of the clinical measures should be increased in the ESRD QIP, and expressed concerns that the proposed scoring methodology will result in less weight for the clinical measures. Specifically, commenters recommended adopting the alternative scoring methodology, in which clinical measures and reporting measures are weighted at 90 percent and 10 percent, respectively.

Response*:* We appreciate the numerous comments we received on the RMA methodology. As a result of the significant concerns expressed about the RMA methodology, we have decided not to finalize the methodology at this time. We will further review the RMA

methodology, and we may decide to propose to adopt it in future rulemaking. In its stead, we will retain the current scoring methodology used in the ESRD QIP to weight measures and, as proposed, increase the weight assigned to clinical measures. Under this methodology, clinical measures will be weighted as finalized for the Clinical Domain score, and the Clinical Domain Score will comprise 90 percent of a facility's TPS. Reporting measures will be weighted equally to form 10 percent of the facility's TPS.

For these reasons we are not finalizing the RMA scoring methodology as proposed. Instead, we are finalizing the alternative scoring methodology, under which clinical measures will we weighted as finalized for the Clinical Domain score, and the Clinical Domain score will comprise 90 percent of a facility's TPS, with the reporting measures weighted equally to form the remaining 10 percent of a facility's TPS.

8. Example of the PY 2018 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the 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 3 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

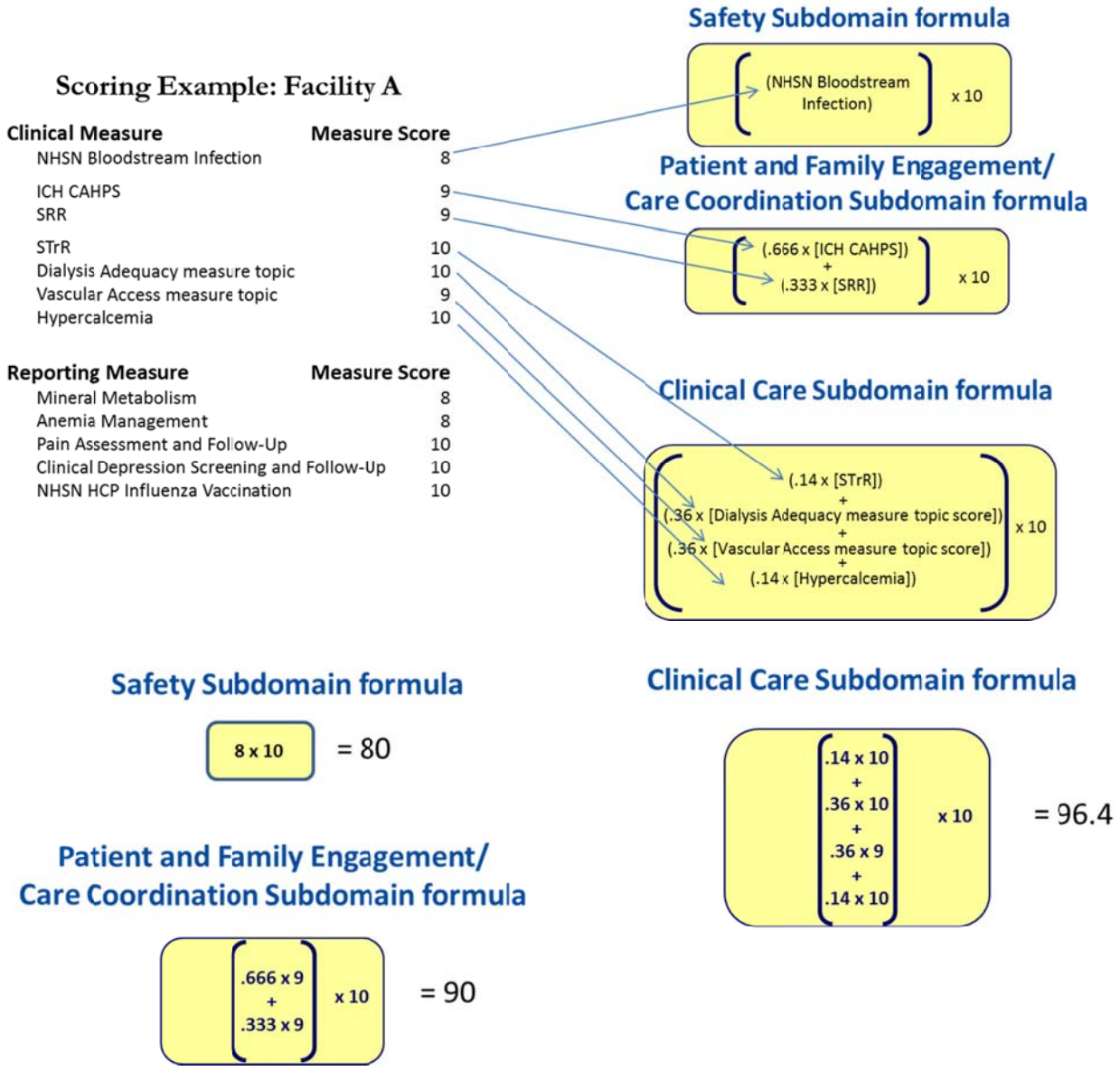
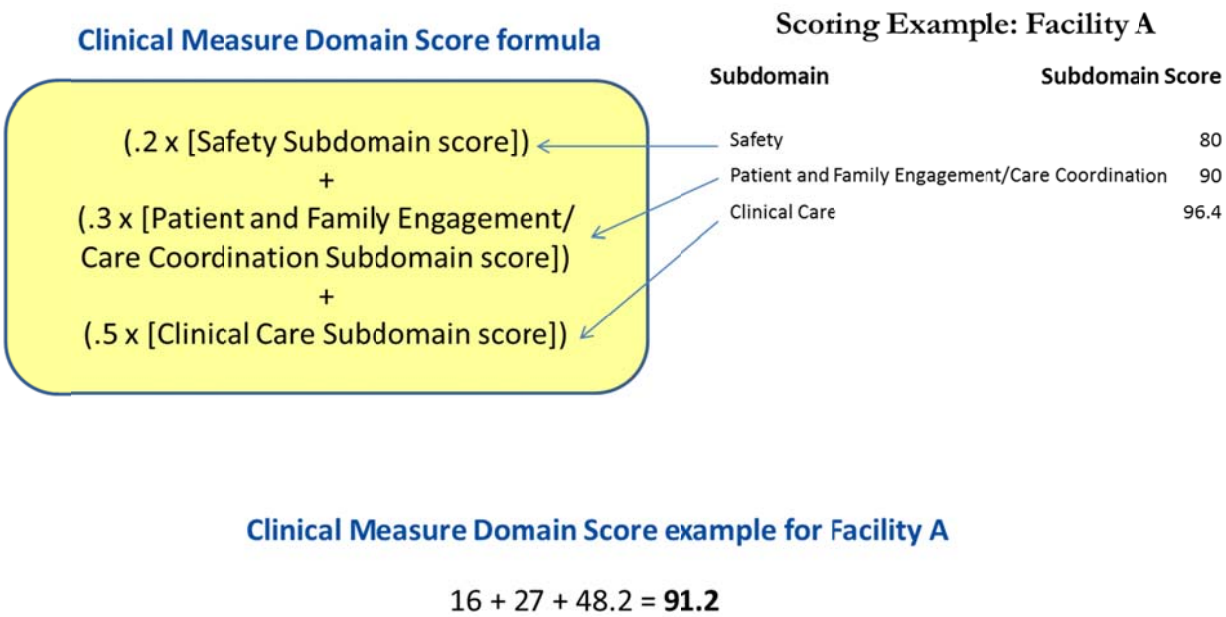


Figure 4 illustrates the general methodology for weighting subdomains in the clinical measure domain, as well as the example calculations for Facility A's clinical measure domain score.

Figure 4



Figures 5 and 6 illustrate the general methodology for calculating a facility's reporting measure domain score and TPS, as well as the example calculations for Facility A.

Figure 5

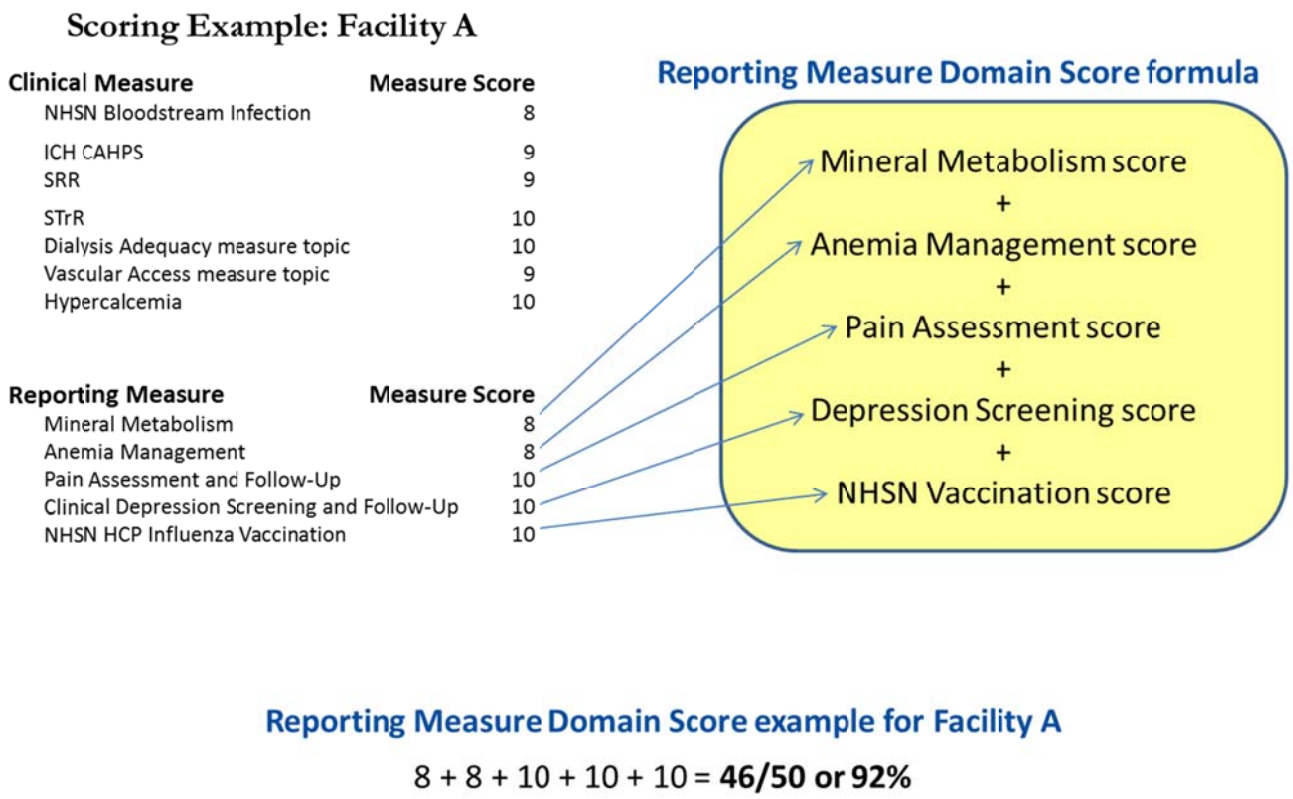
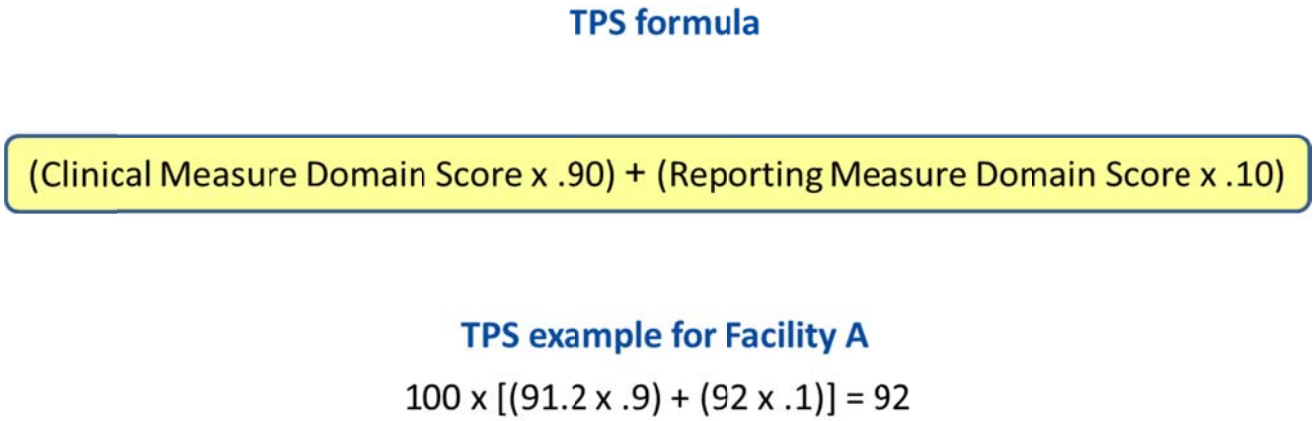


Figure 6



9. 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 proposed 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 (that is, 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.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2014 ESRD PPS Final Rule (78 FR 72223 through 72224), we finalized a payment reduction scale for PY 2016 and future payment years: For every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction on its ESRD PPS payments for PY 2016 and future payment years, with a maximum reduction of 2.0 percent. We did not propose any changes to this policy.

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 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 sought comments on this proposal. We did not receive any comments and are finalizing it as proposed.

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 therefore sought comments on whether it would be feasible to stratify ESRD QIP

measures based on whether the beneficiary is a dual eligible. We were interested in whether stakeholders recommend stratification and, if so, for what specific measures stakeholders would find stratification most compelling.

We were 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 sought comments on the meaningfulness of stratifying measures, and the feasibility and burden associated with reporting stratified measures.

The comments and our responses are set forth below.

Comment*:* Some commenters did not support stratifying ESRD QIP measures based on whether the beneficiary is dually eligible for Medicare and Medicaid, because the commenter feels this constitutes risk adjusting for patients' socioeconomic status, which may obscure differences in facilities' risk-adjusted quality scores and mask potential disparities in care. One commenter recommended that CMS instead consider evaluating facilities in relation to their peers by comparing facilities serving similar shares of dual-eligible beneficiaries, because "such an approach adjusts for socioeconomic status without masking differences in quality." The commenter further recommended that CMS compare facilities using only ESRD QIP measures that are claims-based, in order to minimize administrative burden to facilities and the agency resulting from the comparison. Another commenter stated that stratifying ESRD QIP scores on the basis of dual-eligibles is an "interesting idea," but one that is complex and would require considerable collaboration with the ESRD community. Some commenters did not support stratifying ESRD QIP measures based on whether the beneficiary is dually eligible. Commenters stated it is not operationally feasible for facilities to separately report ESRD QIP measures for

dual eligible beneficiaries, because dual eligibility status can change on a monthly basis. Another commenter also stated its belief that this stratification would include dual eligible patients in the facility's Medicare patient population and the dual eligible population, raising the possibility that a facility could be penalized twice for the same patient. Another commenter recommended stratifying ESRD QIP measures solely for investigative purposes, and not using these scores to determine payment reductions. Another commenter expressed reservations about the effects of stratifying for dual eligible patients, but recommended that CMS place greater emphasis on the role of socioeconomic status and demographic factors when assessing facility performance under the ESRD QIP.

Response*:* We appreciate commenters' input and we will take it into consideration as we continue to evaluate how to account for dual-eligibles in the ESRD QIP and other CMS ESRD quality initiatives.

IV. Technical Corrections for 42 Part 405

A. Background

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.

B. Summary of the Proposed Provisions and Responses to Comments on the CY 2015 ESRD PPS

In the CY 2015 ESRD PPS proposed rule, we proposed to make a technical correction that deletes the outdated terms and definitions at §405.2102. Specifically, we proposed 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, qualified personnel, chief executive officer, dietitian, medical record practitioner, nurse responsible for nursing service, physician-director, and social worker. We also proposed 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 30 below."

TABLE 30: Technical Corrections to §405.2102

Term	Proposed Action	Other CFR 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	--
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)

We did not receive any public comments addressing this technical correction. Therefore, we are finalizing the deletion of obsolete definitions in §405.2102 as proposed.

V. Methodology for Adjusting DMEPOS Payment Amounts using Information from

Competitive Bidding Programs

A. Background

1. Fee Schedule 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 the Medicare DMEPOS Competitive Bidding Program (CBP), as authorized under section

1847(a)(2)(B) of the Act. Additional background discussion about DMEPOS items subject to section 1834 of the Act, rules for calculating reasonable charges, and fee schedule payment methodologies for PENs and for DME prosthetic devices, prosthetics, orthotics, and surgical dressings, was provided in the proposed rule (79 FR 40275 through 40277).

2. 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 competitive bidding areas (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.

3. 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. 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."

B. Summary of the Proposed Provisions and Responses to Comments on the Methodology for Adjusting DMEPOS Payment Amounts using Information from Competitive Bidding Programs

The proposed rule for implementing section 1834(a)(1)(G) of the Act to establish a methodology for using information from CBPs to adjust the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii) of the Act was published on July 1, 2014 (79 FR 40208). We proposed applying the methodology proposed in this rule in making adjustments to the payment amounts for enteral nutrition as authorized by section 1842(s)(3)(B) of the Act (79 FR 40281). We received 89 public comments on the proposed rule, including comments from patient organizations, patients, manufacturers, health care systems, and DME suppliers. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received, our responses to the comments, and the policies we are finalizing for DMEPOS furnished under section 1834 of the Act. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

We proposed establishing three methodologies for adjusting DMEPOS fee schedule amounts in areas where CBPs have not been established for these items and services based on single payment amounts SPAs established in accordance with the payment rules at § 414.408 (79 FR 40281). We stated that the use of SPAs that may be established in accordance with the payment rules proposed in section VI of the proposed rule 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. The first methodology we proposed is summarized in subsection V. B. 1 below and would utilize regional adjustments limited by

national parameters for items bid in more than 10 CBAs throughout the country. The second methodology we proposed is summarized 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. The third methodology we proposed is summarized in subsection 5 and would be used for mail order items furnished in the Northern Mariana Islands. We also proposed rules that would apply to all of these proposed methodologies, which are discussed in sections V.B.3, V.B.4, and V.B.6 below.

1. Proposed Regional Adjustments Limited by National Parameters

CBPs are currently in place in 100 of the largest metropolitan statistical areas (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 that are fully or partially located within a given state range from one to twelve. One CBA is for a non-contiguous area of the United States (Honolulu, Hawaii) and 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 proposed 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 (79 FR 40281).

Under the proposed methodology, adjusted fee schedule amounts for areas within the contiguous United States would be determined based on regional SPAs or regional single payment amounts (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 average of the RSPAs established for all states. This limits the range in the regional fee schedule amounts from highest to lowest to no more than 20 percent, 10 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 proposed 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 (79 FR 40284). 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 proposed 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 proposed 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.

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 proposed 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 (79 FR 40284). 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.

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 proposed 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 above.

We proposed 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 (79 FR 40284). 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 proposed 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 (79 FR 40284). 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 we proposed 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 solicited 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 proposed that the designation of rural and frontier states could change as the U.S. Census information changes. We proposed 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 proposed 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 (79 FR 40285). We proposed 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 proposed 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 proposed 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 proposed 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.

We indicated in the proposed rule (79 FR 40285) that some of the comments received on the advance notice of proposed rulemaking 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. In summary, we proposed 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 solicited public comments on whether payment in rural areas of states that are not designated as rural or frontier states should be set differently. For the purpose of ensuring access to necessary items and services in states that are more rural or sparsely populated than others, we proposed 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.

In addition, we proposed that the adjustments to the fee schedule amounts for areas outside the contiguous United States would not be based on the RSPAs. Rather, we proposed 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 (79 FR 40285). These proposals were made in consideration of 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 proposed that any SPAs from programs in these areas be excluded from the calculation of the RSPAs in section a. In addition, we proposed that the adjustments to the fee

schedule amounts for areas outside the contiguous United States would not be based on the RSPAs. Rather, we proposed 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 proposed 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 (79 FR 40285).

For the purpose of establishing the boundaries for the regions, we proposed using 8 regions developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce (79 FR 40282). Research and analysis conducted by the

BEA indicated 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 proposed to revise the definition of *region* in § 414.202 to mean a region developed for economic analysis purposes by the 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 the proposed rule are listed in Table 31 below. Further information can be obtained at http://www.bea.gov/

TABLE 31: 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 solicited public comments on whether different regional boundaries should be considered that would better reflect potential regional differences in the costs of furnishing items and services subject to the DMEPOS CBP.

The comments on these proposals and our responses are set forth below.

Comment: Many commenters stated that the DMEPOS CBP and the SPAs established under the program are flawed because the bids they are based on are not binding and therefore result in the submission of non-bona fide bids and because the SPA is based on the median of supplier bids for an item rather than the maximum bid resulting in some suppliers being paid less than the amount they bid. The commenters therefore believe that the SPAs should not be used to adjust payment amounts for items and services furnished in other areas of the country. A few commenters said that no decisions should be made before future Office of the Inspector General (OIG) reports on competitive bidding are published because these reports might validate their claims that the SPAs are flawed.

Response: We do not agree that the DMEPOS CBP and the SPAs established under the program are flawed because the bids they are based on are not binding and therefore result in the submission of non-bona fide bids or because the SPA is based on the median of supplier bids for an item rather than the maximum bid resulting in some suppliers being paid less than the amount they bid. Bids are screened to ensure that they are bona fide. Suppliers that submit the lowest bids are required to provide invoices and other information to validate the bid and bids that are not validated are rejected. Regarding calculation of the SPA using the median rather than maximum bid, suppliers offered contracts under the program do not have to accept these amounts, but if they do, they are accepting the payment amounts in the contract and suppliers have successfully furnished items at these amounts with no impact on access. Over 90 percent of suppliers accept contracts they are offered, indicating that the SPAs are appropriate. We therefore do not agree with the commenters that the SPAs should not be used to adjust payment amounts for items and services furnished in other areas of the country and we do not agree that waiting for an OIG evaluation of this issue is necessary. Section 1834(a)(1)(F)(ii) of the Act mandates use of information on the payment determined under CBPs to adjust the payment amount that would otherwise be made for DME for an area that is not a CBA by no later than January 1, 2016, therefore, we believe it is appropriate to establish the methodology in rulemaking so that it takes effect on January 1, 2015, allowing time for calculation and implementation of the adjusted fee schedule amounts on January 1, 2016.

Comment: Some commenters suggested that a survey of supplier costs in areas outside of CBAs should be conducted to determine whether the costs in these areas are greater than the costs in CBAs or to otherwise provide information on how the payment amounts in areas outside CBAs should be adjusted.

Response: We disagree with this comment. The statute requires CMS to use CBP information (as opposed to survey data of supplier costs as the commenters suggest).

Comment: Many commenters suggested that as an alternative to using SPAs to adjust payment amounts, the methodology should use either the highest bid submitted for each item under the competition or the highest bid submitted for the item by the suppliers in the winning range.

Response: We disagree with this suggestion. We believe that the median bid is a better reflection of the costs of furnishing items by suppliers as whole as reflected in their bids than either the lowest bid or the highest bid. Medicare payment methods at 42 CFR 405.502 used in the past for DME have relied on customary charges from suppliers based on the median of their charges as well as fee schedule amounts based on average reasonable charges. In no case have the highest supplier charges or highest reasonable charges been used to establish Medicare allowed amounts for DME in the past, and in no case has use of median or average charges in establishing Medicare allowed payment amounts resulted in significant problems related to obtaining access to items and services in the past.

Comment: Some commenters stated that bids submitted by suppliers unable to fulfill the terms of their contract, for example, due to problems associated with meeting State licensure requirements, should be excluded and SPAs should be recalculated before they are used to determine the adjusted fee schedule amounts.

Response: We disagree with this comment. We have observed no significant negative impacts on access to items and services under the CBPs since they were initially phased in on January 1, 2011. In the limited situations where bids used in the calculation of the SPAs were

from suppliers that later were determined to be ineligible, these bids did not impact access to items and service.

Comment: One commenter indicated that the boundaries for the regions based on the 8 regions developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce are too broad and are not representative of current regional economic characteristics.

Response: We disagree. The BEA regional designations have been evaluated and have evolved over the years to continue to encompass socio-economic patterns.

Comment: Many commenters stated that the proposed methodology does not adequately address the costs of furnishing items and services in areas of the country where CBPs have not been established, particularly for rural areas, non-contiguous areas, or remote areas where suppliers must incur extraordinary delivery expenses. Some commented that the SPA-based pricing is too low for a supplier to stay in business and for the beneficiaries to receive equipment. Some commenters believe that the quality of items and services furnished will be compromised by the proposed methodology for adjusting payment amounts. Many commenters did not agree with the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor for rural states and frontier states and suggested varied ways to adjust prices in rural areas, including raising the national ceiling to 120 or 150 percent, or having rural and low population density areas add-on payments at the ZIP code or county level similar to the add-on payments allowed for rural areas under the ambulance fee schedule. Commenters believe that considerations should be made for all rural areas within states regardless of whether the state meets the proposed definitions of rural or frontier state. Some commenters stated that the SPAs

do not account for unique costs of delivering items to extremely remote locations and should not be used to adjust payments in these areas.

Response: We agree that the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor for rural states and frontier states should be applied to all rural areas and on a statewide basis depending on whether or not the state meets the proposed definitions for rural or frontier state. We believe the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor should be applied, at least initially, in other areas within a state that are designated as rural areas rather than entire states in order to ensure access to items and services in these areas. Although we do not have direct evidence that cost in rural areas are higher than costs in urban areas or vice versa or that the SPAs do not cover costs in rural areas, we believe it is prudent for the sake of ensuring access to items and services in these areas to proceed cautiously in adjusting fee schedule amounts in these areas. Therefore, in response to comments that considerations should be made for all rural areas within states regardless of whether the state meets the proposed definitions of rural or frontier state, we are finalizing a definition for rural area at §414.202 to mean a geographic area represented by a postal zip code of at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). The definition of rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at § 414.210(g) are applied. As part of the methodology we are finalizing for adjusting fee schedule amounts using information from CBPs, we are finalizing a provision that the adjusted fee schedule amounts for any area meeting the definition of rural area will be no lower than the

national ceiling amount. We are not finalizing the proposed definitions of rural state and frontier state because we have decided to apply provisions proposed for these areas (79 FR 40284) to all rural areas based on comments received and as explained in more detail below. Lastly, we note that Medicare program guidance at section 60 of chapter 20 of the Medicare Claims Processing Manual (Pub. 100-04) allows for payment of separate charges for delivery expenses in rare and unusual circumstances in order to meet the needs of beneficiaries living remote areas that are not served by a local supplier.

Comment: Some commenters recommended a 4 year phase-in of the adjusted fees by payment amounts or regions so suppliers have time to adjust to the change in payment amounts.

Response: We agree that phasing in the adjustments to the payment amounts would allow time for suppliers to adjust to the new payment rates and would allow time to monitor the impact of the change in payment rates on access to items and services; however, we do not believe that a phase in period of 4 years is necessary. We believe that time frame is excessive. Therefore, we are finalizing a phase in of 6 months, which we believe provides suppliers with an adequate amount of time to make adjustments to their businesses in light of the reduced payment amounts and is more than enough time to determine if the payment amounts are impacting access to items and services in any part of the country. CMS will monitor access and health outcomes using real time claims data and analysis. Therefore, in this final rule at § 414.210(g)(9), we finalizing the adjustments to the fee schedule amounts for use in paying claims with dates of service from January 1 2016, thru June 30, 2016, based on 50 percent of the un-adjusted fee schedule amount and 50 percent of the adjusted fee schedule amount. For example, if the fee schedule amount that would have gone into effect on January 1, 2016, without any adjustments would have been $100.00, and the amount resulting from the methodology established in this

rule would have been $75.00, the fee schedule amount taking effect on January 1, 2016, will be $87.50. Beginning on July 1, 2016, the fully adjusted fees will apply.

Comment: Many commenters urged CMS to monitor patient access, utilization, and satisfaction levels after the implementation of the adjusted fees. Commenters also recommended adding a methodology to adjust prices if access problems develop.

Response: We concur with the recommendation to closely monitor the impact of the reductions in payment on access to items and services and health outcomes. We do not believe that the reductions in payment will negatively impact access to items and services, so we do not find it necessary to adopt an additional methodology to account for access problems; however, we can address the matter in future rulemaking, if necessary.

After consideration of the public comments, and for the reasons we discussed in the proposed rule and above, we are finalizing the proposed provisions summarized above and in the proposed rule (79 FR 40208), with the exception of the proposed definitions for rural state and frontier state and the proposed provision to use the national ceiling or 110 percent of the average of the RSPAs as a payment floor for adjusting the fee schedule amounts for these states. We are finalizing a definition of rural area and revising the definition of "Region" as described above at § 414.02. We are finalizing the proposed § 414.210(a) and (g), except we have amended 42 CFR 414.210(g) to note the application of competitive bidding information and limitation of inherent reasonableness authority, and the payment adjustments for areas within and outside the contiguous United States using information from CBPs.

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 proposed 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 (79 FR 40285). 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 proposed 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.

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 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 proposed 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 proposed 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 proposed 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 9 Round 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 proposed 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 9 Round 1 areas where CBPs are implemented (79 FR 40285). 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 109 CBAs means that suppliers submitting bids for wheelchairs have 2,725 bid amounts to develop and enter for these low volume items, if biding 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 proposed 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 (79 FR 40286). 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. The comments and our responses are set forth below.

Comment: Several commenters suggested that in the instances where the items and services included in limited number of CBPs, the adjusted fee schedule amounts for rural, frontier and non-contiguous areas should be greater than 110 percent of the average of the SPAs because the commenters believe that the cost of furnishing DMEPOS items in these areas are more than 10 percent higher than the cost of furnishing DMEPOS items in the CBAs. The commenters suggested using greater than 110 percent of the average of the SPAs to adjust the fee schedule amounts for rural, frontier, and non-contiguous areas.

Response: We disagree with this comment because we do not have direct evidence that the cost of furnishing DMEPOS items in rural, frontier, or non-contiguous areas is greater than the costs of furnishing the items in CBAs. In some cases, the cost of furnishing DMEPOS items in the CBAs may be greater than the costs of furnishing the items in rural, frontier, or non-contiguous areas, but we have no direct evidence of this either. Our proposal struck a balance by using 110 percent of the average of the SPAs rather than 100 percent of the average of the SPAs to account for the possibility that there may be slightly higher costs for furnishing items and services in certain areas than the cost of furnishing the items in the CBAs. Absent additional evidence, we believe that paying more than 110 percent of the average of the SPAs for the CBAs is not appropriate. However, we can consider making changes in the future if new information is made available.

Comment: Some commenters stated that that items that were excluded from CBP after initially being in the program should be excluded from the adjustment of fees One commenter argued that the SPAs for items only included in CBPs during the Round 1 Rebid are no longer

reflective of the true and current cost of the items. Also, one commenter argued that if CMS included items in CBPs and then decides not to include the items in subsequent CBPs, this is an indication that CMS believes the items are not well-suited for competitive bidding.
Other commenters stated that data from less than 10 CBPs is not enough data to determine what the payment amounts should be for the items on a national basis.

Response: We disagree with these comments. We believe that SPAs based on supplier bids from CBPs established in recent years are far more reflective of the true and current cost of the items than fee schedule amounts based on supplier charges from 1986 and/or 1987. There may be reasons why items are not included in subsequent CBPs, such as the fact that the item is a low volume item such as one of the hundreds of HCPCS codes for wheelchair options and accessories that is not included in subsequent CBPs to reduce the burden and cost of suppliers submitting bids for a product category (for example, wheelchairs) that already includes over a hundred higher volume items (HCPCS codes). It does not mean that CMS believes that the item is not suitable for competitive bidding. We believe that recent data from less than 10 CBPs is enough data to determine what the payment amounts should be for the items on a national basis, especially for those items that are furnished on a limited basis to a small number of beneficiaries throughout the United States yet are items for which implementation of CBPs or adjustments to payment amounts using information from CBPs is mandated by the statute. Using pricing from 10 or fewer CBPs allows for implementation of the statutory requirement to implement competitive bidding for the item.

After consideration of the public comments, we are finalizing the rule in § 414.210(g)(3) to include payment adjustments for items and services included in no more than ten competitive bidding programs reduced to 110 percent of the unweighted average of the single payment

amounts. We added technical changes to the final regulation text from the proposed regulation text by adding the term "ten or fewer" for added clarification. We are also finalizing the rule in § 414.210(g)(4) for payment adjustments using data on items and services included in competitive bidding programs no longer in effect and specify that we will be updating the payment amounts prior to adjusting the fee schedule amounts as described above.

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 proposed (79 FR 40286) 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 sought 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 proposed 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 proposed methodology, national allowed services would be used to compute a weighted average of the SPAs for code Exxx1 in each of the CBAs. So, rather than having 2 different SPAs for the same HCPCS 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 proposed to use the SPAs for the item from that PC in applying the payment adjustment methodologies proposed above (79 FR 40287). The comments and our responses are set forth below.

Comment: Several commenters argued that accessories used with different base equipment have higher service costs. They pointed out cases where CMS established different SPAs for the same accessories when used with different base equipment included in different PCs. The commenters do not believe that SPAs established for a HCPCS code describing an accessory used with one type of base item (for example, standard power wheelchair) should be used to adjust the fee schedule amounts for the HCPCS code that would govern payment for the accessory when it is used with a different type of base item (for example, complex rehabilitative power wheelchair).

Response: We disagree. We believe that using the weighted average of the SPAs established for accessories used with different base equipment takes into account any difference in the cost of furnishing the accessories with different types of base equipment in setting the overall rate for the accessories. We believe it is administratively burdensome and unnecessary to have more than one fee for the same item.

Comment: Some commenters suggested that composite bids and items weights make some accessories under-bid when they have a low weight relative to other items in the PC or

relative to the same item in a different PC. For example, a HCPCS code describing a wheelchair accessory included in two different PCs, one for power wheelchairs and one for manual wheelchairs might be underbid in one PC if the item weight for the item is very low relative to the item weight for the item in the other PC. The commenter argued that, creating a weighted payment amount from the SPAs for the item from the manual and power wheelchair PCs distorts the true cost of the item if the item was under-bid in one PC because it had a low weight.

Response: We disagree. Suppliers are required to submit a bona fide bid for every item in every product category and the bids are screened to ensure that they are all bona fide. In addition, we believe that the costs of the accessories described by a single HCPCS code do not vary depending on what type of base equipment the item is used with. To the extent that the costs do vary, combining the SPAs for the accessories from different product categories results in payment amounts that reflect the average costs of the accessory when used in conjunction with various types of base equipment. If an item was underbid due to its low volume, that bid would not be considered for a contract.

After consideration of the public comments, we are finalizing the rule as proposed in § 414.210(g)(5) for adjusted payment amounts for accessories used with different types of base equipment, when 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 based on the total number of allowed services for the item on a national basis for the code from each product category prior to applying the payment adjustment methodologies under the section. We also made an additional change to the regulation from the proposed rule for added clarification by specifying that "the total number of allowed services for the item on a national basis for the code from each product category" is completed "prior to applying the payment

adjustment methodologies under the section."

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). 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 product category (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. In the proposed rule (79 FR 40287), we identified the case where unbalanced bidding resulted in higher SPAs for enteral infusion pumps without alarms than enteral infusion pumps with alarms, even though pumps without alarms have become virtually obsolete. In this case, the alarm is the hierarchal feature. Only 0.3 percent of beneficiaries using enteral infusion pumps received a pump without an alarm in 2012 according to Medicare claims data. Clearly, separately identifying pumps with alarms and pumps without alarms is no longer necessary, yet the codes for both types were included in the CBPs, resulting in a case of unbalanced bidding that could have been avoided if only one code for enteral infusion pumps existed. Likewise, in 2006, codes were added for portable power wheelchairs and power wheelchairs with less functionality (Group 1) than those commonly used by beneficiaries (Group 2). All of the codes for standard power wheelchairs meet the same needs for power wheelchairs used in the patient's home. The features of being more expensive, sturdier non-portable power wheelchairs or higher performing power wheelchairs are the hierarchal features for the standard

power wheelchairs. Although the codes for portable power wheelchairs and Group 1 power wheelchairs were added in order to provide a less expensive alternative for power wheelchairs used in the home, beneficiaries did not take advantage of the lower priced, alternative equipment. Only 0.9 percent of beneficiaries using standard power wheelchairs received a portable or Group 1 power wheelchair in 2012 according to Medicare claims data. The goal of creating savings for beneficiaries by having codes for economy power wheelchairs did not materialize, yet the codes for these types of power wheelchairs were included in the CBPs, resulting in a case of unbalanced bidding that could have been avoided if the codes for the economy power wheelchairs did not exist. 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 proposed 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 (79 FR 40287). We sought public comments on this issue and our proposed provision to address this issue. The comments and our responses are set forth below.

Comment: A commenter suggested that "hierarchal feature" be better defined. Another commenter suggested that weighing based on utilization rates ignores whether there were supply issues that affected the utilization rates. One commenter also suggested that balanced bidding does not reflect SPA cost differences based on the features of equipment.

Response: We agree that hierarchal features should be clearly identified for the purpose of implementing the proposed rule. We will limit the final policy by identifying two specific scenarios where the hierarchal features involved are additional features or features with

additional functionality. In the future, we will either add other scenarios or develop a definition of "hierarchal features." Therefore, the final policy will only apply to the specific cases of unbalanced bidding that were identified in the proposed rule that clearly show that certain equipment has features that exceed that of other equipment.

After consideration of the public comments, we will limit the final policy by identifying two specific scenarios where the hierarchal features involved are additional features or features with additional functionality. In the future, we will either add other scenarios or develop a way to define "hierarchal features" in general, or in a way that would identify various scenarios, which we expect to address in future rulemaking. Therefore, the final policy will only apply to the specific cases of unbalanced bidding that were identified in the proposed rule (79 FR 40287) that clearly show that certain equipment has features that exceed that of other equipment. Specifically, we are adding § 414.210(g)(6) and requiring that adjusted fee schedule amounts for Group 1 power wheelchairs or Group 2 portable power wheelchairs cannot exceed the adjusted fee schedule amounts for Group 2, non-portable power wheelchairs in order to avoid situations where Medicare allowed payment amounts for power wheelchairs with less functionality are established that are higher than fee schedule amounts for power wheelchairs with more functionality. We are also finalizing a rule at § 414.210(g)(6) that adjusted fee schedule amounts for enteral infusion pumps without alarm cannot exceed the adjusted fee schedule amounts for enteral infusion pumps with alarm. We believe that wheelchairs that can go farther, faster, can climb over higher obstacles, or are not portable and more sturdy have features that exceed wheelchairs that travel shorter distances, go slower, climb over lower obstacles, or are portable and less sturdy. Payment amounts for shorter distance, slower, smaller obstacle climbing, less sturdy, power wheelchairs should not be higher than the payment amounts for longer distance,

faster, higher obstacle climbing, sturdy, power wheelchairs. An enteral feeding pump with a safety alarm includes additional features than a pump without such an alarm. Payment amounts for enteral feeding infusion pumps without an alarm should not be higher than the payment amounts for pumps with an alarm. We will consider whether to add a definition of hierarchal feature, or to apply the rule we proposed to other items not identified above through future notice and comment rulemaking.

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 proposed 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 (79 FR 40287). We proposed that the adjusted fee schedule amounts would be equal to 100 percent of the amounts established under the national mail order CBP (79 FR 40287).

We solicited comments on these proposals. The comments and our responses are set forth below.

Comment: A few commenters recommended waiting for the second round of bidding for the national mail-order CBP before applying the payment amount in order to allow more time to determine if the competitive bidding payment amounts allow access to items and services and acquire more pricing points over an extended period of time. They further recommended increasing payment amounts for the national mail order SPA for the Northern Mariana Islands to

limit any access or pricing complications.

Response: We disagree with these suggestions. The national mail order SPAs currently apply to items shipped to various remote areas of the United States and have not resulted in any problems with access to mail order items in these areas. Therefore, we believe these amounts can be used to adjust the mail order fee schedule amounts for the Northern Mariana Islands effective January 1, 2016.

After consideration of the public comments and for the reasons we previously articulated, we are finalizing the proposal regarding the National Mail Order Program and the Northern Mariana Islands at § 414.210 (7) to provide that the fee schedule amounts for mail order items furnished 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 program.

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 proposed 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 (79 FR 40287). 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 proposed 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 proposed to use these SPAs to adjust payment amounts using the methodologies described above and we proposed to do so following application of inflation adjustment factors. We proposed 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 (79 FR 40288).

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 total payments made to contract suppliers in the CBA are expected to be 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. 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 (79 FR 40288).

We solicited comments on these proposals. The comments and our responses are set forth below.

Comment: Some commenters suggested updating adjusted fees yearly with CPI-U and not freeze it for 3 years until the next.

Response: We disagree. Contracts and SPAs are replaced at least once every 3 years, following one or more new competitions and as other items are added to programs established under Subpart F of this part, and increased costs in doing business are factored into the bids with each new competition. In addition, suppliers submitting bids under the CBPs are educated that their bids will be used in establishing SPAs that will be in effect for the entire duration of the contract period. Therefore, we believe that suppliers take increased costs and prices into account when developing their bids. In addition, because section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under a CBP if the total amounts paid to contract suppliers are expected to be more than the total amounts that would otherwise be paid, we believe that the intent of competitive bidding is to product a reduction in payment amounts rather than an increase in payment amounts. In lieu of establishing a CBP in an area, the authorities under the statute for adjusting fee schedule amounts based on information from CBPs must be used; however, in no case should it result in an increase in the amounts that would otherwise be paid. If an inflation adjustment factor is applied to fee schedule amounts that are adjusted by the methodologies we are adopting in this final rule, it could result in an amount that is greater than the fee schedule amount that would otherwise be paid, and we believe that this is contrary to the intent of the statute.

After consideration of the public comments, for the reasons we set forth above, we are finalizing the proposals and are adding § 414.210(g)(8) to indicate that adjusted fee schedule

amounts are revised each time an SPA 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.

Table 32 provides a summary of the final methodologies intended to achieve savings by adjusting fee schedule amounts using information from CBPs. With regard to all methodologies in this final rule that are intended to achieve savings by adjusting fee schedule amounts using information from CBPs, we are adding a provision specifying that in any case where application of these methodologies results in an increase in the fee schedule amount, the adjustment to the fee schedule amount is not made.

TABLE 32 - Summary of Final Methodologies for Adjusting Payment in Non-Bid Areas

Proposed Methodology	**Calculations**
1) Adjustments for Items Included in More than 10 CBAs*	
(a) 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 average of the RSPAs calculated for each of the 48 contiguous states and District of Columbia (national average RSPA).
(b) Adjustments for Rural Areas	-Adjusted payment for areas designated as rural areas based on 110 percent of the national average RSPA
(c) 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 average RSPA 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.

Proposed Methodology	Calculations
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	
(a) 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)
(b) 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)
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

VI. Final 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 continuous positive airway pressure (CPAP)

devices.

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 (Public Law 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 explained in more detail below, we proposed to revise the regulation by adding a new section at 42 CFR 414.409 with special payment rules to replace existing payment rules at § 414.408 for certain items and services in no more than 12 CBPs where these rules are applied. We also proposed to revise § 414.412 to address the submission of bids for furnishing items and services paid in accordance with these proposed special payment rules.

B. Summary of the Proposed Provisions and Responses to Comments on the Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished under the Competitive Bidding Program

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

We proposed to update the regulations to include proposed special payment rules for paying claims for certain DME or enteral nutrition under a limited number of CBPs. We proposed 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 CBPs where the special rules are applied. We also proposed to revise § 414.412 regarding submission of bids for furnishing items and services paid in accordance with these special payment rules.

We believe that alternative payment models for certain DME and enteral nutrition may

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. We sought comments on these proposals.

We proposed (79 FR 40291 through 40292) to phase-in the special payment rules described in sections VI.B.1 and VI.B.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, quality of care, and access to items and services. In order to monitor the impact of phasing in the special payment rules in no more than 12 CBAs, we proposed 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 proposed 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 proposed 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 proposed 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 proposed to analyze the effect of the proposed payment rules on beneficiary cost sharing.

We proposed 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 proposed 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.

We proposed 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 proposed 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 proposed 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 requested 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.

The Affordable Care Act (Patient Protection and Affordable Care Act of 2010, P.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. We solicited 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 proposed to undertake rigorous evaluation to determine the rules' effects on program costs, quality, and access.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

We received 28 public comments on this proposal from manufacturers, DMEPOS suppliers, coalitions, and beneficiaries. The comments and our responses are set forth below.

1. Payment on a continuous rental basis for select items

Under our general authority under section 1847(a) and (b) of the Act to establish payment rules for DME and enteral nutrition equipment, we proposed (79 FR 40292) 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 (RADs), and hospital beds. We proposed 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 proposed 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.

Comment: Several commenters indicated that CMS does not have the authority to use bundled payments under the CBP.

Response: We do not agree with this comment. The existing payment rules under section 1834 of the Act govern DMEPOS paid under the various fee schedules and do not directly apply to the CBP; therefore, CMS is not explicitly required to apply such rules to the CBP. Section 1847 of the Act mandates the implementation of CBPs throughout the United States for the purpose of awarding contracts for furnishing competitively priced items and services described under section 1847(a)(2) of the Act. As discussed in the proposed rule (79 FR 40290), we believe we have broad authority under section 1847 to establish payment rules for the CBP. In particular, consistent with section 1847(a)(6), the general payment rules for the CBPs are governed by section 1847(b) which mandates payment based on bids submitted and accepted by Medicare for the competitively priced items and services. Therefore, we believe that we have discretion to establish rules on whether covered items are paid for on a purchase or rental basis as long as total payments to contract suppliers are expected to be less than the total amounts that

would otherwise be paid.

Comment: Several commenters felt that CMS has not demonstrated that a CBP that includes bundling meets the criteria for a demonstration under the CMMI.

Response: We thank the commenters for their comments. If a decision is made to use CMMI demonstration authority to implement and evaluate payment on a bundled, continuous rental basis for DME and/or enteral nutrition, it would only be after CMMI has determined that a particular payment model meets the criteria established for such a demonstration.

Comment: Many commenters expressed concerns that monthly bundled payments for DME and enteral nutrition would reduce quality and access to care. For example, they believe that if separate payments are not made for certain items, such as the ongoing replacement of CPAP accessories, contract suppliers will not have an incentive to replace the items when they need to be replaced. Other commenters suggested that specific parameters or guidelines for replacement of such items, such as the usual maximum number of accessories needed as provided in DME MAC local coverage policies, be established under the programs. Commenters were particularly vocal about the fact that these rules should not be phased in for enteral nutrition and that enteral nutrition is not a suitable product category for bundled monthly payments.

Response: We do not agree. The rules are not being phased-in in limited areas due to concerns that suppliers contracted to provide items and services under these rules will not provide those items and services. The rules are being phased in to gauge whether rental caps are necessary in order to save money for items used on a longer term basis and whether the rules can address problems associated with repair of beneficiary-owned equipment. Suppliers awarded contracts under the programs must be in compliance with DMEPOS quality standards and

supplier standards in order to remain a contract supplier and in order to continue to be an enrolled DMEPOS supplier under Medicare. As always, we will closely monitor contract suppliers and real time claims data and health outcomes data to ensure that suppliers are in compliance with the standards. Guidelines for the usual maximum amount of accessories expected to be medically necessary have already been established under local DME MAC policies, and suppliers will be educated to take the cost of replacing these accessories into account when establishing their bids. Suppliers submitting bids under the program will be educated that they cannot receive payment for furnishing DME without furnishing everything the patient needs each and every month they continue to need and use the equipment. As stated in the proposed rule, the impact of the rules on program expenditures, beneficiary cost sharing, access to items and services, and quality of care will be closely monitored and compared to impacts under comparator areas. However, in light of concerns regarding the impact of the rules on access to quality items and services, we are further limiting the scope of the phase in to CPAP devices and standard power wheelchairs, and we are not finalizing the remaining categories of items at this time. These two categories of items generate the greatest amount of separate payments for accessories and repair compared to enteral nutrition or any other category of DME described in section 1847(a)(2) of the Act.

We will apply a focused and intense monitoring program to these two categories of items to evaluate quality of care and access to items and services, including specific accessories prescribed for beneficiaries under the programs to these two categories. Using real time claims analysis and health outcomes data, we will quickly identify potential problems and take action to ensure that contract suppliers are providing access to quality items and services under the programs. We believe these two DME categories will provide sufficient information in order to

determine the overall effect of the special payment rules on program and beneficiary costs, quality, and access to items and services.

Comment: Some commenters supported bundling for enteral nutrition. They noted that the beneficiary would not be responsible for maintaining the pump and temporary cessation of therapy would not occur while the pump is being repaired if it is not owned. Other commenters believed that bundled payment for enteral nutrition would be beneficial for short term nutritional therapy because the patient would no longer own a pump that is not needed. However, other commenters argued that CMS should exclude enteral nutrition from the bundled initiative because of the wide variation in cost of the enteral nutrients. Some commenters recommended establishing a monthly rental bundled payment based upon mode of delivery. Other commenters recommended establishing a separate bundled payment amount that would only cover the supplies and equipment used for each mode of delivery (syringe, gravity and pump) and would exclude enteral formulas from the bundle because of wide variation in cost and treatment.

Response: We thank the commenters for their support and input. After careful consideration of the comments received on this topic, we will not be finalizing the proposal to phase in bundled, continuous monthly rental payment for enteral nutrition at this time.

Comment: One commenter made suggestions for calculating the bundled payment rates for oxygen and oxygen equipment.

Response: We thank the commenter for their input. We will not be finalizing the proposal to phase in bundled, continuous monthly rental payment for oxygen at this time.

Comment: Many commenters opposed bundling monthly payment for all standard manual wheelchair bases with accessories or all standard power wheelchair bases with accessories or all standard and power wheelchair bases with accessories because they feel the

different types are wheelchair bases are unique and should not be bundled together. Some recommended a bundled bid approach for standard manual or standard power wheelchairs and only those accessory items that are tied to the same medical necessity as the wheelchair. Some suggested bundling only 3 codes or 6 accessory codes with each base code for wheelchairs based on utilization in order to simplify billing. Some suggested excluding repair and replacement items from the bundle. Commenters believed that bundling of multiple HCPCS codes into a single code for payment will further decrease access and quality of products and services and is complex. The commenters believes that a single bid code cannot accommodate the characteristics of the various technologies and varying manufacturing costs for standard manual or power wheelchairs. The commenters believe that there will be no mechanism to track utilization to ensure the beneficiaries still have access to the range of medically necessary technology. If base codes are combined then distinguishing coverage policies that reflect the medical and functional needs of beneficiaries cannot be developed. It provides a disincentive to suppliers to avoid high risk or complex beneficiaries and decreases beneficiary choices.

Response: We will not be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for standard manual wheelchairs at this time. The specific power wheelchair items and HCPCS codes included in competitions where special payment rules are applied will be announced to suppliers and beneficiaries in advance of the competitions with an explanation of why wheelchair bases are bundled together to the extent that they are under the competition.

Comment: Many commenters were opposed to applying bundled monthly continuous rental payment rules to CPAP devices and RADs. Some commenters recommended enforcing the current replacement schedule for CPAP and RAD accessories as outlined in DME MAC local

coverage policies under the CBPs that utilize the special payment rules. Other commenters stressed that the CPAP supply replacement schedules should be factored into the development of any bundled payment data and should be used to determine bundles and their respective amounts. In addition, commenters were concerned that bundling of CPAP removes all ability of CMS and providers to ensure that beneficiaries receive medically necessary equipment because they will not see claims for the items to know how often they are being replaced. For CPAP, some commenters urged CMS to craft policies integral to bundling such as a minimum service/contract level requirement for the provider to maintain with the beneficiary. Some commenters suggested that we require suppliers to check in on supply requirements with the beneficiaries.

Response: After consideration of the public comments we received, we will not be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for respiratory assist devices. But we will be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for CPAP devices. We note that Medicare paid on a bundled, continuous monthly rental basis for CPAP devices under the fee schedules from 1989 thru 1993 and did not encounter any problems related to access to necessary items and services during this time. The tables in the DME MAC local coverage policies listing the usual maximum amount of CPAP accessories expected to be reasonable and necessary are not tables that indicate how often these items need to be replaced. They represent how often claims for the accessories would be paid without the need to have additional medical documentation in the patient's record. They can be used as guidelines for the usual maximum amount that are typically needed, but under a bundled, continuous rental payment method for CPAP devices, the supplier would be expected to replace the accessories as often as necessary for the effective use

of the CPAP device. If the usual number of masks needed is once every 6 months, the masks may need to be replaced less often in the case of some beneficiaries and more often than once every 6 months in the case of other beneficiaries. In any case where a replacement of an accessory is needed during a month, the contract supplier would be responsible for furnishing the necessary accessory, just as they would be responsible for repairing rented equipment whenever necessary. We will closely monitor contract suppliers to ensure that they are doing so.

Comment: Two commenters opposed our proposal that the bids submitted for furnishing CPAP devices on a bundled, continuous monthly rental basis 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. The commenters contended that equipment features developed since the establishment of the base year fees, such as a heated humidifier, would not be encompassed in the bid limits and instead suggested using a more recent base period for these items. Other commenters noted that the proposal to set bid limits for CPAP to 1993 fee schedule is inconsistent with the proposed methodology for the other bundled product categories which would use recent expenditures per beneficiary.

Response: We do not agree with these comments. Historical bundled, monthly rental fee schedule amounts are available for CPAP devices and reflect a bundled monthly rental payment that was previously mandated and established for these items under the Medicare program. We believe that separate payment for CPAP accessories has led to overutilization of the accessories based on complaints received from beneficiaries over the years about suppliers shipping unnecessary quantities of accessories. Therefore, we believe that the average payment per beneficiary for equipment and accessories could result in a bid limit that is artificially high when compared to historic Medicare bundled monthly rental fees for CPAP devices that were in place

for 5 years and did not result in any problems with access to necessary items and services. The 1993 fee schedule amounts for CPAP devices are based on historic reasonable charges that are representative of payment made to a supplier for furnishing these items on a bundled, continuous rental basis over a period of 5 years. The application of the covered item updates for DME in general, in section 1834(a)(14) of the Act, account for changes in the costs of furnishing covered items and services. Historic continuous bundled fee schedule amounts are not available to use to set the bid limit for the standard power wheelchair bundled category, therefore, current expenditure data would be used to set bid limits for the standard power wheelchair product category.

Comment: Many commenters believed that continuous monthly rental payments for DME would increase the financial burden of the beneficiaries because instead of being limited to paying coinsurance for no more than 13 months of continuous use, they would be required to make coinsurance payments for as long as they use the equipment.

Response: Our analysis strongly suggests that the benefits associated with paying on a continuous monthly rental basis outweigh the potential of increased copayments for the beneficiary. For items that are paid on a capped rental basis where title to the item transfers to the beneficiary after conclusion of the 13-month rental period, beneficiaries are responsible for maintaining and repairing the item after title transfer. Under the special payment rules that provide for payment on a continuous rental basis, beneficiaries will no longer be responsible for repair and maintenance of equipment because they will not own the equipment. The supplier will retain the title to the equipment and will be responsible for repair and maintenance. Although beneficiaries who use a CPAP device or power wheelchair for more than 13 months of continuous use will pay coinsurance payments for additional rental months beyond 13 months of

continuous use, the monthly payments include payment for ongoing costs such as replacement of accessories and repair and maintenance of equipment, which are also ongoing costs that exist under the current capped rental payment methodology. The cost of furnishing items and services is the same regardless of whether payment is made on a capped rental basis for equipment with separate payment for accessories, maintenance and servicing or on a bundled, continuous rental basis.

Most importantly, the statute prohibits the awarding of contracts under a CBP if the total payments to contract suppliers under the CBP are expected to be more than what would otherwise be paid and we would confirm that this requirement is met prior to implementing prices established under these special payment rules.

Comment: Some commenters were concerned that beneficiaries would not have the choice of opting out of the program although they would be notified about the alternative payment initiative.

Response: We proposed to phase-in the special payment rules because we believe they will have a positive impact on beneficiary access to quality equipment that continues to remain in good working order, while lowering the administrative costs of the program, and eliminating the need for beneficiaries to locate suppliers willing to repair equipment they own. In order to receive payment for equipment subject to this program, beneficiaries do not have the option to opt out. The programs will be closely monitored.

Comment: Most commenters were supportive of phasing in or testing the continuous rental bundled payment methodology on select products in limited areas. Some stakeholders suggested that bundled payment should be pilot tested first with a small subset of items and exclude complex items. Many commenters agreed that bundling will simplify complex

administration procedures.

Response: We agree with commenters that a phase-in limited to only a few select categories would be the best way to evaluate the impact of the special payment rules at this time. As such, we are not finalizing bundled, continuous payment rules for the following categories of items: enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, respiratory assist devices and hospital beds. The special payment rules would only be phased in initially for the following categories of DME items: CPAP devices and standard power wheelchairs. We selected the category of CPAP devices because we believe the cost of paying separately for the expensive accessories used with these devices exceeds the amount of savings achieved from capping the rental payments for the equipment. We selected the category of power wheelchairs because we believe that payment on a separate, piecemeal basis for hundreds of various power wheelchair options and accessories is unnecessary and overly complex. In addition, power wheelchairs are the most frequently repaired DME item and we believe that phasing in payment on a continuous monthly rental basis would ensure access to power wheelchairs that are in good working order. As discussed in our proposal (79 FR 40291), the CBPs would be phased in as early as 2017, and would be closely monitored. Subsequent rulemaking would be necessary to adopt special payment rules for other items or in more than 12 CBAs.

Comment: Some commenters recommended a bundled bid approach comprised of products associated with a single medical necessity or single coverage and payment policy. Some suggested accessories that are included in a bundle with the base equipment must be tied to the same medical necessity as the base equipment. One commenter suggested that beneficiaries meeting medical necessity for a support surface may also meet the medical necessity for a hospital bed; however, support surfaces and hospital beds should never be included in the same

bundle.

Response: These are issues that would be addressed in Medicare program guidance.

Comment: Some commenters were concerned that CMS has not provided information about how the Agency will administer a bundled bid program so the lack of information violates the Administrative Procedure Act (APA). The commenter's claim the proposed rule only gives general outline of the bundling program but does not explain what makes up a bundle, how bids will be evaluated or pivotal bids will be selected to establish payment amounts. These commenters stated that CMS must publish a new proposed rule soliciting comments on the elements of the biding program.

Response: We disagree. We have issued rules concerning the general dictates of the CBP and this competition would be consistent with those rules. We would evaluate suppliers and bids consistent with those provisions except that the bids and the SPAs established based on those bids would be for the monthly rental of DME and all items and services necessary for the effective use of the DME (that is, all related supplies, accessories, maintenance and servicing, etc.). Bids would not be submitted for purchase of any item or for separate payment for accessories used with base DME items. Under the existing CBP, CMS specifies certain parameters, but then through the Request for Bids (RFB) and competitive bidding process, further addresses certain details. Similar to other CBPs that do not employ the special payment rules, we intend to conduct extensive education outreach programs prior to implementing competitions that apply the bundled continuous rental methodology so that suppliers are educated about the rules and understand what is required of the bidding suppliers. This includes advance notice of bidding and comparator areas and defining the bundled categories. We believe that our proposed rules were sufficiently detailed to enable the public to provide meaningful

comments on them.

Comment: Many commenters urged CMS to share the bundled bidding methodology with stakeholders and establish quality metrics before beginning the program. Some commenters suggested that to facilitate accurate bidding CMS must give suppliers per patient utilization and expenditures data by HCPCS codes. Some commenters argued that CMS states in the proposed rule that it will monitor and evaluate the quality and success of bundled payments but no metrics have been determined or shared by CMS. Some suggested that submitted claims data versus paid claims data must be used. Those commenters stated that bid limits must take into account all repairs, accessories, and rental payments divided by number of patients to create a monthly per patient allowable. Commenters stated that bids must include only patients with active rental periods in calculating the bid limit. Commenters also stated that CMS must identify the data parameters from which it will take data. Many commenters recommended that CMS establish quality metrics before implementing the bundled payment. Some commenters recommended providing safeguards for Medicare beneficiaries, setting proper expectations with providers and evaluating the feasibility of the bundled payment methodology by creating methods to identify beneficiaries not identified in claims data, establishing minimum standards of quality and quantity of services, tracking products provided to the beneficiaries furnished with equipment paid on a bundled continuous rental basis as compared to all other Medicare beneficiaries to ensure quality care is being provided and beneficiaries have access to most innovative products. Commenters suggested we conduct a long term longitudinal study to determine comorbidity costs and access to care with bundled payments.

Response: We thank the commenters for their input. Consistent with the current CBP monitoring and oversight, CMS will employ a wide range of monitoring techniques before

beginning any competition that applies the special payment rules. We will provide advance notice of the areas and comparator areas, defining bundles, verifying bona fide bids, and setting up monitoring techniques before beginning the competition. As we proposed in the proposed rule (79 FR 40291), in any competition where these final special payment rules are applied, we will provide advance notice of the rules at the time the competitions that utilize the rules are announced.

In order to monitor the impact of phasing in the special payment rules in the no more than 12 CBAs we are finalizing, we will 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 will at a minimum, 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 will monitor utilization trends for each product category and track beneficiary complaints related to access issues. To evaluate the cost of the program, we intend to 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 will also analyze the effect of the proposed payment rules on beneficiary cost by analyzing number of monthly rental payments made compared to reductions in coinsurance payments. Medicare has established quality standards, supplier standards, local medical review policies and other requirements that currently address furnishing medically necessary items and services, and CMS monitors whether these requirements have been met by suppliers, as applicable. Submitted charge data is not used to establish Medicare allowed payment amounts and therefore would not

be a good bid limit or a limit used to ensure that payments under the programs are less than what would otherwise be paid.

Comment: Some commenters argued that CMS did not provide information on how bids will be evaluated, what constitutes a bundle or how the pivotal bid will be selected to establish payment amounts. Commenters also indicated that CMS did not identify CBAs and comparator areas. Commenters also stated that there is no baseline for what constitutes a bundle in a product category so suppliers will not know what to bid. Commenters raised concerns that CMS has no way to compare bids because there is no consensus on what it takes to service patients who receive the bundle. Without an assessment tool and a baseline tool, those commenters believe that CMS has no way of comparing bids, or determining pivotal bids or verifying bona fide bids because there is no consensus on what is in the bundle or the intensity of the services patients who receive the bundle need. It would be difficult for suppliers to determine the appropriate amount to bid under a bundled payment method because there are many factors that would influence the cost associated with supplies, maintenance and repairs. Some expressed concerns about supplier challenges in determining the appropriate amount to bid because of factors such as case mix, variable cost of different types of base equipment and accessories and the variable cost associated with supplies, maintenance, repairs and frequency of replacement parts. Suppliers will have to guess the type of equipment and frequency of services different patients may need. Under a bundled bid, commenters were concerned that CMS will not be able to track utilization patterns that could be harmful to the beneficiaries.

Response: We thank the commenters for their input. Although specific CBAs were not identified in the proposed rule, we will be identifying the areas and comparator areas, defining the bundles, and setting up monitoring techniques before beginning the competition as we have

done during the previous rounds. As we proposed in the proposed rule (79 FR 40291), in any competition where these final special payment rules are applied, we will provide advance notice of implementation at the time the competitions that utilize the rules are announced. This notice could take the form of the competitive bidding request for bids or a CMS web posting or programs instructions or listserv messages and would define the related products and services included in a category's single bundled grouping. The process for setting the SPA and determining the pivotal bid in competitions where the special payment rules are applied would follow the existing process that is in place for a product category and outlined in sections 42 CFR 414.414 and 414.416 of our regulations.

Using the CPAP and standard power wheelchair bid limits, which we will announce in advance of the competitions and calculate, consistent with what we proposed in the proposed rule (79 FR 40291) and are finalized in this rule, as well as past CBA utilization data for these bundled items, we believe bidding suppliers can use their experience in furnishing these items to develop a monthly bundled rental bid that would be reflective of their costs and profit for all items identified in the bundle. In competitions where the single bundled bid rules apply, CMS would continue to employ the wide range of resources used to monitor the CBP including use of real-time claims analysis to monitor the health outcomes status of groups in CBAs. Suppliers are responsible for providing all items and services to beneficiaries in accordance with the orders of their physicians. This responsibility does not change depending on whether one payment is made for the monthly rental of DME and all related supplies, accessories, and services or whether piece meal payments are made for each individual item or service. For example, a supplier furnishes a CPAP device and accessories in accordance with the physician's order and replaces the accessories and services the rented equipment for up to 13 months of continuous use

for individual beneficiaries.

As stated in the proposed rule, the impact of the rules on program expenditures, beneficiary cost sharing, access to items and services, and quality of care will be closely monitored and compared to impacts under comparator areas. To evaluate the quality of care for beneficiaries affected by the special payment rules, we will at a minimum, 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 will monitor utilization trends for each product category and track beneficiary complaints related to access issues. To evaluate the cost of the program, we intend to 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 will also analyze the effect of the proposed payment rules on beneficiary cost by analyzing number of monthly rental payments made compared to reductions in coinsurance payments.

Comment: Some commenters contended that payment on a continuous rental basis for select bundled items instead of on a capped rental basis would result in additional administrative burden for suppliers because they would have to submit more than 13 claims for rental of equipment to a beneficiary. Commenters reacted unfavorably to repeated billings for monthly rental claims for as long as the item is medically necessary.

Response: While suppliers may need to submit additional claims for the monthly rental of CPAP devices and power wheelchairs, they would no longer have to submit separate claims for accessories and repairs and would no longer have to keep track of periods of continuous use or when a rental cap is approaching. In addition, suppliers would no longer have to transfer title

to equipment after 13 months of continuous use, and would therefore need to replace items in their inventory less often.

Comment: Numerous commenters requested a delay in the implementation of payment on a continuous rental basis for select bundled items. One commenter stated that more time is needed to educate practitioners, suppliers, and patients along with receipt of adequate program guidance. Several commenters stated CMS should convene advisory groups to study bundling payment methods and bidding factors. Another comment from a manufacturer's association requested CMS establish an additional HCPCS Advisory Panel to review and revise current HCPCS codes for improved bundling.

Response: The final rule does not set forth an exact timeframe for when the special payment rules will be implemented. CMS will be providing additional guidance and education, if needed.

Comment: Various commenters expressed concern that our proposal did not include a listing of existing HCPCS base codes along with HCPCS accessory codes that may comprise a bundled item code. As a result, several commenters submitted recommended coding bundles of existing HCPCS codes for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, power wheelchairs, CPAP, RADs, and hospital beds.

Response: CMS will follow the HCPCS coding process. We appreciate these comments and thank the commenters for their helpful suggestions for coding bundles. When further steps for implementing a continuous rental basis for select bundled items are developed, we will review the submitted information to ensure compliance with the Medicare coverage and coding guidelines. As noted in an earlier response, specific information on the items that comprise a bundled bid for the CPAP category or standard power wheelchairs category will be announced

well in advance of a competition that would use the continuous rental payment methodology.

Comment: Commenters stated that the proposed change in payment rules will be adopted by payers other than Medicare and therefore should not be adopted.

Response: Such issues are beyond the scope of this rulemaking and we have not taken such things into consideration when finalizing our policies for the Medicare program. We appreciate that changes in Medicare policy may affect other insurers who choose to base their payments on Medicare payment rules; however, it is our obligation to set our policies based upon the needs of Medicare and its beneficiaries.

Comment: One commenter asked for clarification on how CMS will establish coverage criteria for a bundle of HCPCS codes consisting of a base and all options and accessories including what data will be used to establish the coverage criteria that will identify whether or not a beneficiary qualifies for a bundle of equipment, services, and supplies.

Response: These comments are outside the scope of the proposed rule, and therefore are not addressed in this final rule. The process for reviewing coverage for an item or bundle of items is not addressed in this payment rule.

We received many additional comments that were out of the scope of this rule.

In this final rule we are finalizing our proposal for only two items, CPAP devices and standard power wheelchairs. This rule finalizes the phase-in of special payment rules for CPAP and power wheelchairs as noted previously in the proposed rule (79 FR 40293) under the DMEPOS CBP in no more than 12 CBAs at 42 CFR 414.408, 414.409, and 414.412.

Comment: Some commenters noted that making payments for DME on a bundled, continuous rental basis will not eliminate repair issues and will increase financial burden on the beneficiaries. Some commenters noted that the ability for a beneficiary to switch to another

provider should he/she feel the service is not appropriate would drive competition for better care but bundling would not eliminate the need for patients to requalify for equipment when they change suppliers. Beneficiaries would still need to re-establish medical necessity when changing suppliers. Some suggested allowing beneficiaries to switch suppliers without restarting documentation. Some commented that mandating suppliers repair will not solve beneficiary's inability to obtain repairs for beneficiary-owned equipment.

Response: Contract suppliers paid for furnishing DME paid for on a bundled, continuous rental basis would be responsible for all necessary repairs, maintenance and servicing needed to keep the rental equipment in good working order or for replacing rental equipment that no longer functions and cannot be repaired. The process for documenting medical necessity for items would be addressed outside the rulemaking process.

We proposed to revise the regulation at 42 CFR 414.409 to the 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 proposed to revise the regulation at 42 CFR 414.408 to provide a cross reference to proposed § 414.409. We proposed 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 proposed 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 proposed that non-contract suppliers in these cases would have the option to continue rental agreements; however, we proposed that as part of the process of allowing the rental agreements to continue, the grandfathered supplier would be paid based on existing rules at § 414.408. We solicited comments on this proposed process. We did not receive any specific comment for this section and therefore, for the reasons we discussed previously, we are finalizing the proposed transition rules. This rule finalizes the transition rules as noted previously in the proposed rule (79 FR 40293, 40294) under the DMEPOS CBP at 42 CFR 414.409.

2. Responsibility for repair of beneficiary-owned power wheelchairs furnished under CBPs

We proposed (79 FR 40294) 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. In these CBPs, we proposed 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 proposed 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 proposed that the contract supplier would not receive separate

payment for these services and would factor the costs of these services into their bids. We proposed that the contract supplier would not be responsible for repairing power wheelchairs they did not furnish. We proposed 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 sought comments on these proposals. The comments and our responses are set forth below.

Comment: Some commenters argued that adding a requirement specifying that contract suppliers are responsible for repairing power wheelchairs they furnish will not eliminate problems beneficiaries are experiencing related to obtaining repairs for beneficiary-owned equipment.

Response: We agree that this requirement would not address situations where a beneficiary owns a power wheelchair in need of repairs that they received prior to the start of the CBP or prior to moving into the CBA where the proposed rule would be in effect. It would also not address situations where a beneficiary owns a power wheelchair in need of repairs that they received prior to enrolling in Medicare part B. As stated in our proposal (79 FR 40294) we proposed that a contract supplier would not be responsible for repairing power wheelchairs they did not furnish. As a result, we proposed 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), which allows any Medicare enrolled DME supplier to perform this service and receive payment.

We also proposed 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 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 sought comments on these proposals, did not receive any specific comment for these proposals, and are therefore, for the reasons we discussed previously, we are finalizing these proposals. This rule finalizes the sections Beneficiary-Owned Equipment and Responsibility for Repair of Beneficiary-Owned Power Wheelchairs furnished under CBPs as noted previously in the proposed rule (79 FR 40294) under the DMEPOS CBP at 42 CFR 414.409

We proposed that the CBAs where the proposed rules in (79 FR 40294) 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 proposed that the boundaries of the CBAs would be established in accordance with the rules set forth at §§ 414.406 and 414.410. We proposed that additional CBPs for the items identified in sections 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 proposed 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 proposed 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 proposed 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 proposed 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 sought comments on this proposal, did not receive any specific comment for this proposal, and are therefore finalizing this proposal.

We proposed that 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). We sought comments on this proposal, did not receive any specific comment for this proposal, and are therefore finalizing this proposal.

We are finalizing a change to add special payment rules at §414.409 that will be phased in. In no more than 12 CBAs, payment is made on a bundled, continuous monthly rental basis for standard power wheelchairs and CPAP devices. In addition, in no more than 12 CBAs, payment for power wheelchairs is made on a continuous rental basis, for power wheelchairs furnished in conjunction with competitions that begin 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. In accordance with § 414.408(c), 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.

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 states that hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are excluded from Medicare coverage. 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 (CIs) 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 CIs 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 CIs 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. Additional changes, regarding coverage criteria, have been made to section 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 regulation at 42 CFR 419.66 was revised to add new requirements, effective January 1, 2006, for transitional pass-through payments for medical devices. The auditory osseointegrated implant (AOI) 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 AOI and auditory brainstem devices payable 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 received several benefit category determination requests in recent years for the consideration of non-implanted, bone conduction hearing aid devices for single-sided deafness (SSD), 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.

C. Proposed Provisions

The proposed rule (79 FR 40297) stated that after further considering the statutory Medicare hearing aid exclusion under section 1862(a)(7) of the Act, and re-examining the

different types of non-implanted and implanted devices, we proposed 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, AOI devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea.

We believed that the hearing aid exclusion did not apply to brainstem implants and CIs as discussed in the proposed rule (79 FR 40297). Therefore, we did not propose any changes to our current policy about brainstem implants and CIs 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 proposed, however, to modify § 411.15(d)(2) to specifically note that such devices do not fall within the hearing aid exclusion.

We sought public comment on this proposal and received approximately 2,635 public comments on this provision. After consideration of the comments received we have decided not to finalize our proposal to further interpret the hearing aid statutory exclusion, but in response to comments, this final rule will codify the current program instructions found at section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) noted above. We believe AOIs that provide focused stimulation to the temporal bone structures, through an implant that is physically integrated into the bone of the skull, to the cochlea are outside the scope of the hearing aid exclusion. At the time section 1862(a)(7) of the Act was initially established, hearing aids consisted of non-implanted air and bone conduction devices. AOIs did not exist at

the time the coverage exclusion was drafted and there are clinical distinctions that separate AOIs from all non-implanted air and bone conduction hearing aids. Air conduction and non-osseointegrated bone conduction hearing aids have been in existence since 1965 and have not been covered by Medicare. In accordance with section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), we believe the coverage exclusion applies to all air conduction and non-osseointegrated bone conduction hearing aids or technological refinements of non-implanted air and bone conduction devices that are not osseointegrated. Cochlear devices, brainstem implants, and AOIs are invasive devices and are significantly different than the hearing devices in existence at the time the Medicare coverage exclusion for hearing aids was enacted. We therefore do not consider them to be the hearing aids or technological refinements of the hearing aids excluded from the program in 1965 and after 1965. We consider all types of air conduction and non-osseointegrated bone conduction hearing devices utilized today to be technological refinements of the devices excluded from Medicare coverage; and therefore, we consider all types of air conduction and non-osseointegrated bone conduction hearing devices utilized today to be hearing aids excluded from coverage under the Medicare program. However, we recognize that new technology in this area continues to emerge that may benefit the Medicare population and we will continue to examine this issue as more information becomes available and new devices are introduced.

The comments and responses are set forth below.

Comment: We received many comments relating personal stories on the profound difference the AOI has made on themselves, friends, and relatives who have suffered hearing loss. Many people shared tremendous improvement in the quality of life the AOI has provided for them.

Response: We appreciate these comments. We have reexamined AOIs and the statutory exclusion for hearing aids. We have come to the conclusion that AOIs are not hearing aids because of the clinical distinctions that separate them from hearing aids excluded from coverage under the Medicare program in 1965. Cochlear devices, brainstem implants, and AOIs are invasive devices and are significantly different than the hearing devices in existence at the time the Medicare coverage exclusion for hearing aids was enacted. We therefore do not consider them to be the hearing aids or technological refinements of the hearing aids excluded from the program in 1965 and after 1965. We consider all types of air conduction and non-osseointegrated bone conduction hearing devices utilized today to be technological refinements of the devices excluded from Medicare coverage. Therefore, we have modified the regulation at § 414.15 to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: Many commenters stated an AOI is a prosthetic device that replaces all or part of an internal organ and should remain classified as such. The commenters stated that the AOI is not simply a hearing aid but rather the device replaces the function of the ear. An AOI device meets the definition of a prosthetic device as it requires an implantable post which helps by-pass an impaired ear canal and/or middle ear system to directly stimulate a functional sensory nerve via bone conduction. One commenter stated the AOI replaces the function of the ossicles by 1) converting acoustic energy to mechanical energy, 2) magnifying that mechanical energy, and 3) transmitting that mechanical energy to the inner ear, functions a hearing aid cannot perform. Another commenter added when the implantable post is surgically placed by an otolaryngologist, the post must osseointegrate with the skull and then becomes part of the patient's skull anatomy. It will also compensate for the loss of the cochlea in a single sided deafness (SSD) due to trauma, surgery, infection, nerve injury or congenital defect. One

commenter stated these types of hearing loss result from the loss of organ function. Therefore, an AOI does replace all or part of the internal body organ making it a prosthetic.

Response: The hearing aid statutory exclusion under section 1862(a)(7) of the Act does not identify a particular benefit category. However, we agree that the AOI is distinguishable in that it functions as a prosthetic device that is designed to restore hearing for a limited class of individuals with conductive hearing loss (CHL), mixed hearing loss, or SSD by replacing the function of the middle ear and providing mechanical energy to the cochlea via a mechanical transducer. Therefore, we do not believe it is a hearing aid excluded from coverage by section 1862(a)(7) of the Act. The AOI is functionally and clinically distinct from the hearing aids excluded from coverage in 1965. In this final rule, we are modifying § 411.15 to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: Many commenters stated an AOI is not a hearing aid and does not provide traditional aid to hearing. Those commenters believe that hearing aids are designed to compensate the hearing loss by amplifying the incoming sound to the ear. By design, hearing aids do not replace the function of the ear but rather restore hearing loss using the existing anatomical parts and organ. Several commenters stated air conduction hearing aids operate by amplifying sound to overcome damaged hair cells in the cochlea or inner ear. Other commenters provided the following differences of an AOI compared to a conventional air conduction hearing device: 1) The AOI is surgically implanted in the patients skull where it osseointegrates with the bone and becomes part of the patients anatomy, 2) The components of the AOI function by bypassing the ear canal and middle ear stimulating the hearing nerve directly through bone conduction and 3) The implant replaces the function of outer and middle ear. Bone conduction hearing aids utilize a tight band placed around the user's head to transmit vibrations of sound to

the bones in the head. One commenter stated an AOI is physically and functionally distinguishable from a bone conduction hearing aid in that they: (1) are never retained by a headband, and (2) supply focused stimulation to the temporal bone structures through an implant that is physically integrated into the bone of the skull. Further, traditional hearing aids require no surgery, may be purchased without a physician's prescription, and are removed and placed "in the drawer" by the hearing impaired person. In addition, traditional hearing aids treat presbycusis which is the cumulative effect of aging on hearing. One commenter stated candidates for the AOIs do not have a functioning ear(s) and cannot benefit even from the most advanced hearing aid. While an AOI does provide access to sound to patients that would not, in most cases, otherwise have that access it is not a hearing aid. Several commenters stated a hearing aid is just that; it "aids" what residual hearing an individual has, it does not restore hearing. An AOI restores hearing loss in a completely non-functioning ear.

Response: We agree with commenters that an AOI is not a hearing aid excluded from coverage under the Medicare statute for some of the same clinical and technological reasons set forth by the commenters. Therefore, we are modifying § 411.15 in this final rule to reflect that AOI's are outside the scope of the hearing aid exclusion.

Comment: We received many comments stating that candidates for AOI devices typically have no other reasonable option for hearing assistance or restoration and do not get benefit from hearing aids. Instead, an AOI is the modality of last resort for many of patients, CMS's current coverage position provides that AOIs are indicated only when hearing aids are medically inappropriate or cannot be utilized. Additionally, commenters were concerned that patients with congenital malformations and chronic diseases (Treacher Collins, Aural Atresia and Microtia) will be left without an effective option as they are not candidates for traditional hearing

aids. AOI technology is for a small and very special group. AOIs have specific indications -- for example unilateral anacousis (deafness), and particular patterns of severe conductive and mixed hearing loss. Patients with a conductive or mixed hearing loss with a chronic draining ear are unable to wear a conventional air conduction hearing device. The air conduction device blocks the ear canal, which exacerbates the build-up of infectious material in the ear canal. The AOI is remote from the ear canal. Therefore, chronic ear drainage is often stopped or minimized in these patients.

Response: We have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids given how they are functionally and clinically distinct from the hearing aids excluded from coverage in 1965. , as noted in section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02). An AOI is an osseointegrated device that is implanted in the skull that replaces the function of the middle ear and provides mechanical energy to the cochlea via a mechanical transducer. Therefore, we are finalizing changes to § 414.15 to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: Some commenters stated that although there are other options for treatment of SSD, patients report that the sound quality of the AOI is far superior to these other treatment options for SSD (for example, CROS hearing system, TransEar hearing device). In addition the use of conventional non-osseointegrated bone conduction aids may be associated with complications including: discomfort and breakdown of skin at stimulation point; feedback from mechanical coupling via a steel headband; poor compliance for consistent wear due to discomfort, difficulty with fit and feedback as well as poor sound quality through all of the options that were attempted prior to being fit with AOI devices.

Response: We understand there are other bone conduction hearing aids that may be used instead of the AOI devices for some individuals with SSD. In addition, as technology continues to evolve there will be other new hearing aid devices coming onto the market for the treatment of SSD. However, non-osseointegrated air and bone conduction hearing aids were in use in 1965 when the coverage exclusion for hearing aids was enacted and have not been covered under the program. We believe that given how they function, they should continue to fall under the hearing aid exclusion. However, osseointegrated hearing devices were not in use in 1965 and as commenters have pointed out, there are significant clinical and technological difference between osseointegrated hearing devices and non-osseointegrated hearing devices reasons.

Comment: A few commenters stated if the fiscal impact on Medicare is so insignificant why would you deny thousands of men, women, children and infants the ability to hear?

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying the § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: We received many comments stating without Medicare coverage patients who use AOIs would otherwise benefit greatly in terms of quality of life, productivity, engagement in their community's life, etc. will not have the opportunity. Several commenters stated denial of coverage of these AOIs will affect not only hearing and communication ability in older adults but because CMS also provides benefits under Social Security Disability Insurance (SSDI) program, denial of coverage also will prevent the normal development of language and speech ability in young children. It would cost much more not having the AOI option than to have the relatively inexpensive surgery that would help them for the rest of their lives.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying the § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: Some commenters believe most private insurers follow CMS policies as they design their own coverage which will inevitably lead to the loss of this very valuable technology for everyone. Others stated, not covering this procedure will mean many thousands of people with this condition will forego treatment. A great many people benefit from an AOI and otherwise will not be able to afford it if insurance no longer covered the device. Another commenter stated private third party payers would eventually eliminate coverage for AOIs, affecting both children and adults, as these payers' looks to Medicare for coverage guidelines.

Response: Coverage by private insurers is outside the scope of this rulemaking. However, we have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: Several commenters stated that AOIs have been in use for over 30 years and have been shown to provide significant, cost-effective benefit for recipients. There is a large body of published literature to support the use of this technology for appropriate indications.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: One commenter stated given the recent research on increased presence of cognitive decline in individuals with hearing loss, one would think that the CMS would be looking for ways to improve access to sound for our Medicare and Medicaid patients, thereby

decreasing the overall costs of managing dementia, not for ways to make that situation even worse. Hearing allows people to stay connected to people; it increases their earning potential thus increasing the tax base of our society. In the retired population, good access to hearing keeps people engaged in their community, volunteering, helping to raise grandchildren, and in general participating in life. As we all know the more connected and engaged in society and life around us, the lower financial burden we present to society.

Response: We appreciate the comments. However, Congress excluded hearing aids from the Medicare program in section 1862(a)(7) of the Act. We have reexamined this issue and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified § 414.15 to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: Other commenters stated AOIs restore a sense of safety to individuals who have SSD as the implant allows them to hear sounds on the dead ear. In the SSD application, a patient must have an unaidable ear (meaning the hearing loss is so great or their ability to understand speech is so poor that use of a hearing aid is not possible as a hearing aid would not correct that degree of hearing loss). In these cases, the AOI can be implanted on the bad ear and allow patients to have awareness of the sounds on the dead ear because the sound is delivered via bone conduction to the good ear which can process the speech signal. In unilateral hearing losses (such as described above), individuals experience difficulty localizing sounds, an inability to hear sounds immediately to the side with hearing loss and they also experience difficulty understanding in background noise. The recovery of sound on the dead ear can provide a sense of stability and safety as they no longer have to work about people sneaking up on the dead side.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: Some commenters stated there was no rationale provided articulating reasoning or new evidence that a change in Medicare policy, after 8 years of coverage, is necessary due to law or for the benefit of Medicare patients was necessary. Another commenter stated AOIs function the same way they did in 2006 when CMS correctly recognized them as prosthetics. One commenter stated that the decision in 2005 that AOIs replace the function of the middle ear and are prostheses was made based on an extensive record. In contrast, the proposed rule fails to cite any evidence on which CMS now contends that its position has reversed. There are no studies or other data mentioned, no professional standards are cited, nor is there any description of the content of the benefit category determination requests that are mentioned. Since CMS has not disclosed the basic clinical or legal information underlying the proposed reversal of its benefit policy and its interpretation of Section 1862(a)(7), CMS should defer any action.

Response: As discussed in the proposed rule, CMS has received several new benefit category determinations that initiated a new review of devices that are considered hearing aids. However, in light of the comments and upon further examination, we have decided not to change the policy in section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), that AOIs are not hearing aids and therefore, are modifying § 414.15 to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: One commenter provided their interpretation of the Congressional intent and scope of the hearing aid exclusion as meant to exclude routine items and services, and not

medical treatment for disability created by disease, trauma, infection, or congenital deformity. They provided a comparison of various Court decisions on the eyeglass exclusion. Another commenter stated while Medicare does not cover eye glasses and/or contact lenses, they do cover intraocular lenses because the patient's sensory organ cannot benefit from nonsurgical treatment- the same logic should hold for implantable hearing devices, for patients who are not able to benefit from amplification.

Response: The eyeglass exclusion is not an appropriate comparison to the hearing aid exclusion. Congress amended the Social Security Act to make allowances for eyeglasses and intraocular lenses by amendments to section 1862(a)(7) of the Act. There has not been a similar allowance made for hearing aids. As noted above, upon consideration of the comments and for the reasons outlined, we are modifying the final regulation, as discussed above.

Comment: Several commenters discussed the National Coverage Determination for CIs stating that CMS states in the NCD CIs are prosthetic devices primarily because a CI replaces the function of the cochlear by creating an electrical output that stimulates the auditory nerve as opposed to the mechanical output of a bone conduction device. There is no scientific, clinical, or legal rational for distinguishing the devices based on the type of energy output. Nor does the agency provide any medical or other justification as to why the replacement of the function of the cochlea meets the requirement of replacing an organ function, but replacing the function of the middle ear does not. Another commenter stated in both cases, the device in question bypasses an organ and replaces its function, in one case; it is part of the cochlea, in the other, the ossicles and/or auditory canal. Since in both cases a device replaces the function of a component of the ear, there is no basis on which to classify one as a hearing aid and the other as a prosthetic.

Response: A National Coverage Determination (NCD) is provided upon request or internally generated, and is vetted through a thorough scientific and medical review. The information provided for NCD 50.3 was provided specifically for CIs. It is important to understand that an item or device must not be statutorily excluded and fall within a benefit category as a prerequisite to Medicare coverage. We believe that AOIs 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). Therefore, we've concluded that AOIs are not hearing aids and do not fall within the statutory exclusion.

Comment: One commenter stated a policy that deems which technology is a Medicare benefit based on whether that technology replaces hearing by a particular means (electrical versus mechanical energy), or whether it has a surgically implanted component or not (osseointegrated versus a dental anchored device), or whether the deafness is bilateral or unilateral, are arbitrary distinctions without clinical justification. Medicare policy should focus on whether attributes of a device replace the function of all or part of the ear to restore hearing, not the means by which it is accomplishes this task.

Response: We disagree that our policy creates an arbitrary distinction. The policy is based on whether a device qualifies as a hearing aid as defined in section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), or whether a device functions in such a way that it falls outside this definition.

Comment: A few commenters stated withdrawing coverage of these devices will preclude coverage and designing new innovations that improve SSD treatment and are more cost effective than existing alternatives. One commenter explained its concern that the proposal will stifle innovation and advances in auditory prosthetics and will send a negative and damaging

message to the medical technology development community as a whole--that Medicare coverage is unpredictable, even when there is long established policy in favor of coverage. Such unreliability makes it impossible for investors to make reasoned decisions about future investments and will lead to the freezing of meaningful innovation.

Response: We do not agree. We believe new innovations will continue to be pursued without Medicare coverage as other payers would continue to provide AOIs. However, we have reexamined AOIs and the applicability of the hearing aid statutory exclusion. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: Some commenters equated removing coverage of the AOI as to denying coverage for glasses, a prosthetic leg, and colostomy.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: Several commenters provided their definition of a hearing aid. Several commenters stated the definition should include "wearable" and another commenter stated it should include "amplify sound" and another stated it should be "air conduction devices." Commenters provided additional criteria as well, such as there must be a medical evaluation and physician prescription. In addition several commenters advocated for a plain and ordinary meaning of hearing aid provided in the dictionary.

Response: We disagree with the commenters' definition of a hearing aid; as stated in the proposed rule, in section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) Medicare defines hearing aids as "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." We believe the Medicare definition captures the provisions we are finalizing and accurately defines a hearing aid. Upon re-examining the Medicare hearing aid exclusion provision at section 1862(a)(7) of the Act, and its applicability to AOIs, we have determined that AOIs are not hearing aids because they are functionally and clinically distinct from the hearing aids excluded from coverage in 1965. . They are implants that replace the function of the middle ear and are physically integrated into the temporal bone structure of the skull to provide mechanical stimulation through the temporal bone to the cochlea. Therefore, we have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: One commenter stated according to the Food and Drug Administration (FDA) definition of a hearing aid and state hearing aid dispensing laws, the AOI is in fact not a hearing aid because it is not removable, is not available to the general public for purchase and the primary purpose is not to amplify sound. Another commenter believed CMS should recognize the FDA's classification system as these devices are Class II whereas hearing aids are Class I devices.

Response: Medicare does not adhere to the same definition as the FDA regarding hearing aids. For the reasons state above, we have come to the conclusion that AOIs are not hearing aids in the context of section 1862(a)(7) of the Act and the Medicare program and coverage exclusion

and therefore have modified our final rule to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: A few commenters stated neither the statute nor its legislative authority support the broad interpretation CMS seeks in order to prohibit AOIs under the hearing aid exclusion. After review of the Congressional Record and hearings held by Congress before enactment of this provision clearly shows Congress' intent was to exclude "routine care" from the Medicare program. The majority of the technologies that would be considered hearing aids under this proposed rule were not available in 1965. In particular, AOIs could not have been contemplated by Congress at the time the hearing aid exclusion was enacted, because they did not exist. At that time patients could self-select available hearing aids, no physician order was required, and patients where accustomed to paying out of pocket for these items.

Response: We believe we understand the Congressional intent in 1965 regarding the hearing aid exclusion. We believe air and bone conduction devices were available and commonly used when the exclusion was established and therefore are excluded. However, since AOIs were not in existence and are clinically and functionally distinct from bone conduction hearing aids in 1965, we do not believe the exclusion applies. Different refinements of bone conduction hearing aid technologies have been introduced over the years that represent variations of non-implanted devices that send mechanical energy to the cochlea through bone without the need to surgically implant a transducer into the patient's skull. These implanted, osseointegrated devices were not part of the general technology and category of devices excluded from coverage from 1965 to the present. We have therefore come to the conclusion that AOIs are not hearing aids and have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: One commenter stated the AOI has a record of demonstrated cost effectiveness in studies conducted around the world. One example includes a significant reduction in the number of medical visits and prescribed medications to address repeated infections for individuals with chronic suppurative otitis media following AOI surgery. Another commenter stated for patients that have failed previous surgical attempts at hearing reconstruction using conventional techniques, it makes better sense for Medicare to provide AOIs for these patients in lieu of repeated, costly traditional surgical attempts without an AOI.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: A few commenters stated current users on Medicare who are benefiting from an AOI will be unable to maintain and upgrade their equipment. Several commenters stated discontinuing coverage for the numerous existing recipients of AOIs is unethical and discriminatory. These individuals have existing AOIs that require maintenance and fully functioning systems in order to hear and communicate. By discontinuing coverage, the medical community is forced to unjustly discontinue care of these individuals unless they can financially assume the cost of their implant. This is an unreasonable assumption, as many Medicare recipients are no longer working and living on a fixed income.

Response: As we stated above, we have determined that AOIs are outside the scope of the hearing aid exclusion. So Medicare beneficiaries with existing AOIs will continue to receive upgrades and maintenance of these devices.

Comment: One commenter stated that the patient's medical condition should be the primary consideration for providing coverage, not the technology. Many commenters stated there are currently very specific patient selection criteria for AOIs.

Response: We disagree; while the patient's medical condition is important, we do not believe it should be the primary consideration for providing coverage of a particular device. Medicare is a defined benefit program. It is important to understand that an item or device must not be statutorily excluded and fall within a benefit category as a prerequisite to Medicare coverage. We must analyze whether the device is a hearing aid as they are statutorily excluded from coverage. We have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: One commenter stated hearing aids cost on average $1,675 per device. AOIs including surgery cost are in the range of $12,000 and that cost is moderated by the significant availability of insurance coverage. This cost would likely double in the absence of insurance coverage, which would clearly make AOIs unaffordable for many people. Another commenter stated CMS is undermining the goals of the Medicare program by decreasing access and affordability to Medicare patients.

Response: We understand, however, Medicare is a defined benefit program with certain coverage requirements. We have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: Several commenters urged CMS to continue to provide coverage of CIs, brain stem implants, and AOIs, to extend coverage to dental anchored bone conduction devices since

these devices also meet the definite of covered prosthetics and are not hearing aids, and to provide coverage to other clinically proven bone conduction hearing device technologies with restrictive principles applied.

Response: We will continue to cover AOI devices that replace the function of the middle ear and provide mechanical energy directly to the cochlea, because we do not consider them to be hearing aids and excluded from coverage.

Comment: One commenter stated over the past 8 years CMS has established a precedent for providing coverage of AOIs for Medicare beneficiaries, upon which Medicare beneficiaries who have received these technologies and health care providers who establish patient treatment plans have relied.

Response: While CMS had established a precedent for coverage of AOIs, we reexamined AOIs and the statutory exclusion applicability. CMS received requests for informal benefit category determinations from manufacturers of certain non-implanted hearing devices. We elected to address the issue of the applicability of the Medicare coverage exclusion for hearing aids to all hearing devices in light of these requests and initially determined and proposed (79 FR 40296) that all external, internal, and implanted air conduction and bone conduction hearing devices were subject to the coverage exclusion for hearing aids. Based on our review and in light of comments received on the proposed rule, for the reasons stated above, CMS has decided that AOIs are not hearing aids subject to the statutory exclusion.

Comment: One commenter opposed the classification of middle ear implants as a hearing aid, stating these devices do not meet the definition of a hearing aid and do bypass or supersede a non-functioning organ in the auditory pathway. In addition, this commenter stated CMS is over-reaching its authority in including implantable bone conduction hearing aids in this

definition. This commenter recommended seeking input from the medical and scientific community convening a public meeting to discuss the definitions at stake in this rule.

Response: For the reasons stated above, CMS has decided to continue covering AOIs because we have decided they are not hearing aids subject to the statutory exclusion.

Comment: One commenter felt the current proposal would reverse the 2005 NCD.

Response: The proposed rule (79 FR 40297) would not reverse the NCD. As we stated in the proposed rule, "we continue to believe that the hearing aid exclusion does not apply to brain stem implants and CIs 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 did not propose any changes to our current policy about brain stem implants and CIs and how such implants fall outside of the hearing aid statutory exclusion.

Comment: Several commenters agreed with the decision CMS made in 2005 by providing coverage for AOIs as prosthetics and not hearing aids.

Response: We agree the decision in 2005 to provide coverage for AOIs was correct. We believe AOIs are not hearing aids since they are functionally and clinically distinct from the hearing aids excluded from coverage in 1965. Therefore, this final rule will codify the current program instructions found at section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02).

Comment: One commenter stated the statute at section1861(s)(8), regulations at 42 CFR 414.202, and program manuals in the Medicare Benefit Policy Manual, Ch. 15, 120 set out a straightforward test for defining a covered prosthetic device which have not been changed.

Response: We have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

After consideration of the comments received we have decided not to finalize § 411.15, as proposed. In response to comments, this final rule will codify the policy in the current program instructions found at section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) noted above.

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) proposed rule 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 addition, questions were raised regarding when it is appropriate for a supplier to bill for a prefabricated orthotic as having been custom fitted versus one furnished OTS. In order to address this specific question, the DME MACs issued a policy article on March 27, 2014, which details what custom fitting of an orthotic involves and indicating that furnishing custom fitted orthotics "requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements." The DMEPOS quality standards have been updated to reflect this requirement and we decided to revise the definition of minimal self-adjustment in the regulation to address this issue as well.

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 believed it was 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 believed the term "individual with specialized training" must be clarified in regulations as well as in

contractor policies and DMEPOS quality standards. In addition, we believed that suppliers who are not certified orthotists should not be allowed to furnish custom fitted orthotics unless they have specialized training equivalent to a certified orthotist for the provision of custom fitted orthotic devices. We believed that these suppliers must 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 appropriate care and safety for Medicare beneficiaries.

C. Summary of the Proposed Provisions and Responses to Comments on the Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

For reasons discussed above, we proposed that 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. We proposed these types of practitioners because we believe physicians, treating practitioners, occupational therapists, and physical therapists possess equivalent or higher educational degrees, continuing education requirements, licensing, and certification and/or registration requirements. Each of these professionals has undergone medical training in various courses such as kinesiology and anatomy.

Specifically, we proposed to update the definition of minimal self-adjustment in § 414.402 to recognize as an individual with specialized training: 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.

At this time, we have decided not to finalize any changes to the definition of minimal self-adjustment in § 414.402 to recognize as an individual with specialized training. We may address this provision in future rulemaking.

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 competitive bidding programs (CBPs) in competitive bidding area (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 Change of Ownership (CHOW) must include the assumption of the entire contract, including all CBAs and PCs awarded under the contract.

B. Summary of the Proposed Provisions and Responses to Comments on the Revision to Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. We received 1 public comment on this proposal from a manufacturer and supplier. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

Specifically, we proposed (79 FR 40298) 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 and accepts as a contract supplier. We proposed to 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 new qualified successor entity who meets all competitive bidding requirements (that is, financial standards, licensing, and accreditation) (79 FR 40299). The 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 also proposed that a contract supplier that wants to sell a distinct company which furnishes one

or more specific PCs or serves one or more specific CBAs would be required 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 proposed 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 proposed that several conditions would have to be met. First, we proposed that every CBA, PC, and location of the company being sold must be transferred to the new owner. Second, we proposed 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 proposed that all requirements in 42 CFR 414.422 (d)(2) must be met. Fourth, we proposed that the sale of the company must include all of the company's assets associated with the CBA and/or PC(s). Finally, we proposed that CMS must determine that transferring part of the original contract will not result in disruption of service or harm to beneficiaries. No transfer would 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 invited comments on whether more or different conditions would be appropriate.

We proposed to update the current CHOW regulation at § 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 sought comments on all changes proposed for § 414.422. The comment and our responses are set forth below.

Comment: One commenter recommended that CMS implement financial penalties for suppliers who sell their contracts along with selling their organizations prior to providing the product/service at the contracted payment rate, and/or remove an entity's bid from calculation of the SPA if they have failed to supply the awarded contract items for a period of time prior to re-sale. The commenters also believed that bids by suppliers who have no intention of providing services to Medicare beneficiaries should not be given the same weight as those of reputable suppliers in the community.

Response: CMS does not agree with the suggestions raised by this commenter. CMS cannot require a contract supplier to furnish a certain amount of competitive bid items. However, contract suppliers must be ready, available and willing to furnish contracted competitive bid items starting on day one of implementation to any beneficiary within a CBA. A contract supplier is not permitted to sell just its competitive bidding contract. CMS ensures that the successor entity 1) assumes all rights, obligations, and liabilities of the entire competitive bidding contract, 2) meets all requirements applicable to a contract supplier, and 3) is acquiring the assets of the existing supplier. In addition, the competitive bidding contract specifically

states that CMS does not guarantee a minimum amount of business. In response to the comment on the recalculation of the single payment amount (SPA), CMS carefully screens and evaluates bids to ensure that they are bona fide (rational and feasible) before determining the single payment amounts and offering contracts. Since only bona fide bids from qualified suppliers are included in the array of bids used to set prices, recalculating payment amounts based on contract rejections would not improve the validity of the single payment amounts. Also, the SPAs are set at the time of contract award and cannot be changed. It would not be possible for CMS to re-calculate the SPAs each time a contract supplier goes through a change of ownership. Contract offers include the SPAs applicable throughout the duration of the contract period for each HCPCS code in each CBA. Therefore, it is not possible for CMS to re-compute the SPAs whenever there is a change in contract suppliers as this would require continued re-contracting.

Therefore, for the reasons CMS stated above, CMS is finalizing the proposed changes to § 414.422(d) of the regulation and making one additional technical change to replace certain terms with "a new qualified entity," when referring to a company that is approved to purchases a contract supplier and assume the competitive bidding contract in whole or in part. We are making this technical change for purposes of consistency and to avoid possible confusion.

X. Changes to the Appeals Process for Termination of Competitive Bidding Contract

We proposed (79 FR 40299) to modify the DMEPOS CBPs appeals process for termination of competitive bidding contracts under § 414.423. First, we proposed 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 proposed to change these references to emphasize that the contract will automatically be terminated if the supplier does not file a hearing request or submit a corrective action plan.

In 42 CFR 414.423(l), we also proposed (79 FR 40299) deleting the lead-in sentence, as it does not properly lead into the first paragraph. Additionally, we proposed 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 proposed 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 proposed 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. We did not receive any comments on this proposal (79 FR 40299). For the reasons we noted previously, we are finalizing these changes to § 414.423, with two modifications to the regulation text to address errors in citation references. First, in the proposed regulation of the proposed rule (79 FR 40315), we incorrectly referenced § 414.423(b)(1) instead of §414.423(b)(2), so we are correcting that citation in this final rule. Second, although we made clear in the preamble our proposal to delete the lead-in language in § 414.423(l), we inadvertently failed to note that deletion in the proposed regulation text. Therefore, we are making technical corrections in the final rule to reflect final decision to delete the lead-in sentence in § 414.423(l).

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 DME and medical supplies. The statute specifically states that this category includes "items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME." Implementation of CBPs for infusion drugs is therefore specifically mandated by the statute.

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 proposed 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 proposed 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. Infusion drugs have 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=7065f17b411e37b3788b6e7fcce21f89&rgn=div8&view=text&node=42:3.0.1.1.1.9.1.3&idno=42. We proposed 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 sought comments on this proposal and received 4 comments. The comments and responses are set forth below.

Comment: Some commenters stated that CMS does not have authority to change payment amounts for infusion drugs using competitive bidding. One commenter stated that home infusion therapy is one of the most clinically complex therapies covered under the DME benefit and involves more than the delivery of infusion drugs to patients. The commenter believed that payment amounts for infusion drugs could be improperly reduced if CMS sets the payment rate using bids from inexperienced providers who do not adequately account for the cost of the services.

Response: Section 1847(a)(2)(A) of the Act includes infusion drugs in the list of items subject to the DMEPOS Competitive Bidding Program. Therefore, we are finalizing our

proposal to modifying § 414.414(f) of the regulations, with an additional modification to make a general reference to Subpart I. We note, however, that at this time there are no CBPs in effect that include infusion drugs. The phase-in of infusion drugs would occur under a future CBP(s).

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 (health IT) 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 health IT and HIE services through Medicare and Medicaid payment policies, 2) adoption of common standards and certification requirements for interoperable health IT, 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 instance, to increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC) regulatory certification structure Health IT Certification Program, ONC expressed in the 2014 Edition Release 2 final rule (79 FR 54472 through 54473) an intent to propose future changes to the program that would permit the

certification of health IT for other health care settings, such as long-term and post-acute care and behavioral health settings.

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).

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.E and section II.G of this final rule, we are implementing changes to regulatory text for the ESRD PPS in CY 2015. However, the changes that are being finalized do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, this final rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP

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 final rule outlines our data validation studies for PY 2017. Specifically, we proposed 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 estimated that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities x 2.5 hours). 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 estimated that the aggregate cost of the CROWNWeb data validation would be $24,847.50 (750 hours x $33.13/hour) total or $82.83 ($24,847.50 / 300 facilities) per facility in the sample.

We sought comments on these estimates but did not receive any comments.

Under the feasibility study for validating data reported to the NHSN Dialysis Event Module, we proposed to randomly select nine facilities to provide CMS with a quarterly list of all positive blood cultures drawn from their patients during the quarter, including any positive blood cultures collected on the day of, or the day following, a facility patient's admission to a hospital. A CMS contractor will review the lists to determine if dialysis events for the patients in question were accurately reported to the NHSN Dialysis Event Module. If we determine that additional medical records are needed to validate dialysis events, facilities will be required to provide those records within 60 days of a request for this information. We estimated 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 estimated 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 estimated the quarterly burden for these facilities would be 72 hours per year (9 facilities x 2 hours/quarter x 4 quarters/year). Again, we estimated the mean hourly wage of a registered nurse to be $33.13/hour, and we anticipated that nurses (or administrative staff who would be paid at a lower hourly wage) would be responsible for preparing and submitting the list. Because we anticipated that nurses (or administrative staff who would be paid at a lower hourly rate) would compile and submit these data, we estimated that the aggregate annual cost of the feasibility study to validate NHSN data would be $2,385.36 (72 hours x $33.13/hour) total or

$265.04 per facility ($2,385.36 / 9 facilities).

We sought comments on these estimates. The comment we received and our response is set forth below.

Comment: One commenter stated that the cost estimate provided for the proposed NHSN Data Validation study is too low, because the study requirements will likely be completed by the facility's Nurse Manager, who is paid more than a Registered Nurse.

Response: We understand the commenter's concerns; however, the Bureau of Labor Statistics does not separately itemize Nurse Managers. Based on our experience, Nurse Managers are typically Registered Nurses; therefore, we believe that the costs of collecting this information have been estimated correctly.

b. NHSN Healthcare Personnel Influenza Vaccination Reporting Measure for PY 2018

We proposed 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 proposed 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 estimated 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 estimated that approximately 5,996 facilities will treat ESRD patients in PY 2018. We estimated 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 x 5,996 facilities]. Again, we estimated the mean hourly wage of a registered nurse to be $33.13, and we anticipated that nurses (or administrative staff who would be paid at a lower hourly wage) would be responsible for this reporting. In total, we stated that we believe the cost for all ESRD facilities to comply with the reporting requirements associated with the NHSN Healthcare Personnel Influenza Vaccination reporting measure would be approximately $248,309 (7,495 hours x $33.13/hour) total, or $41.37 ($248,309 / 5,996 facilities) per facility.

We sought comments on these estimates but did not receive any comments.

XIV. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We examined the impacts of this 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 final rule.

2. Statement of Need

This rule finalizes a number of routine updates for renal dialysis services in CY 2015 and implements several policy changes to the ESRD PPS. The routine updates include: wage index values, wage index budget-neutrality adjustment factor, and the outlier payment threshold amounts. The final 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 of the low-volume payment adjustment and the billing of short frequent hemodialysis services, and additions and corrections to the ICD-10-CM codes that will be used for the co-morbidity payment adjustment when compliance with ICD-10-CM is required beginning October 1, 2015. In addition, this rule implements sections 1881(b)(14)(F)(i) and (I) of the Act, 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 final rule would result in ESRD facilities not receiving appropriate payments in CY 2015.

This final rule implements requirements for the ESRD QIP by adopting measure sets for the PYs 2017 and 2018 programs, as directed by section 1881(h) of the Act. Failure to finalize requirements for the PY 2017 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2016. In addition, finalizing 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 final rule establishes a methodology for adjusting DMEPOS fee schedule amounts using information from the Medicare DMEPOS CBP. The final rule phases in special payment

rules for certain DME in a limited number of areas under the Medicare DMEPOS CBP. This rule also clarifies the Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act. Finally, this final rule modifies the rules for a 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 finalized requirements related to the ESRD QIP will cost approximately $27 thousand total, and the payment reductions will result in a total impact of approximately $12 million across all facilities. For PY 2018, we estimate that the finalized requirements related to the ESRD QIP will cost approximately $248 thousand total, and the payment reductions will result in a total impact of approximately $12.7 million across all facilities, resulting in a total impact from the ESRD QIP of approximately $13 million.

We estimate that the final methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs would save over $4.4 billion in gross payments over FYs 2016-2020. The gross savings would be primarily achieved from the reduced payment amounts for items and services.

We estimate the special payment rules at § 414.409 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 fiscal impact generally would be the same as is under the current payment rules. Furthermore, as indicated above, the special payment rules would be phased in under a limited number of areas to gradually determine effects 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 will give beneficiaries more choice and flexibility in changing suppliers. We estimate the clarification of the statutory Medicare hearing aid coverage exclusion will not have a significant fiscal impact on the Medicare program because we are not changing the current coverage for devices for Medicare payment purposes. This regulation at § 411.15(d) will provide guidance as to coverage of DME with regard to the statutory exclusion.

We estimate finalizing a change to the CHOW rules under the Medicare DMEPOS CBP will 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 final rule, we used the June 2014 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.C of this rule. Table 33 shows the impact of the estimated CY 2015 ESRD payments compared to estimated payments to ESRD facilities in CY 2014.

TABLE 33: IMPACT OF FINAL CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2015 FINAL RULE

Facility Type	Number of Facilities A	Number of Treatments (in millions) B	Effect of 2015 Changes in Outlier Policy C	Effect of 2015 Changes in Wage Indexes, CBSA designations and Labor-Related Share D	Effect of 2015 Changes in payment rate update E	Effect of Total 2015 changes F
All Facilities	6,096	43.6	0.3%	0.0%	0.0%	0.3%
Type						
Freestanding	5,615	40.7	0.3%	0.0%	0.0%	0.3%
Hospital based	481	2.9	0.3%	0.2%	0.0%	0.5%
Ownership Type						
Large dialysis organization	4,209	30.5	0.3%	-0.1%	0.0%	0.2%
Regional chain	890	6.6	0.2%	0.2%	0.0%	0.5%
Independent	599	4.1	0.2%	0.2%	0.0%	0.3%
Hospital based[1]	398	2.4	0.3%	0.1%	0.0%	0.4%
Geographic Location						
Rural	1,230	6.5	0.3%	-0.8%	0.0%	-0.5%
Urban	4,866	37.0	0.3%	0.1%	0.0%	0.4%
Census Region						
East North Central	1,000	6.5	0.3%	-0.1%	0.0%	0.2%
East South Central	504	3.2	0.3%	-1.2%	0.0%	-0.9%
Middle Atlantic	672	5.2	0.3%	0.7%	0.0%	0.9%
Mountain	356	2.1	0.2%	0.0%	0.0%	0.2%
New England	179	1.4	0.3%	1.2%	0.0%	1.4%
Pacific[2]	725	6.1	0.2%	1.7%	0.0%	1.9%
Puerto Rico and Virgin Islands	44	0.3	0.3%	-3.9%	0.0%	-3.6%
South Atlantic	1,353	10.1	0.3%	-0.5%	0.0%	-0.2%
West North Central	441	2.3	0.2%	-0.3%	0.0%	-0.1%
West South Central	822	6.3	0.3%	-0.9%	0.0%	-0.6%

Facility Type	Number of Facilities A	Number of Treatments (in millions) B	Effect of 2015 Changes in Outlier Policy C	Effect of 2015 Changes in Wage Indexes, CBSA designations and Labor-Related Share D	Effect of 2015 Changes in payment rate update E	Effect of Total 2015 changes F
Facility Size						
Less than 4,000 treatments[3]	1,283	3.2	0.3%	-0.2%	0.0%	0.1%
4,000 to 9,999 treatments	2,261	11.8	0.3%	-0.3%	0.0%	0.0%
10,000 or more treatments	2,536	28.6	0.3%	0.1%	0.0%	0.4%
Unknown	16	0.0	0.3%	-2.2%	0.0%	-1.9%
Percentage of Pediatric Patients						
Less than 2%	5,978	43.1	0.3%	0.0%	0.0%	0.3%
Between 2% and19%	52	0.4	0.3%	-0.2%	0.0%	0.1%
Between 20% and 49%	12	0.0	0.1%	0.0%	0.0%	0.1%
More than 50%	54	0.1	0.1%	0.1%	0.0%	0.1%

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 1,283 ESRD facilities with less than 4,000 treatments, only 407 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low-volume facilities is a 0.1 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 changes to the outlier payment policy described in section II.C.4 of this final 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 0.1 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 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 2.2 percent decrease to a 1.7 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 sections 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 outlier policy changes, the wage index, the CBSA delineations, the 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 1.9 percent to increase of 1.9 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 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 $9.0 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 3.3 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 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 final rule, we will implement a 50/50 blended wage index for CY 2015 that will apply to all ESRD facilities, experiencing an impact, or not, due to the implementation of the new CBSA delineations. We considered implementing 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, we will implement the updated labor-related share using a 2-year transition. Therefore, for CY 2015, we will apply 50 percent of the value of the current labor-related share under the ESRD PPS (41.737) and 50 percent of the percent to the revised labor-related share (50.673). In CY 2016, we will apply 100 percent, or 50.673 percent, as the labor-related share.

We considered implementing 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 final 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 19 percent or 1,123 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 34 shows the overall estimated distribution of payment reductions resulting from the PY 2017 ESRD QIP.

TABLE 34: Estimated Distribution of PY 2017 ESRD QIP Payment Reductions.

Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	4,541	80.17%
0.5%	784	13.84%
1.0%	282	4.98%
1.5%	44	0.78%
2.0%	13	0.23%

Note: This table excludes 332 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 35.

TABLE 35: 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
SRR	Jan 2012 – Dec 2012	Jan 2013 – Dec 2013

Clinical measure topic areas with less than 11 cases for a facility were not included in that facility's Total Performance Score. Each facility's Total Performance Score was compared

to the estimated minimum Total Performance Score and the payment reduction table found in section III.F.8 of this final 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 final rule, we multiplied the total Medicare payments to the facility during the 1-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 1,123 facilities estimated to receive a reduction is approximately $11.9 million ($11,927,399). Further, we estimate that the total costs associated with the collection of information requirements for PY 2017 described in section III.F.9 of this final 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 $12 million ($27,232 + $11,927,399 = $11,954,631) in PY 2017, as a result of the PY 2017 ESRD QIP.

Table 36 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 36: Estimated Impact of Finalized 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	5,664	1,123	-0.13%
Facility Type:					
Freestanding	5,520	36.6	5,275	1,008	-0.12%
Hospital-based	476	2.5	389	115	-0.21%
Ownership Type:					
Large Dialysis	4,150	27.5	3,987	704	-0.11%
Regional Chain	871	5.9	828	170	-0.14%
Independent	582	3.6	529	151	-0.23%
Hospital-based (non-chain)	393	2.1	320	98	-0.22%
Facility Size:					
Large Entities	5,021	33.5	4,815	874	-0.11%
Small Entities[1]	975	5.7	849	249	-0.22%
Rural Status:					
1) Yes	1,212	5.9	1,156	181	-0.10%
2) No	4,784	33.3	4,508	942	-0.14%
Census Region:					
Northeast	792	5.8	756	161	-0.15%
Midwest	1,341	7.7	1,259	268	-0.14%
South	2,527	17.5	2,451	487	-0.12%
West	1,015	7.1	964	128	-0.08%
US Territories[2]	321	1.0	234	79	-0.27%
Census Division:					
East North Central	979	5.8	897	224	-0.17%
East South Central	497	2.9	473	81	-0.11%
Middle Atlantic	661	4.8	619	135	-0.15%
Mountain	352	1.9	334	35	-0.07%
New England	177	1.3	167	33	-0.14%
Pacific	710	5.4	670	104	-0.10%
South Atlantic	1,333	9.1	1,272	301	-0.15%

	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)*
West North Central	438	2.0	410	59	-0.09%
West South Central	807	5.6	782	126	-0.10%
US Territories[2]	42	0.3	40	25	-0.43%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,086	2.7	901	163	-0.13%
4,000-9,999 treatments	2,226	10.5	2,167	371	-0.11%
Over 10,000 treatments	2,523	25.7	2,504	561	-0.14%
Unknown	161	0.3	92	28	-0.28%

[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 using to determine a facility's TPS for the PY 2018 ESRD QIP is described in section III.G.9 of this final 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 21 percent or 1,284 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 37 shows the overall estimated distribution of payment reductions resulting from the PY 2018 ESRD QIP.

TABLE 37: Estimated Distribution of PY 2018 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	4,338	77.2%
0.5%	1,023	18.2%
1.0%	225	4.0%
1.5%	33	0.6%
2.0%	3	0.1%

Note: This table excludes 374 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 38.

TABLE 38: 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 2012 – Dec 2012	Jan 2013 – Dec 2013
STrR	Jan 2012 – Dec 2012	Jan 2013 – Dec 2013

Clinical measure topic areas with less than 11 cases for a facility were not included in

that facility's Total Performance Score. Each facility's Total Performance Score was compared to a proxy minimum Total Performance Score developed consistent with the policies outlined in sections III.G.9 of this final 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 final rule, we multiplied the total Medicare payments to the facility during the 1-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 1,284 facilities expected to receive a reduction is approximately $11.6 million ($11,576,214). Further, we estimate that the total costs associated with the collection of information requirements for PY 2018 described in section III.G.2.f of this final 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 $11.8 million ($248,309 + $11,576,215 = $11,824,524) in PY 2018, as a result of the PY 2018 ESRD QIP.

Table 39 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 will 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 39: Estimated Impact of Finalized 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	5,622	1,284	-0.14%
Facility Type:					
Freestanding	5,520	36.6	5,251	1,150	-0.13%
Hospital-based	476	2.5	371	134	-0.23%
Ownership Type:					
Large Dialysis	4,150	27.5	3,976	789	-0.11%
Regional Chain	871	5.9	823	212	-0.16%
Independent	582	3.6	520	174	-0.22%
Hospital-based (non-chain)	393	2.1	303	109	-0.23%
Facility Size:					
Large Entities	5,021	33.5	4,799	1,001	-0.12%
Small Entities[1]	975	5.7	823	283	-0.23%
Rural Status:					
1) Yes	1,212	5.9	1,151	250	-0.13%
2) No	4,784	33.3	4,471	1,034	-0.14%
Census Region:					
Northeast	792	5.8	748	175	-0.14%
Midwest	1,341	7.7	1,247	317	-0.15%
South	2,527	17.5	2,445	530	-0.12%
West	1,015	7.1	955	153	-0.10%
US Territories[2]	321	1.0	227	109	-0.36%
Census Division:					
East North Central	979	5.8	888	256	-0.17%
East South Central	497	2.9	472	94	-0.12%
Middle Atlantic	661	4.8	612	150	-0.15%
Mountain	352	1.9	334	46	-0.08%
New England	177	1.3	164	35	-0.12%
Pacific	710	5.4	660	122	-0.11%

	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)
South Atlantic	1,333	9.1	1,268	328	-0.15%
West North Central	438	2.0	405	81	-0.12%
West South Central	807	5.6	779	146	-0.11%
US Territories[2]	42	0.3	40	26	-0.42%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,086	2.7	869	219	-0.16%
4,000-9,999 treatments	2,226	10.5	2,163	429	-0.11%
Over 10,000 treatments	2,523	25.7	2,502	587	-0.13%
Unknown	161	0.3	88	49	-0.49%

[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 Final Methodology for Adjusting DMEPOS Payment Amounts using Information from Competitive Bidding Programs

We estimate that the final methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs will save over $4.4 billion in gross payments over FY 2016 through 2020. The gross savings will 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 40.)

TABLE 40: Impact of Pricing Items in Non-Competitive Areas Using Competitive Bidding Pricing*

FY	Impact on the gross impact in dollars (to the nearer ten million)	Impact on beneficiary cost sharing in dollars (to the nearer ten million)
2016	-550	-130
2017	-1,120	-280
2018	-1,330	-330
2019	-1,430	-360
2020	-1,530	-380

*-The impacts of the final rule differ from those of the proposed rule due to six-month phase-in in 2016 of the adjusted fees and the expanded definition of rural areas.

b. Effects of the Final Special Payment Methodologies under the Competitive Bidding Program

We believe that the final special payment rules will 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 will reflect the cost of furnishing items in accordance with the new payment rules, we expect the overall savings will be generally the same as they are under the current payment rules. Section 1847(b)(2)(A)(iii) prohibits the awarding of contracts under a CBP unless total payments made to contract suppliers in the CBA are expected to be less than the payment amounts that would otherwise be made. Furthermore, as indicated above, we are finalizing a phase-in of the special payment rules under a limited number of areas to gradually determine effects on the program, beneficiaries, and suppliers. If supported by evaluation results, a decision to expand the special payment rules to other areas will be addressed in future rulemaking.

c. Effects of the Final Clarification of the Scope of the Medicare Hearing Aid Coverage Exclusion

This final rule clarifies the scope of the Medicare coverage exclusion for hearing aids. This rule will not have a fiscal impact on the Medicare program because there will be no change in the coverage of devices for Medicare payment purposes. This clarification will provide clear guidance about coverage of DME with regard to the statutory hearing aid exclusion.

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

The final rule will not finalize a modification to the definition of minimal self-adjustment.

e. Effects of the Final Revision to Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business

This final rule modifies the change of ownership rules to reduce interference with the normal course of business for DME suppliers. This rule establishes 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 under certain specific circumstances. This change impacts 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 41 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 41. Accounting Statement: Classification of Estimated Transfers and Costs/Savings				
ESRD PPS for CY 2015				
Category	**Transfers**			
Annualized Monetized Transfers	$30 million			
From Whom to Whom	Federal government to ESRD providers			
Category	**Transfers**			
Increased Beneficiary Co-insurance Payments	$10 million			
From Whom to Whom	Beneficiaries to ESRD providers			
ESRD QIP for PY 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	-$11.6 million			
From Whom to Whom	Federal government to ESRD providers			
Category	**Costs**			
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	Period Covered
	-$288.0 million	2014	7%	2016 – 2020
	-$292.5 million	2014	3%	2016 - 2020
From Whom to Whom	Beneficiaries to Medicare providers			
	Transfers			
Annualized Monetized Transfer Payments	Estimates	Year Dollar	Discount Rate	Period Covered
	-$1,160.9 million	2014	7%	2016 - 2020
	-$1,178.5 million	2014	3%	2016 - 2020
From Whom to Whom	Federal government to Medicare providers.			

XV. 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 $38.5 million in any 1 year. Individuals and States are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at http://www.sba.gov/content/small-business-size-standards (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 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 33. Using the definitions in this ownership category, we consider the 599 facilities that are independent and the 398 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS final updates 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 0.3 percent

increase in payments for CY 2015.

We estimate that of the 1,123 ESRD facilities expected to receive a payment reduction in the PY 2017 ESRD QIP, 249 of those facilities would be ESRD small entity facilities. We present these findings in in Table 34 ("Estimated Distribution of PY 2017 ESRD QIP Payment Reductions") and Table 36 ("Estimated Impact of Finalized QIP Payment Reductions to ESRD Facilities for PY 2017") above. We estimate that the payment reductions will average approximately $10,621 per facility across the 1,123 facilities receiving a payment reduction, and $10,329 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 249 small entity facilities with the aggregate ESRD payments to all small facilities. We estimate that there are a total of 975 small facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.22 percent in PY 2017.

We estimate that of the 1,284 ESRD facilities expected to receive a payment reduction in the PY 2018 ESRD QIP, 283 are ESRD small entity facilities. We present these findings in Table 37 ("Estimated Distribution of PY 2018 ESRD QIP Payment Reductions") and Table 39 ("Estimated Impact of Finalized QIP Payment Reductions to ESRD Facilities for PY 2018") above. We estimate that the payment reductions will average approximately $9,016 per facility across the 1,284 facilities receiving a payment reduction, and $9,009 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 283 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 0.23 percent in PY 2018.

We expect the final methodologies for adjusting DMEPOS fee schedule amounts using information from DMEPOS CBPs will 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 fee schedule amounts for these items and services will be reduced using the methodology established as a result of the final rule. The statute requires that the methodology for adjusting fee schedule 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 V.A.5.). The final methodology for making payment adjustments will allow for adjustments based on bids in different geographic regions to reflect regional costs of furnishing items and services or the national limits for adjustments in areas with costs outside of MSAs and areas subject to section 1847(a)(3)(A) of the Act. We believe that suppliers will 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 final special payment rules for certain DME will not have a significant impact on small suppliers. We believe that these rules will benefit affected suppliers since payment for rental of certain DME would no longer be capped and suppliers would retain ownership to the equipment.

We expect the final rule which clarifies the scope of the Medicare statutory exclusion for hearing aids will have no impact on small suppliers as we are not changing current coverage of devices for Medicare payment purposes.

We expect that the final revisions to CHOW rules to allow contract suppliers to sell specific lines of business provision will have a positive impact on suppliers and no significant negative impact on small suppliers.

Therefore, the Secretary has determined that this final rule will have a significant economic impact on a substantial number of small entities. We solicited comment on the RFA analysis provided. The comments and our responses are set forth below.

Comment: Some commenters noted that CMS has not considered the economic and regulatory flexibility analysis under the proposed rule for applying special payment rules for certain DME in competitive bidding areas and the final Methodology for Adjusting DMEPOS Payment Amounts using Information from Competitive Bidding Programs.

Response: We thank the commenters for their input. The continuous rental bundled payment methodology will be phased in for only two items, CPAP device and power wheelchairs in no more than 12 CBAs at this time. Our analysis indicates that establishing single payment amounts based upon bids submitted by suppliers using the continuous rental bundled methodology instead of capped rental methodology for these two items in no more than 12 CBAs will not have a significant impact because the bid limits for power wheelchairs will be based upon current utilization and expenditure in the 12 CBAs. The updated 1993 fee schedule amounts would be the bid limits for CPAP. The 1993 fee schedule represents a fairly accurate bundled rental payment amount for the CPAP and the covered item update factor would cover for improvements in technology. The CPAP fees from 1993 were based on average reasonable

charges from July 1986 through June 1987 for rental of the device with no separate payment for the accessories; we believe the historic amounts fairly reflect the utilization and payment for accessories used with the device. We expect that the final special payment rules will not have a significant impact on small suppliers because of the limited scope of the program. The phase-in of the special payment rules would be limited to only two product categories; Power Wheelchairs and CPAP devices in no more than 12 CBAs.

We expect the final methodologies for adjusting DMEPOS fee schedule amounts using information from DMEPOS CBPs will have a significant impact on a substantial number of small suppliers. However, 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, therefore, the only alternative we can consider other than paying based on adjusted fee schedule amounts is to implement CBPs in all areas, however, our analysis indicates that this approach would have an even greater impact on small suppliers. The statute requires that the methodology for adjusting fee schedule amounts take into consideration the costs of furnishing items and services in areas where the adjustments will occur and we have considered these factors in developing the final methodology, thereby reducing the extent of impact on small suppliers. We believe that suppliers will 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.

XVI. 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 final 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.

XVII. 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 final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

XVIII. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

XIX. 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 website 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 amends 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, "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 hearing aids that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound and bone conduction hearing aids that provide

mechanical stimulation of the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

(2) Devices not subject to the hearing aid exclusion. Paragraph (d)(1) of this section shall not apply to the following devices that produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve:

(i) Osseointegrated implants in the skull bone that provide mechanical energy to the cochlea via a mechanical transducer, or

(ii) 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.

* * * * *

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. No. 113-93.

§ 413.174 [Amended]

6. Section 413.174 (f)(6) is amended by removing “January 1, 2016” and by adding in its place “January 1, 2024”.

7. Section 413.232 is amended by revising paragraph (b) introductory text and paragraph (f) and adding paragraph (h) to read as follows:

§413.232 Low-volume adjustment.

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(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, except that, for calendar year 2012, the attestation must be provided by January 3, 2012, and for, calendar year 2015, the attestation must be provided by December 31, 2014.

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(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.

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).

11. The heading of Subpart D is revised to read as follows**:**

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

12. Section 414.202 is amended by revising the definition of "region" and adding in alphabetical order a definition of "rural area" to read as follows:

§414.202 Definitions.

* * * * *

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 area means, for the purpose of implementing §414.210(g), a geographic area represented by a postal zip code if at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). A rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at §414.210(g) are applied.

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, and for DME items furnished on or after January 1, 2016, the fee schedule amounts shall 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. The methodologies for adjusting fee schedule amounts are provided below. In any case where application of these methodologies results in an increase in the fee schedule amount, the adjustment to the fee schedule amount is not made.

(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 of this part, the fee schedule amounts for such item or service for areas within the contiguous United States shall be adjusted 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 amounts 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 that contains the state or District of Columbia.

(ii) CMS determines a national average price equal to the un-weighted 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.

(iv) The fee schedule amount for all areas within a state that are not defined as rural areas for purposes of this subpart is adjusted to the regional price determined under paragraphs (g)(1)(i) and (iii) of this section.

(v) The fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) <u>Payment adjustments for areas outside the contiguous United States using information from competitive bidding programs</u>. For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States are reduced to 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 reduced to 110 percent of the un-weighted average of the single payment amounts from the ten or fewer competitive bidding programs for the item or service in the areas where the ten or fewer competitive bidding programs are in place.

(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 single payment amounts are updated before being used to adjust the fee schedule amounts. The single payment amounts are updated 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 single payment amounts were in effect to the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustments to the fee schedule amounts, if the adjustments continue to be based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts used to reduce the fee schedule amounts are 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 based on the total number of allowed services for the item on a national basis for the code from each product category prior to applying the payment adjustment methodologies in this section.

(6) Payment adjustments for enteral infusion pumps and standard power wheelchairs. (i) In situations where a single payment amount in a CBA for an enteral infusion pump without alarm is greater than the single payment amount in the same CBA for an enteral infusion pump with alarm, the single payment amount for the enteral infusion pump without alarm is adjusted to be equal to the single payment amount for the enteral infusion pump with alarm prior to applying the payment adjustment methodologies in this section.

(ii) In situations where a single payment amount in a CBA for a Group 1, standard, sling/solid seat and back power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, sling/solid seat and back power wheelchair, the single payment amount for the Group 1, standard, sling/solid seat and back power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, sling/solid seat and back power wheelchair prior to applying the payment adjustment methodologies in this section.

(iii) In situations where a single payment amount in a CBA for a Group 1, standard, captains chair power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, captains chair power wheelchair, the single payment amount for the Group 1, standard, captains chair power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, captains chair power wheelchair prior to applying the payment adjustment methodologies in this section.

(iv) In situations where a single payment amount in a CBA for a Group 2, standard, portable, sling/solid seat and back power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, sling/solid seat and back power wheelchair, the single payment amount for the Group 2, standard, portable, sling/solid seat and back power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, sling/solid seat and back power wheelchair prior to applying the payment adjustment methodologies in this section.

(v) In situations where a single payment amount in a CBA for a Group 2, standard, portable, captains chair power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, captains chair power wheelchair, the single payment amount for the Group 2, standard, portable, captains chair power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, captains chair power wheelchair prior to applying the payment adjustment methodologies in this section.

(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.

(9) Transition rules. The payment adjustments described above are phased in as follows:

(i) For applicable items and services furnished with dates of service from January 1,

2016, through June 30, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(ii) For items and services furnished with dates of service on or after July 1, 2016, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

14. 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 (h), (j)(2), (j)(3), and (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.

15. Section 414.409 is added to read as follows:

§ 414.409 Special payment rules.

(a) Payment on a bundled, continuous rental basis. In no more than 12 CBAs, in conjunction with competitions that begin after January 1, 2015, payment is made on a bundled, continuous monthly rental basis for standard power wheelchairs and continuous positive airway pressure (CPAP) devices. 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 (h), (j)(2), (j)(3), and (j)(7), and (k). The single payment amounts are established based on bids submitted and accepted for furnishing rented standard power wheelchairs and CPAP devices on a monthly basis for each month of medical need during the contract period. The single payment amount for the monthly rental of the 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 circumstance.

(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 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. 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 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 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.

16. 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 standard power wheelchairs 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 D of this part.

(4) The bids submitted for continuous positive airway pressure (CPAP) 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.

* * * * *

17. Section 414.414 is amended by revising paragraph (f) to read as follows:

§414.414 Conditions for awarding contracts.

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(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.

* * * * *

18. Section 414.22 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 needed 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)(C) 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 qualified 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 new qualified entity, 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.

* * * * *

19. Section 414.423 is amended by revising paragraphs (b)(2)(vi), (l) introductory text, (l)(2) introductory text, and (l)(2)(i) to read as follows:

§ 414.423 Appeals Process for Termination of Competitive Bidding Contract.

* * * * *

(b) * * *

(2) * * *

(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) Effect of contract termination.

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(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.

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(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: October 22, 2014.

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: October 26, 2014.

Sylvia M. Burwell,

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