DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413, 414 and 494

[CMS-1651-P]

RIN 0938-AS83

Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model

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

ACTION: Proposed rule.

SUMMARY: This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2017 as well as proposing to implement policies for coverage and payment for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. This rule also proposes to set forth requirements for the ESRD Quality Incentive Program, and proposes to establish and revise requirements for quality reporting and measurement, including the inclusion of new quality measures for payment year (PY) 2020 and beyond and updates to programmatic policies for the PY 2018 and PY 2019 ESRD QIP. This rule also proposes to implement statutory requirements for bid surety bonds

and state licensure for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). This rule also proposes to expand suppliers' appeal rights in the event of a breach of contract action by CMS. In particular, this rule proposes a revision to current regulations to provide that the appeals process is applicable to all breach of contract actions taken by CMS, rather than just for the termination of a competitive bidding contract. It also proposes changes to the methodologies for adjusting fee schedule amounts for DMEPOS using information from Competitive Bidding Programs and for submitting bids and establishing single payment amounts under the Competitive Bidding Programs for certain groupings of similar items with different features. Changes are also proposed to the methodology for establishing bid limits for items under the DMEPOS Competitive Bidding Programs. In addition, this rule also solicits comments on the impacts of coordinating Medicare and Medicaid Durable Medical Equipment for dually eligible beneficiaries. Finally, this rule announces a request for information related to the Comprehensive ESRD Care Model and future payment models affecting renal care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 23, 2016.

Application Submission Deadline: Applications must be received on or before July 15, 2016 for the Comprehensive ESRD Care Model.

ADDRESSES: In commenting, please refer to file code CMS-1651-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on this regulation to

http://www.regulations.gov. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1651-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1651-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

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

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1810.

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

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

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

FOR FURTHER INFORMATION CONTACT:

Janae James, (410) 786-0801 or Michelle Cruse, (410) 786-7540, for issues related to the ESRD PPS, and coverage and payment for renal dialysis services furnished to individuals with AKI.

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

Julia Howard, (410) 786-8645, for issues related to DMEPOS CBP and bid surety bonds, state

licensure, and the appeals process for breach of DMEPOS CBP contract actions.

Anita Greenberg, (410) 786- 4601, or Hafsa Vahora, (410) 786-7899, for issues related to competitive bidding and payment for similar DMEPOS items with different features and bid limits.

Kristen Zycherman, for issues related to DME access issues.

Tom Duvall, (410) 786-8887 or e-mail tom.duvall@cms.hhs.gov, for issues related to the Comprehensive ESRD Care Model.

SUPPLEMENTARY INFORMATION:

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

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

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Regulations Text

Acronyms

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

AAPM	Advanced Alternative Payment Model
ABLE	The Achieving a Better Life Experience Act of 2014
AHRQ	Agency for Healthcare Research and Quality
AKI	Acute Kidney Injury
AMCC	Automated Multi-Channel Chemistry
ANOVA	Analysis of Variance
APM	Alternative Payment Model
ARM	Adjusted Ranking Metric
ASP	Average Sales Price
ATRA	The American Taxpayer Relief Act of 2012
BEA	Bureau of Economic Analysis
BLS	Bureau of Labor Statistics
BMI	Body Mass Index
BSA	Body Surface Area
BSI	Bloodstream Infection

CB	Consolidated Billing
CBA	Competitive Bidding Area
CBP	Competitive Bidding Program
CBSA	Core Based Statistical Area
CCN	CMS Certification Number
CDC	Centers for Disease Control and Prevention
CEC	Comprehensive ESRD Care
CFR	Code of Federal Regulations
CHIP	The Children's Health Insurance Program
CIP	Core Indicators Project
CKD	Chronic Kidney Disease
CLABSI	Central Line Access Bloodstream Infections
CMS	Centers for Medicare & Medicaid Services
CPM	Clinical Performance Measure
CPT	Current Procedural Terminology
CROWNWeb	Consolidated Renal Operations in a Web-Enabled Network
CY	Calendar Year
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics Supplies
DFR	Dialysis Facility Report
ESA	Erythropoiesis stimulating agent
ESCO	End-Stage Renal Disease Seamless Care Organization
ESRD	End-Stage Renal Disease
ESRDB	End-Stage Renal Disease Bundled

ESRD PPS	End-Stage Renal Disease Prospective Payment System
ESRD QIP	End-Stage Renal Disease Quality Incentive Program
FDA	Food and Drug Administration
HAIs	Healthcare-Acquired Infections
HCFA	Health Care Financing Administration
HCPCS	Healthcare Common Procedure Coding System
HD	Hemodialysis
HHD	Home Hemodialysis
HHS	Department of Health and Human Services
HCC	Hierarchical Comorbidity Conditions
HRQOL	Health-Related Quality of Life
ICD	International Classification of Diseases
ICD-9-CM	International Classification of Disease, 9th Revision, Clinical Modification
ICD-10-CM	International Classification of Disease, 10th Revision, Clinical Modification
ICH CAHPS	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IGI	IHS Global Insight
IIC	Inflation-indexed charge
IPPS	Inpatient Prospective Payment System
IUR	Inter-unit reliability
KDIGO	Kidney Disease: Improving Global Outcomes
KDOQI	Kidney Disease Outcome Quality Initiative

KDQOL	Kidney Disease Quality of Life
Kt/V	A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO	Large Dialysis Organization
MAC	Medicare Administrative Contractor
MAP	Medicare Allowable Payment
MCP	Monthly Capitation Payment
MFP	Multifactor Productivity
MIPPA	Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275)
MLR	Minimum Lifetime Requirement
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003
MMEA	Medicare and Medicaid Extenders Act of 2010 Pub. L. 111-309
MSA	Metropolitan statistical areas
NHSN	National Healthcare Safety Network
NQF	National Quality Forum
NQS	National Quality Strategy
NAMES	National Association of Medical Equipment Suppliers
OBRA	Omnibus Budget Reconciliation Act
OMB	Office of Management and Budget
PAMA	Protecting Access to Medicare Act of 2014
PC	Product category
PD	Peritoneal Dialysis
PEN	Parenteral and Enteral nutrition

PFS	Physician Fee Schedule
PPI	Producer Price Index
PPS	Prospective Payment System
PSR	Performance Score Report
PY	Payment Year
QIP	Quality Incentive Program
RCE	Reasonable Compensation Equivalent
REMIS	Renal Management Information System
RFA	Regulatory Flexibility Act
SBA	Small Business Administration
SFA	Small Facility Adjuster
SPA	Single Payment Amount
SRR	Standardized Readmission Ratio
SSA	Social Security Administration
STrR	Standardized Transfusion Ratio
The Act	Social Security Act
The Affordable Care Act	The Patient Protection and Affordable Care Act
The Secretary	Secretary of the Department of Health and Human Services
TPEA	Trade Preferences Extension Act of 2015
TPS	Total Performance Score
URR	Urea reduction ratio
VAT	Vascular Access Type
VBP	Value Based Purchasing

I. Executive Summary

A. Purpose

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

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled prospective payment system for renal dialysis services furnished by ESRD facilities. This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2017. 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.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. No. 114-27). Section 808(a) of TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) to an individual with AKI. Section 808(b) of TPEA amended section 1834 of the Act by adding a new paragraph (r) of the Act that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017.

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

This rule also proposes to set forth requirements for the ESRD QIP, including for payment years (PYs) 2018, 2019, and 2020. 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.

4. Durable Medical Equipment, Prosthetics, Orthotics Supplies (DMEPOS) Competitive Bidding Bid Surety Bonds, State Licensure and Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions Proposals

This rule proposes to implement statutory requirements for Bid Surety Bonds and State Licensure. This rule also proposes to expand suppliers' appeal rights in the event of a breach of contract determination to allow suppliers to appeal any breach of contract action CMS takes, rather than just a termination action. To effect this policy change, we propose revisions to the regulations to provide that the appeals process applies to all breach of contract actions that CMS may take.

5. Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program and Fee Schedule Adjustments

This rule proposes to adjust the methodology for adjusting DMEPOS fee schedule amounts for certain groupings of similar items with different features using information from DMEPOS competitive bidding programs (CBPs), submitting bids and determining single payment amounts for certain groupings of similar items with different features under the DMEPOS CBPs, and establishing bid limits for individual items under the DMEPOS CBP.

B. Summary of the Major Provisions

1. ESRD PPS

- Update to the ESRD PPS base rate for CY 2017: The proposed CY 2017 ESRD PPS base rate is $231.04. This amount reflects a reduced market basket increase as required by section 1881(b)(14)(F)(i)(I) (0.35 percent), and application of the wage index budget-neutrality adjustment factor (0.999552) as well as the application of the training budget-neutrality adjustment factor (0.999729). The proposed CY 2017 ESRD PPS base rate is $231.04 ($230.39 x 1.0035 x 0.999552 x 0.999729 = $231.04).
- Annual update to the wage index and wage index floor: We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2017, we are not proposing any changes to the application of the wage index floor and we propose to continue to apply the current wage index floor (0.400) to areas with wage index values below the floor.
- Update to the outlier policy: Consistent with our proposal to annually update the outlier policy using the most current data, we are proposing to update the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments (MAPs) for adult and pediatric patients for CY 2017 using 2015 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries would increase from $62.19 to $67.44 and the MAP amount would increase from $39.20 to $39.92, as compared to CY 2016 values. For adult beneficiaries, the fixed-dollar loss amount would decrease from $86.97 to $83.00 and the MAP amount would decrease from $50.81 to $47.26. The 1

percent target for outlier payments was not achieved in CY 2015. We believe using CY 2015 claims data to update the outlier MAP and fixed dollar loss amounts for CY 2017 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage.

- Payment for hemodialysis when more than 3 treatments are furnished per week: We are proposing an equivalency payment for hemodialysis (HD) when more than 3 treatments are furnished in a week, similar to what is applied to peritoneal dialysis (PD). Specifically, we would calculate the total weekly amount that would be paid for 3 HD treatments per week and divide that number by the number of treatments furnished in a week when a beneficiary receives more than 3 HD treatments per week.
- The home and self-dialysis training add-on payment adjustment: We are proposing to increase the total number of hours of training by an RN for PD and HD that is accounted for by the home and self-dialysis training add-on payment adjustment (hereinafter referred to as the home dialysis training add-on). The current amount of the home dialysis training add-on is $50.16, which reflects 1.5 hours of training by a nurse per treatment. We propose to calculate the increase based on the average treatment times and weights based on utilization for each modality. We propose to use treatment times as proxies for the total time spent by nurses training beneficiaries for home or self-dialysis in calculating the proposed increase to the home dialysis training add-on, with the assumed hourly wage for a nurse providing dialysis training for 2017 being $35.93. Under this proposal, we would increase the hours of per-

treatment training time provided by a nurse that is accounted for by the home dialysis training add-on to 2.66 hours.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals with AKI

We are implementing the TPEA amendments to sections 1834(r) and 1861(s)(2)(F) by proposing to cover renal dialysis services furnished by renal dialysis facilities paid under section 1881(b)(14) of the Act to individuals with acute kidney injury. We are also proposing to pay ESRD facilities for renal dialysis services furnished to individuals with acute kidney injury at the amount of the ESRD PPS base rate, as adjusted by the ESRD PPS wage index. In addition, drugs, biologicals, and laboratory services that ESRD facilities are certified to furnish, but that are not renal dialysis services, may be paid for separately when furnished by ESRD facilities to individuals with AKI. In addition, because AKI patients are often under the care of a hospital, physician, or other practitioner, these providers could continue to bill Medicare for services outside of the ESRD PPS payment rate.

3. ESRD QIP

This rule proposes to set forth requirements for the ESRD QIP, including for payment years (PYs) 2018, 2019 and 2020.

Updating the Hypercalcemia Clinical Measure: Beginning with the PY 2018 ESRD QIP, we are proposing to update the technical specifications for the Hypercalcemia clinical measure so that they incorporate two substantive updates to the measure that were made during the measure maintenance process at National Quality Forum (NQF). First, plasma was added as an acceptable substrate in addition to serum calcium. Second, the denominator definition changed such that it now includes patients regardless of whether any serum calcium values were reported at the facility during the 3-month study period. These changes will ensure that the measure

aligns with the NQF-endorsed measure and can continue to satisfy the requirements of the Protecting Access to Medicare Act (PAMA), which requires that the ESRD QIP include in its measure set measures (outcomes-based, to the extent feasible), that are specific to the conditions treated with oral-only drugs.

Proposed New Requirements for the PY 2019 ESRD QIP: For PY 2019 and future payment years, we are proposing to reintroduce the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure back into the ESRD QIP measure set. Additionally, for PY 2019 and future payment years, we are proposing to create a new NHSN BSI Measure Topic which will consist of the proposed NHSN Dialysis Event Reporting Measure and the existing NHSN BSI Clinical Measure. We are also proposing to establish a new Safety Measure Domain, which will be separate from, and in addition to, the existing Clinical Measure and Reporting Measure Domains for the purposes of scoring in the ESRD QIP. The proposed Safety Measure Domain will initially consist of the proposed NHSN BSI Measure Topic.

PY 2020 Measure Set: For PY 2020 and future payment years, we are proposing to replace the Mineral Metabolism Reporting Measure with the proposed Serum Phosphorus Reporting Measure because replacing this measure is consistent with our intention to increasingly rely on CROWNWeb as the data source used to calculate measures in the ESRD QIP. Additionally, we are proposing to adopt two new measures: (1) the Standardized Hospitalization Ratio (SHR) Clinical Measure and (2) the Ultrafiltration Rate Reporting Measure.

Updates to Weighting for the Clinical Measure Domain, the Reporting Measure Domain and the Proposed Safety Measure Domain: With the proposed addition of the Safety Measure Domain into the ESRD QIP, we are proposing changes to the weighting of the Clinical Measure

Domain, the Reporting Measure Domain, and we are proposing to establish weights for the proposed Safety Measure Domain for PY 2019 and for PY 2020.

Specifically, for PY 2019 we are proposing to assign 15 percent of a facility's TPS to the proposed Safety Measure Domain, 75 percent of the TPS to the Clinical Measure Domain and 10 percent to the Reporting Measure Domain. To accommodate the removal of the Safety Subdomain from the Clinical Measure Domain, we are proposing to adjust individual measure weights for the measures that remain in the Clinical Measure Domain. For PY 2020, we are proposing to reduce the weight of the Safety Measure Domain to 10 percent of a facility's Total Performance Score. This modification, in combination with the proposed addition of the SHR measure necessitates further adjustments to individual measure weights in the Clinical Measure Domain.

Data Validation: In section IV.C.8 of this proposed rule, we set forth the updates we are proposing to make to the data validation program in the ESRD QIP. For PY 2019, we are proposing to continue the pilot validation study for validation of CROWNWeb data. Under this continued validation study, we are proposing to continue using the same methodology used for the PY 2017 and PY 2018 ESRD QIP. We will sample the same number of records (approximately 10 per facility) from the same number of facilities (that is, 300) during CY 2017. 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.

For PY 2019, we are also proposing to increase the size of the NHSN BSI Data Validation study. Specifically, we propose to randomly select 35 facilities to participate in an NHSN dialysis event validation study for two quarters of data reported in CY 2017. A CMS

contractor will send these facilities requests for medical records for all patients with "candidate events" during the evaluation period, as well as randomly selected patient records. Each facility selected will be required to submit 10 records total to the validation contractor. The CMS contractor will utilize a methodology for reviewing and validating the candidate events and will analyze those records to determine whether the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event Protocol. Information from the validation study may be used to develop a methodology to score facilities based on the accuracy of their reporting of the NHSN BSI measure.

4. DMEPOS Competitive Bidding Bid Surety Bonds, State Licensure and Appeals Process for a Breach of DMEPOS Competitive Bidding Program Contract Action Proposals.

This proposed rule proposes to implement statutory requirements for the DMEPOS CBP for bid surety bonds and state licensure. In addition, we are proposing to define the term "bidding entity" for purposes of the DMEPOS CBP. We also propose to expand suppliers' appeal rights in the event of a breach of contract determination to allow suppliers to appeal any breach of contract action CMS takes, rather than just a termination action. We propose revisions to the regulations to extend the appeals process to all competitive bidding breach of contract actions.

- A bidding entity must obtain a bid surety bond from an authorized surety on the Department of the Treasury's Listing of Certified Companies, submit proof of the surety bond by the deadline for bid submission, and the bond must meet certain specifications. We are proposing to define the term "bidding entity" to mean the entity whose legal business name is identified in the "Form A: Business Organization Information" section of the bid.

- If the bidding entity is offered a contract for any product category for a competitive acquisition area (herein referred to as a "Competitive Bidding Area" or "CBA"), and its composite bid for such product category and area is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for the product category/CBA combination (herein also referred to as "competition"), and the entity does not accept the contract offered, the entity's bid surety bond for the applicable CBA will be forfeited and CMS will collect on the bid surety bond via Electronic Funds Transfer from the respective authorized surety. If the forfeiture conditions are not met, the bond liability will be returned to the bidding entity. Bidding entities that provide a falsified bid surety bond will be prohibited from participation in the DMEPOS CBP for the current round of the CBP in which they submitted a bid and also from bidding in the next round of the CBP. Bidding entities that provide a falsified bid surety bond will also be referred to the Office of Inspector General and Department of Justice for further investigation.
- We propose to conform the language of our regulation at 42 CFR 414.414(b)(3) to the language of section 1847(b)(2)(A)(v) of the Act, as added by section 522 of MACRA, which requires bidding entities to meet applicable State licensure requirements in order to be eligible for a DMEPOS CBP contract. We note, however, that this does not reflect a change in policy as CMS already has a regulation in place to require suppliers to meet applicable State licensure requirements.
- Appeals process for breach of DMEPOS CBP contract actions would extend the appeals process, specified in §414.423, that currently only applies to contract terminations to all breach of contract actions taken by CMS and specified in §414.422(g)(2). We propose to

revise §414.422(g)(2) to eliminate certain breach of contract actions for the reasons explained below. We also propose to revise 414.423(l) to describe the effects of certain breach of contract actions CMS may take.

5. DMEPOS Competitive Bidding Program and Fee Schedule Adjustments

This rule proposes to set forth requirements for the CBP and Fee Schedule Adjustments.

- Methodologies for Adjusting DMEPOS Fee Schedule Amounts for Certain Groupings of Similar Items with Different Features using Information from Competitive Bidding Programs: Within the Healthcare Common Procedure Coding System (HCPCS), there are many instances where there are multiple codes for an item that are distinguished by the addition of a feature (for example, non-powered versus powered mattress, Group 1 versus Group 2 power wheelchair, pump without alarm versus pump with alarm, walker without wheels versus walker with wheels, etc.) Under CBPs, the code with the higher utilization (typically the item with additional features and higher fee schedule amounts) receives a higher weight and the bid for this item has a greater impact on the supplier's composite bid than the bids for the less frequently used codes. This is resulting in price inversions where the single payment amounts (SPAs) for the item without the feature are higher than the SPAs for the item with the feature. This could lead to a program vulnerability by shifting beneficiaries from products with features to less appropriate products without the features because the latter receives higher payment under competitive bidding. We are proposing to limit SPAs for items without a feature to the weighted average of the SPAs for the items both with and without the feature prior to using the SPAs in adjusting the fee schedule amounts for certain groupings of similar items specified below. The item

weights would be the same weights used in calculating the composite bids under the CBP.

- Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items with Different Features under the DMEPOS CBP: This proposal addresses the price inversions under competitive bidding to prevent situations where beneficiaries receive items with fewer features at a higher price than items with more features. In addition to affecting the appropriateness of items supplied to beneficiaries, these price inversions also undermine the CBP and diminish the savings intended from implementation of the program. We are proposing to revise the provisions of §414.408 to add a lead item bidding methodology where all of the HCPCS codes for similar items with different features would be grouped together and would be priced relative to the bid for the lead in order to prevent price inversions under the DMEPOS CBPs. We are proposing this as an alternative to the current bidding methodology that CMS would be able to apply to situations where groupings of similar items have resulted in price inversions based on past experience. This methodology would only replace the current method of bidding for select groupings of similar items within product categories.
- Bid Limits for Individual Items under the DMEPOS CBP: Current regulations require that bids submitted by suppliers under the CBP be lower than the amount that would otherwise apply (that is, the fee schedule amount). This ensures that total payments expected to be made to contract suppliers in a CBA are less than the total amounts that would otherwise be paid, which is a condition mandated by the section 1847(b) of the Act for awarding contracts under the program in an area. Beginning in 2016, the fee schedule amounts for DMEPOS items and services are adjusted based on information from the

CBPs. We indicated in the final rule (79 FR 66232), which was published in the **Federal Register** on November 6, 2014, that these adjusted fee schedule amounts become the bid limits for future competitions (79 FR 66232). We have heard concerns that as the amounts paid under CBPs decline, this may ultimately make it difficult for suppliers to bid below the adjusted fee schedule amounts and accept contract offers at the median bid level. To avoid this situation and enhance the long term viability of the CBPs, we are proposing to limit bids for future competitions to the fee schedule amounts that would otherwise apply as if CBPs had not been implemented and prior to making adjustments to the fee schedule amounts using information from CBPs. This would allow suppliers to take into account both decreases and increases in costs in determining their bids, while ensuring that payments under the CBPs do not exceed the amounts that would otherwise be paid had the DMEPOS CBP not been implemented.

C. Summary of Costs and Benefits

In section XVI.A of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact chart in section XVI.B.1 of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2017 compared to estimated payments in CY 2016. The overall impact of the CY 2017 changes is projected to be a 0.5 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.7 percent increase in payments compared with freestanding facilities with an estimated 0.5 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately

$50 million from CY 2016 to CY 2017. This reflects a $30 million increase from the payment rate update and a $20 million increase due to the updates to the outlier threshold amounts. As a result of the projected 0.5 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 0.5 percent in CY 2017, which translates to approximately $10 million.

2. Impacts of the Proposed Coverage and Payment for Renal Dialysis Services Furnished to Individuals with AKI

We anticipate an estimated $2.0 million being redirected from hospital outpatient departments to ESRD facilities in CY 2017 as a result of some AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus continuing to receive those services in the hospital outpatient setting.

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the ESRD QIP will be approximately $15.5 million in PY 2019 and $113 million in PY 2020. The $15.5 million figure for PY 2019 includes costs associated with the collection of information requirements, which we estimate will be approximately $21 thousand.[1] For PY 2020, we estimate that ESRD facilities will experience an aggregate impact of approximately $113 million as a result of the PY 2020 ESRD QIP.

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

4. Impacts of the DMEPOS Competitive Bidding Bid Surety Bonds, State Licensure and

1 We note that the aggregate impact of the PY 2019 ESRD QIP was included in the CY 2016 ESRD PPS Final Rule (80 FR 68971). The previously finalized aggregate impact of $15.5 million reflects the PY 2019 estimated payment reductions and the collection of information requirements finalized in the PY 2019 ESRD QIP Final Rule.

Appeals Process for a Breach of DMEPOS Competitive Bidding Program Contract Actions Proposals

The DMEPOS CBP bidding entities will be impacted by the bid surety bond requirement as they will be required to purchase a bid surety bond for each CBA in which they are submitting a bid. The state licensure requirement will have no new impact on the supplier community because this is already a Medicare DMEPOS supplier requirement and the appeals process for a breach of a DMEPOS CBP contract action(s) is expected to have a beneficial, positive impact on suppliers.

Overall, the bid surety bond requirement may have a positive financial impact on the program as CMS anticipates that the requirement will encourage all bidding entities to submit substantiated bids. However, there will be an administrative burden for implementation of the bid surety bond requirement for CMS. The state licensure and appeals process for breach of DMEPOS CBP contract actions proposals will have minimal administrative costs.

We do not anticipate that the proposed DMEPOS CBP regulations for bid surety bonds, state licensure, and the appeals process for breach of DMEPOS CBP contract actions will have an impact on Medicare beneficiaries.

5. Impacts of the Proposed DMEPOS Competitive Bidding Program and Fee Schedule Adjustments Proposals

The overall economic impact for the proposed changes to the DMEPOS CBPs and Fee Schedule Adjustments would be about $20 million dollars in savings to the Part B Trust Fund over five years beginning January 1, 2017. The savings is a result of avoiding price inversions. This proposal should have a minor impact on the suppliers of CBAs and in the non-competitive bidding areas (non-CBAs). Beneficiaries would have lower coinsurance payments and receive the most appropriate items as a result of this proposal.

II. Calendar Year (CY) 2017 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

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

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112-240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year

transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required 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, Congress enacted the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93). Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CYs 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. No. 113-295). Section 204 of ABLE

amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at 42 CFR §413.171 and our other payment policies are included in regulations in subpart H of 42 CFR part 413. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area (BSA), low body mass index (BMI), onset of dialysis, four co-morbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (42 CFR 413.235(a) and(b)).

In addition, the ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (42 CFR 413.232). The second adjustment reflects differences in area wage levels developed from Core Based Statistical Areas (CBSAs) (42 CFR 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (42 CFR 413.233).

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

3. Updates to the ESRD PPS

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

On November 6, 2015, we published in the **Federal Register** a final rule (80 FR 68968 through 69077) titled, "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Final Rule" (hereinafter referred to as the CY 2016 ESRD PPS final rule). In that final rule, we made a number of routine updates to the ESRD PPS for CY 2016, refined the ESRD PPS case-mix adjustments, implemented a drug designation process, updated the outlier policy, and made additional policy changes and clarifications. Specifically, in that rule, we finalized the following:

- ESRD PPS refinement: In accordance with section 632(c) of ATRA, we analyzed the case-mix payment adjustments under the ESRD PPS using more recent data. We revised the adjustments by changing the adjustment payment amounts based on our updated regression analysis using CYs 2012 and 2013 ESRD claims and cost report data. In addition, we removed two comorbidity category payment adjustments (bacterial pneumonia and monoclonal gammopathy). Because we conducted an updated regression analysis to enable us to analyze and revise the case-mix payment adjustments, we also revised the low-volume payment adjustment (LVPA) and implemented a new rural adjustment based on that regression analysis. We finalized new patient and facility-level

adjustment factors and also revised the geographic proximity eligibility criterion for the LVPA and removed grandfathering from the criteria for the adjustment.

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

- Update to the ESRD PPS base rate for CY 2016: The CY 2016 ESRD PPS base rate was finalized at $230.39. This amount reflected a reduced market basket percentage rate of increase as required by section 1881(b)(14)(F)(i)(I) (0.15 percent), application of the wage index budget-neutrality adjustment factor (1.000495), and a refinement budget-neutrality adjustment factor (0.960319). The final CY 2016 ESRD PPS base rate was $230.39 ($239.43 x 1.000495 x 1.0015 x 0.960319 = $230.39).

- Annual update to the wage index and wage index floor: We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2016, we completed the 2-year transition to both the updated CBSA delineations and the labor-related share to which the wage index is applied (50.673 percent). In addition, we computed a wage index budget-neutrality adjustment factor of 1.000495, which was applied to the ESRD PPS base rate. We finalized the continuation of the application of the current wage index floor (0.4000) to areas with wage index values below the floor.

- Update to the outlier policy: We update the outlier policy using the most current data. Specifically, we updated the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments (MAPs) for adult and pediatric patients for CY 2016 using 2014 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries increased from $54.35 to $62.19 and the MAP amount decreased from $43.57 to $39.20, as compared to CY 2015 values. For adult beneficiaries, the fixed-dollar loss amount increased from $86.19 to $86.97 and the MAP amount decreased from $51.29 to $50.81. The 1.0 percent target for outlier payments was not achieved in CY 2014 (0.8 percent rather than 1.0 percent). We believe using CY 2014 claims data to update the outlier MAP and fixed dollar loss amounts for CY 2016 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1.0 percent outlier percentage.

B. Provisions of the Proposed Rule

1. Payment for Hemodialysis When More Than 3 Treatments Are Furnished per Week

a. Background

Since the composite rate payment system was implemented in the 1980s, we have reimbursed ESRD facilities for up to three hemodialysis (HD) treatments per week and only paid for weekly dialysis treatments beyond this limit when those treatments were medically justified due to the presence of specific comorbid diagnoses that necessitate additional dialysis treatments (see paragraph (d) of this section). When we implemented the ESRD PPS in 2011, we adopted a per treatment unit of payment (75 FR 49064). This per treatment unit of payment is the same base rate that is paid for all dialysis treatment modalities furnished by an ESRD facility (HD and the various forms of peritoneal dialysis (PD)) (75 FR 49115). Consistent with our policy since

the composite rate payment system was implemented in the 1980s, we also adopted the 3-times weekly payment limit for HD under the ESRD PPS (74 FR 49931). When a beneficiary's plan of care requires more than 3 weekly dialysis treatments, whether HD or daily PD, we apply payment edits to ensure that Medicare payment on the monthly claim is consistent with the 3-times weekly dialysis treatment payment limit. Thus, for a 30-day month, payment is limited to 13 treatments, and for a 31-day month payment is limited to 14 treatments.

Because PD is typically furnished more frequently than HD, we calculate HD-equivalent payment rates for PD that are based on the ESRD PPS base rate per treatment. To do this, we adjust the base rate by any applicable patient- or facility-level adjustments, and then multiply the adjusted base rate by 3 (the weekly treatment limit), and divide this number by 7. This approach creates a per treatment amount that is paid for each day of PD treatment and that complies with the monthly treatment payment limit. With regard to HD, because we do not have a payment mechanism for the ESRD facility to bill and be paid for every treatment furnished when more than 3 treatments are furnished per week (for example, how they bill daily for PD), we apply edits to the monthly claim so that in total for the month (as described above) Medicare does not make payment for more than 3 weekly HD treatments. In the situation where an ESRD facility bills for more than 3 weekly HD treatments (or more than 13 or 14 for the month, depending on the days in the month) without medical justification, we deny payment for the additional HD treatments. We calculate HD-equivalent payments for PD so that the amount we pay for dialysis is modality-neutral. As we explained in the CY 2011 ESRD PPS final rule (75 FR 49115), we chose not to use dialysis modality as a payment variable when we developed the ESRD PPS because utilizing one dialysis-neutral payment resulted in a slightly higher payment for PD than a modality-specific payment, which we believed would encourage home dialysis, which is

typically PD.

In recent years, ESRD facilities have increasingly begun to offer HD where the standard treatment regimen exceeds 3 treatments per week. At the same time, we observed variation in how MACs processed claims for HD treatments exceeding three treatments per week, resulting in payment of more than 13 or 14 treatments per month. As a result, in the CY 2015 ESRD PPS final rule (79 FR 66145 through 66147), we reminded ESRD facilities and MACs that the Medicare ESRD benefit allows for the payment of 3 weekly dialysis treatments, and that additional weekly dialysis treatments may be paid only if there is documented medical justification. Additional conventional HD treatments are reimbursed at the full ESRD PPS payment if the facility's Medicare Administrative Contractor (MAC) determines the treatments are medically justified based on a patient condition, such as congestive heart failure or pregnancy. MACs have developed local coverage determinations and automated processes to pay for all the treatments reported on the claim if the ESRD facility reports diagnoses determined by the MAC to medically justify treatments beyond 3 times per week.

The option to furnish more than 3 HD treatments per week is the result of evolving technology. We believe that use of this treatment option provides a level of toxin clearance on a weekly basis similar to that achieved through 3-times weekly conventional in-center HD. However, HD treatments exceeding three times per week are generally shorter and afford patients greater flexibility in managing their ESRD and other activities. As stated above, under the ESRD PPS, we currently do not have a payment mechanism that could apply a 3 treatments-per week equivalency to claims for patients with prescriptions for more than 3 HD treatments per week that do not have medical justification (see paragraph (d) of this section). As a result, the additional payments for treatments beyond 3 per week are denied, except where medically

justified. Payment for HD treatments that exceed 3 treatments per week occurs when those treatments are medically justified, as indicated by diagnosis codes. There are specific conditions that require more medical attention, documentation in the medical record, and the results of the higher frequency treatments can be objectively measured through the collection of testing data and are therefore justified as necessary. In cases where the HD exceeds 3 treatments per week for reasons other than medical justification, there is a lack of objective data to justify additional payment for HD treatments beyond 3 treatments per week.

ESRD facilities have expressed concern that due to the monthly payment limit of 13 or 14 treatments, they are unable to report all dialysis treatments on their monthly claim, and therefore, they are not appropriately paid for each treatment furnished. We understand ESRD facilities' concerns and also would like to ensure that facilities are able to accurately report all of the treatments they furnish. Therefore, we analyzed 2015 ESRD facility claims data and found that there is a discrepancy between treatments furnished and treatments billed and paid for HD patients. The data indicate that HD patients are receiving HD treatments in excess of 3 per week, but facilities are usually only being paid for 3 treatments per week. The creation of an equivalency payment mechanism serves multiple purposes. First, it allows for payment for situations in which more than 3 HD treatments are furnished in a week that complies with the 3 treatment per week payment limit. Second, it encourages facilities to report all treatments furnished. This, in turn, would provide us with the information necessary to determine exactly how many treatments are being furnished. Finally, it would allocate the total amount of payment based on 3 HD sessions per week in accordance with the number of treatments actually furnished. For these reasons, we are proposing a payment equivalency for HD treatment regimens when more than 3 treatments are furnished per week, similar to the HD-equivalency

payment that has been used for PD since the composite rate payment system was implemented in 1983. As discussed in paragraph (d) of this section, while the policy would be effective January 1, 2017, we are proposing not to implement the HD equivalency payments until July 1, 2017. We believe it is necessary to delay implementation of this policy until July 1, 2017 to allow time to make operational changes to accommodate this new payment mechanism. We would expect that, for dates of service between January 1, 2017 and July 1, 2017, facilities would continue to submit claims under the current claims submission parameters. Once the operational elements are implemented on July 1, 2017, facilities will be expected to have the appropriate billing systems in place to accommodate claims submission changes. Educational materials will be distributed to stakeholders as the claims processing changes are implemented.

b. Proposed Payment Methodology for HD When More Than 3 Treatments are Furnished per Week

For CY 2017, for adult patients, we propose to calculate a per treatment payment amount that would be based upon the number of treatments prescribed by the physician and would be composed of the ESRD PPS base rate as adjusted by applicable patient and facility-level adjustments, the home dialysis training add-on (if applicable), and the outlier payment adjustment (if applicable). As discussed above, the policy would be effective on January 1, 2017, but the operational elements would be implemented no later than July 1, 2017 to give interested parties time to operationalize the changes. For dates of service from January 1, 2017 through June 30, 2017, facilities would submit claims consistent with current payment limits. On July 1, 2017, the operational changes will be implemented and facilities would be expected to submit claims in compliance with the new policy where more than 3 HD treatments can be billed for a week and paid using the HD equivalency payment. To calculate the equivalency payment

where more than 3 HD treatments are furnished per week, we would first adjust the ESRD PPS base rate by the applicable patient-level adjustments (patient age, body surface area, low body mass index, comorbidities – acute and chronic, and onset of dialysis) and facility-level adjustments (wage index, rural facility, and low-volume facility). Second, we would multiply the adjusted ESRD PPS base rate by 3 to develop the weekly treatment amount and then we would divide this number by the number of treatments prescribed to determine the per treatment amount. Third, we would multiply the calculated outlier payment amount by 3 and divide this number by the number of treatments prescribed to determine the per treatment outlier amount. Finally, we would add the per-treatment ESRD PPS base rate and the per treatment outlier amount together to determine the final per treatment payment amount. For example, a beneficiary whose prescription indicates 5 treatments per week would be paid as follows: (Adjusted Base Rate * 3/5) + (Outlier Payment * 3/5) = per treatment payment amount.

While we are proposing an equivalency payment based on 3 HD treatments per week, ESRD facilities submit bills monthly and, as a result, the monthly maximums presented below are the treatment limits that would be applied to 30-day and 31-day months:

Prescribed weekly treatments	Maximum number of monthly treatments – 30 day month	Maximum number of monthly treatments – 31 day month
4	18	19
5	23	24
6	26	27
7	30	31

For pediatric patients, the calculation would be the same as that proposed for adult patients, except that the ESRD PPS payment amount for pediatric patients would be based on the pediatric case mix adjustments and would not include the rural or low-volume facility-level adjustments.

In order to accommodate this proposed policy change, we would establish new claim

processing guidelines and edits that would allow facilities to report the prescribed number of HD treatments for each patient. There would be individual claims processing system identifiers established for treatments provided 4 times per week, 5 times per week, 6 times per week, and 7 times per week. These identifiers would allow the claims processing system to adjust the payment calculation and allow the appropriate payment for each treatment.

c. Proposed Implementation Strategy

We are proposing that this policy change would be effective on January 1, 2017 but implemented on July 1, 2017, in order to allow sufficient time for CMS and ESRD facilities to implement necessary operational and systems changes. We recognize that this is a substantial change for the ESRD facility's billing systems and for the MACs and we want to allow ample time for changes to be implemented.

d. Applicability to Medically-Justified Treatments

While the majority of ESRD patients are prescribed conventional 3-times-per-week HD, we have always recognized that some patient conditions benefit from more than 3 HD sessions per week and as such, we developed a policy for payment of medically necessary dialysis treatments beyond the 3-treatments-per-week payment limit. Under this policy, the MACs determine whether additional treatments furnished during a month are medically necessary and when the MACs determine that the additional treatments are medically justified, we pay the full base rate for the additional treatments. While Medicare does not define specific patient conditions that meet the requirements of medical necessity, the MACs consider appropriate patient conditions that would result in a patient's medical need for additional dialysis treatments (for example, excess fluid). When such patient conditions are indicated on the claim, we instruct MACs to consider medical justification and the appropriateness of payment for the additional

sessions.

Extra treatments that are medically justifiable would be for conditions such as congestive heart failure. The medical necessity for additional dialysis sessions must be documented in the patient's medical record at the dialysis facility and available for review upon request. The documentation should include the physician's progress notes, the dialysis records and the results of pertinent laboratory tests. The submitted medical record must support the use of the diagnosis code(s) reported on the claim and the medical record documentation must support the medical necessity of the services. This documentation would need to be available to the contractor upon request.

In section 50.A of the Medicare Benefit Policy Manual (Pub. 100–02), we explain our policy regarding payment for HD-equivalent PD and payment for more than 3 dialysis treatments per week under the ESRD PPS. This proposal does not affect our policy to pay the full ESRD PPS base rate for medically justified treatments beyond 3 treatments per week. Rather, the intent of this proposal is to provide a mechanism for payment for evolving technologies that provide for a different schedule of treatments that accommodate a patient's preference and thereby improve that patient's quality of life. In the event that a beneficiary receives traditional HD treatments in excess of 3 per week without medical justification for the additional treatments, these additional treatments will not be paid.

e. Applicability to Home and Self-Dialysis Training Treatments

Beneficiary training is crucial for the long-term efficacy of home dialysis. Under our current policy for PD training, we pay the full ESRD PPS base rate, not the daily HD-equivalent payment amount, for each PD training treatment a beneficiary receives up to the limit of 15 training treatments for PD. As we stated in the CY 2011 ESRD PPS final rule (75 FR 49056) we

pay the full ESRD PPS base rate during training because it is the base rate that accounts for the costs involved in furnishing the treatment and the add-on accounts for the additional staffing costs that are incurred. As we discuss in section II.B.2, we are investigating payments and costs related to training and plan to refine training payments in the future. Until that time, we believe that paying the full base rate during training continues to support home dialysis modalities. When training accompanies HD treatments exceeding 3 per week, the training would continue to be limited to 25 sessions, in accordance with our policy for training for conventional HD.

Because the home dialysis training add-on under the ESRD PPS (described in more detail in section II.B.2 of this proposed rule) is applied to each treatment on training claims up to the applicable limits for HD or PD, we anticipate that ESRD facilities will appreciate the ability to receive payment for each training treatment when more than 3 HD treatments are furnished per week and training is furnished with each of those treatments. We believe this effect of our proposed policy would be beneficial to facilities and beneficiaries receiving HD treatment more than 3 times per week because, as mentioned above, under our current policy, our claim edits only allow payment for 13 or 14 HD treatments in a monthly billing cycle. This means that ESRD facilities can only bill for 13 or 14 treatments for the month and may not receive the full number of home dialysis training add-on for the treatments that would otherwise be billable because of these payment limits. We believe that permitting facilities to bill for training treatments that are furnished to beneficiaries receiving more than 3 HD treatments per week will allow these facilities to receive payment for training more consistently with how they are furnishing these treatments. We expect ESRD facilities to engage patients in the decision making process for determining the best candidates for additional weekly hemodialysis beyond 3 treatments per week and thoroughly discuss with the patient the potential benefits and adverse

effects associated with more frequent dialysis. For example, while there could be potential quality of life and physiological benefits there is also risk of a possible increase in vascular access procedures and the potential for hypotension during dialysis.

We believe this proposed payment mechanism, if finalized, would provide several benefits. Facilities would be able to bill for treatments accurately and be paid appropriately for the treatments they furnish. This policy would provide clarity for the MACs and providers on billing and payment for HD regimens that exceed 3 treatments per week and assist MACs in determining which HD treatments should be paid at the equivalency payment rate and which HD treatments should be paid at the full base rate because the facility has provided adequate evidence of medical justification. Beneficiaries and facilities would have more flexibility to request and furnish patient-centered treatment options. Finally, the proposal would increase the accuracy of payments and data and would provide CMS the ability to monitor outcomes for beneficiaries utilizing various treatment frequencies.

2. Home and Self-Dialysis Training Add-on Payment Adjustment

a. Background

In 2014, Medicare paid approximately $30 million to ESRD facilities for home and self-dialysis training claims, $6 million of which is in the form of home dialysis training add-on payments. These payments accounted for 115,593 dialysis training treatments (77,481 peritoneal dialysis (PD) training treatments and 38,112 hemodialysis (HD) training treatments) for 12,829 PD beneficiaries and 2,443 HD beneficiaries. Hereinafter, we will refer to this training as home dialysis training. Under the ESRD PPS, there are three components to payment for home dialysis training: the base rate, a wage-adjusted home dialysis training add-on payment, and an

allowable number of training treatments to which the training add-on payment can be applied.

When the ESRD PPS was implemented in 2011, we proposed that the cost for all home dialysis services would be included in the bundled payment (74 FR 49930), and therefore, the computation of the base rate included home dialysis training add-on payments made to facilities as well as all composite rate payments, which account for facility costs associated with equipment, supplies, and staffing. In response to public comments, in the CY 2011 ESRD PPS final rule, we noted that although we were continuing to include training payments in computing the ESRD PPS base rate, we agreed with commenters that we should treat training as an adjustment under the ESRD PPS. Accordingly, we finalized the home dialysis training add-on amount of $33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either HD or PD training or retraining (75 FR 49063). In addition, we continued the policy of paying the home dialysis training add-on payment for 15 training treatments for PD and 25 training treatments for HD. In 2011, the amount we finalized for the home dialysis training add-on was $33.44, which was updated from the previous adjustment amount of $20. This updated amount of $33.44 per treatment was based on the national average hourly wage for nurses from the Bureau of Labor Statistics data updated to 2011 (75 FR 49063), and reflects 1 hour of training time by a registered nurse (RN) for both HD and PD. Section 494.100(a)(2) of the Conditions for Coverage for ESRD Facilities stipulates that the RN must conduct the home dialysis training, but in the ESRD Program Interpretive Guidance published October 3, 2008 (http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf) we clarify that other members of the clinical dialysis staff may assist in providing the home training. We also elaborate in this guidance that the qualified home training RN is responsible for

ensuring that the training is in accordance with the requirements at § 494.100, with oversight from the ESRD facility's interdisciplinary team.

The $33.44 amount of the home dialysis training add-on was based on the national mean hourly wage for Registered Nurses as published by the Occupational Employment Statistics (OES) data compiled by the Bureau of Labor Statistics (BLS). This mean hourly wage was then inflated to 2011 by the ESRD wages and salaries proxy used in the 2008-based ESRD bundled market basket. In the calendar year (CY) 2014 ESRD PPS final rule (78 FR 72185), CMS further increased this amount from $33.44 to $50.16 to reflect 1.5 hours of training time by an RN in response to stakeholder concerns that the training add-on was insufficient. The $50.16 training add-on amount was consistent with average costs based on an analysis of pre-PPS cost report data.

In response to the CY 2016 ESRD PPS proposed rule, we received a significant number of stakeholder comments concerning the adequacy of the home dialysis training add-on for HD. Because we did not make any proposals regarding the home dialysis training add-on in the CY 2016 ESRD PPS proposed rule, we made no changes to the home dialysis training add-on for CY 2016 but we did provide a history of the home dialysis training add-on and stated our intention to conduct further analysis of the adjustment.

While some commenters, primarily patients on home HD and a manufacturer of home HD machines, requested that we increase the home dialysis training add-on payment adjustment so that more ESRD patients could receive the benefit of home HD, we also heard from large dialysis organizations (LDOs) that the current home dialysis training add-on amount is sufficient. In addition to these differing viewpoints, we received public comments indicating a wide variance in training hours per treatment and the number of training sessions provided. As we

indicated in the CY 2016 ESRD PPS final rule (80 FR 69004), patients who have been trained for home HD and their caregivers have stated that the RN training time per session spanned from 2 to 6 hours per training treatment and the number of training sessions ranged from 6 to 25 sessions. Home HD patients also acknowledged that the training they received took place in a group setting, indicating perhaps that the amount of hands-on RN training time gradually decreased over the course of training so that by the end of training, the patient was able to perform home dialysis independently.

In order to incentivize the use of PD when medically appropriate, Medicare pays the same home dialysis training add-on for all home dialysis training treatments for both PD and HD, even though PD training takes fewer hours per training treatment. It has never been our intention that the training add-on payment adjustment would reimburse a facility for all of its costs associated with home dialysis training treatments. Rather, for each home dialysis training treatment, Medicare pays the ESRD PPS base rate, all applicable case-mix and facility-level adjustments, and outlier payments plus a training add-on payment of $50.16 to account for RN time devoted to training. The home dialysis training add-on payment provides ESRD facilities with payment in addition to the ESRD PPS payment amount. Therefore, the ESRD PPS payment amount plus the $50.16 training add-on payment should be considered the Medicare payment for each home dialysis training treatment and not the home dialysis training add-on payment alone.

As we indicated in the CY 2016 ESRD PPS final rule, we committed to analyzing the home dialysis training add-on to determine whether an increase in the amount of the adjustment is appropriate. To begin an analysis of the home dialysis training add-on payment adjustment, we looked at the information on 2014 ESRD facility claims and cost reports.

b. Analysis of ESRD Facility Claims Data

We analyzed the ESRD facility claims data to evaluate if the information currently reported provides a clear representation of the utilization of training. We note that after an initial home dialysis training program is completed, ESRD facilities may bill for the retraining of patients who continue to be good candidates for home dialysis. Retraining is allowed for certain reasons as specified in the Medicare Claims Processing Manual (Pub 100-4, Chapter 8, section 50.8): the patient changes from one dialysis modality to another (for example, from PD to HD); the patient's home dialysis equipment changes; the patient's dialysis setting changes; the patient's dialysis partner changes; or the patient's medical condition changes (for example, temporary memory loss due to stroke, physical impairment). Currently, we are not able to differentiate training treatments from retraining treatments. That is, all training claims are billed with condition code 73, which is what an ESRD facility would use for both training and retraining treatments. Under the current claims processing systems, there is no mechanism that limits the allowable training treatments to, 25 for HD and 15 for PD. Therefore, we are unable to clearly tell when the patient is still training on the modality versus when they have completed the initial training and need retraining for one of these reasons provided in the claims processing manual noted above. To be able to make informed decisions on future training payment policies we would need to have specificity regarding the utilization for each service. For example, once we have more specific data indicating the actual number of training treatments furnished, we could refine the payment policy. We are interested in assessing the extent to which patients are retrained and the number of retraining sessions furnished. The findings of this assessment will inform future decisions about how we compute the training add-on payment and whether we should consider payment edits for retraining treatments. For this reason, we are planning to issue

sub-regulatory guidance to provide a method for facilities to report retraining treatments. We are soliciting input from stakeholders on retraining, how often retraining occurs, how much RN time is involved, and the most common reason for retraining.

In addition, ESRD facilities have indicated they are unable to report all treatments furnished on the monthly claim. For this reason, we believe the number of training treatments currently reported on claims may be inaccurate. As discussed in detail in section II.B.1.a of this proposed rule, there are claims processing edits in place that prevent reporting of HD treatments, including both training and maintenance treatments, that exceed the number of treatments typically furnished for conventional HD, that is, 3 per week, unless the additional treatments are medically justified. This is because of the longstanding Medicare payment policy of basing payment on 3 HD treatments per week, which, for claims processing purposes is 13 to 14 treatments per month. As we discuss in detail in section II.B.1.a of this proposed rule, for PD, which is furnished multiple times each day, ESRD facilities report a treatment every day of the month and MACs pay for these treatments by applying an HD-equivalent daily rate. We are proposing a similar payment approach for HD treatments furnished more than 3 times per week, which would allow facilities to report all HD treatments furnished, but payment would be made based on a 3 treatments per week daily rate. Implementation of the proposed HD payment equivalency would allow facilities to bill accurately for all the HD treatments furnished during home dialysis training, which would better align Medicare payments for training to when facilities are incurring the cost for training.

Further, we believe that finalizing the proposed HD payment equivalency and establishing coding for retraining will greatly improve the accuracy of the reporting of training treatments. We solicit comments on this approach for improving reporting on ESRD facility

claims.

c. Technical Correction of the Total Training Payment in the CY 2016 Rule

In the CY 2016 Final Rule (80 FR 60093), we incorrectly cited the payment amount to facilities for HD training as $1,881 based on a total of 37.5 hours of training. The amount we should have cited is $1,254. This is the result of a multiplication error.

d. Analysis of ESRD Cost Report Data

CMS has evaluated 2014 ESRD cost report data in an effort to identify the nature of the specific costs reported by ESRD facilities associated with home dialysis training treatments. We found that there is a significant disparity among facilities with regard to their reported average cost per home dialysis training treatment particular to HD training, ranging from under $100 per treatment to as high as several thousand dollars per treatment. Because of this substantial variation, we believe that the cost report data we currently collect cannot be used to accurately gauge the adequacy of the current $50.16 amount of the per treatment training add-on and that additional cost reporting instructions are necessary. We believe that the cost difference between training treatment costs and maintenance treatment costs is primarily the additional staff time required for training and inconsistencies in how to report related costs. All other training costs, that is, equipment, supplies, and support staff are accounted for in the ESRD PPS base rate. Based on this understanding, extreme variations in staff time should not occur as the number of hours required should fluctuate only slightly for some patients depending on modality or other factors. However, one patient needing a total nursing time of 1-2 hours compared to another patient needing 50 hours for the same modality indicates a lack of precision in the data. In response to these findings and in an effort to obtain a greater understanding of costs for dialysis facilities, CMS is considering a 3-pronged approach to improve the quality and the value of the

cost report data and to enable us to use the average cost per home dialysis training treatment reported by ESRD facilities to set the amount of the training add-on payment adjustment in the future.

First, CMS would complete an in-depth analysis of cost report data elements. The analysis would assist CMS in determining what areas of the cost report are being incorrectly populated by ESRD facilities, what fields are left blank, and which ESRD facilities are deviating from the instructions for the proper completion of various fields within the report. Once we identify facilities that are deviating from proper reporting procedures, we would further evaluate the specific nature of how other ESRD facilities' cost reports were completed to see if there is a systemic problem that may be the result of imprecise instructions. If so, we would update the instructions appropriately to fix the common error. If we believe the instructions are clear but facilities are not following the guidance, we would work through the MACs to correct errors. We anticipate the result of our analysis will be greater uniformity in reporting methods and in turn, heightened data quality in future years.

Second, in accordance with section 217(e) of PAMA, CMS is currently performing comprehensive audits of ESRD facility cost reports. We anticipate the audits will result in greater uniformity in reporting methods and in turn, heightened data quality in future years.

Third, we are considering an update to the independent ESRD facility cost report (CMS-265-11) to include new fields and to rework several worksheets in an effort to obtain more granularity in data on home dialysis training. Also, we are considering a locking mechanism that would prevent a facility from submitting a cost report if certain key fields have not been completed, such as those in Worksheet S, allowing CMS to capture the needed information to appropriately pay home dialysis training by an RN.

e. Proposed Increase to the Home and Self-Dialysis Training Add-on Payment Adjustment

Based on our analysis of ESRD facility claims and cost reports which we describe above, we are pursuing changes which we believe will enable us to use the data to set the home dialysis training add-on payment adjustment in the future. Although we have already begun the process to implement changes to the cost report and claims, it will take several years for the changes to be implemented and yield data we could use as the basis for a change in the home training add-on payment adjustment. However, each year since implementation of the ESRD PPS in 2011, we have received public comments about the inadequacy of the home dialysis training add-on payment adjustment. In addition, we are committed to ensuring that all beneficiaries who are appropriate candidates for home dialysis have access to these treatment options, which generally improve beneficiaries' quality of life. For these reasons, we looked for a reasonable proxy for the home training add-on so that we could provide additional payments to support home dialysis in the interim until we are able to make changes to the home dialysis training add-on based on claims and cost report data.

Under the ESRD PPS, and in accordance with section 1881(b)(14)(A)(i) of the Act, we implemented a single base rate that applies to all treatments, even though PD costs facilities less than HD in terms of staff time, equipment, and supplies. To be consistent with this payment approach for routine maintenance dialysis treatments, we implemented a single home dialysis training add-on for both PD and HD, even though home dialysis training for PD takes half the time per training treatment on average than HD.

In order to maintain this payment approach and provide an increase in the payment for home dialysis training treatments, we are proposing an increase in the single home dialysis training add-on amount for PD and HD, based on the average treatment time for PD and HD and

the percentage of total training treatments for each modality as a proxy for nurse training time. We have received industry feedback that our training payment amount is not adequate. In addition, as KDOQI guidelines specify an average HD time of 4 hours and an average PD time of 2 hours, this tells us our payment should reflect a number of hours somewhere in this range. Because our current payment reflects 1.5 hours, we propose increasing the number of hours using the weighted average formula described below, until such time as we have data that concretely indicates what an adequate payment should be.

For wages, we would use the latest Occupational Employment Statistics (http://www.bls.gov/oes/tables.htm) released by BLS ($34.14 in 2015), inflated to CY 2017 using the wages and salaries proxy used in the 2012-based ESRD bundled market basket. This would result in a new RN hourly wage of $35.93. For the hours, we are proposing an increase to the number of hours of home dialysis training by an RN that is accounted for by the home dialysis training add-on. We would use the average treatment times for PD and HD as a proxies for training times. The sources we researched indicated 4 hours is a clinically appropriate length of time for HD and 2 hours is a clinically appropriate length of time for a PD treatment. The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines and educational material from various patient advocacy groups are examples of these sources. Since PD training is approximately 67 percent of total training treatments and takes an average of 2 hours per treatment and HD is 33 percent of total training treatments and takes an average of 4 hours per treatment, we propose to base the payment for home dialysis training on 2.66 hours of treatment time ((.67 x 2 hours) + (.33 x 4 hours) = 2.66 hours) resulting in a training add-on payment of $95.57 (2.66 hours x $35.93 = $95.57). This would provide for an increase of $45.41 per training treatment (that is, $95.57 – $50.16 = $45.41). . This approach would provide a

significant increase in payment for home dialysis training for CY 2017 while maintaining consistent payment for both PD and HD modalities. Again, given that we are unable at this time to utilize cost report information to set the training add-on payment and that the number of hours of home dialysis training by an RN varies over the course of training, we believe using average treatment time for PD and HD as a proxy for training by an RN is reasonable. Once we have more specific and uniform cost report data to analyze, we intend to compare the average cost per training treatment for PD and HD to the proxy value of $95.57, assess the extent to which the home dialysis training add-on reflects ESRD facility costs for home dialysis training on average, and propose a new training add-on which may either be an increase or a decrease from the CY 2017 training add-on amount.

As we did in CY 2014 when we last increased the training add-on payment, we are proposing that the proposed increase in the training add-on payment would be made in a budget neutral manner by applying a budget neutrality adjustment to the ESRD PPS base rate. The proposed increase would result in a budget neutrality adjustment of 0.999729.

3. Proposed CY 2017 ESRD PPS Update

a. ESRD Bundled Market Basket

i. Proposed CY 2017 ESRD Market Basket Update, Productivity Adjustment, and Labor-Related Share for ESRD PPS

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the

increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

Section 1881(b)(14)(F)(i)(I) of the Act, as added by section 217(b)(2)(A) of PAMA, provides that in order to accomplish the purposes of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the market basket percentage increase factor for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1.0 percentage point for 2018. Accordingly, for CY 2017, we will reduce the proposed amount of the market basket percentage increase factor by 1.25 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, and will further reduce it by the productivity adjustment.

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

We propose to use the CY 2012-based ESRDB market basket as finalized and described in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136) to compute the CY 2017 ESRDB market basket increase factor and labor-related share based on the best available data.

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

Using this methodology and the IGI forecast for the first quarter of 2016 of the CY 2012-based ESRDB market basket (with historical data through the fourth quarter of 2015), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2017 ESRDB market basket increase factor is 2.1 percent. As required by section 1881(b)(14)(F)(I)(i) of the Act as amended by section 217(b)(2) of PAMA, we must reduce the amount of the market basket increase factor by 1.25 percent, resulting in a proposed CY 2017 ESRDB market basket percentage increase factor of 0.85 percent.

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. MFP is derived by subtracting the contribution of labor and capital input growth from output growth, the detailed methodology for deriving the MFP projection was finalized in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504). The most up-to-date MFP projection methodology is available on the CMS website at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.

Using IGI's first quarter 2016 forecast, the MFP adjustment for CY 2017 (the 10-year moving average of MFP for the period ending CY 2017) is projected to be 0.5 percent.

For the CY 2017 ESRD payment update, we propose to continue using a labor-related share of 50.673 percent for the ESRD PPS payment, which was finalized in the CY 2015 ESRD final rule (79 FR 66136).

ii. Proposed CY 2017 ESRDB Market Basket Update, Adjusted for Multifactor Productivity (MFP)

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 2017, section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, requires the Secretary to implement a 1.25 percentage point reduction to the ESRDB market basket increase factor in addition to the productivity adjustment.

As a result of these provisions, the proposed CY 2017 ESRD market basket increase is 0.35 percent. This market basket increase is calculated by starting with the proposed CY 2017 ESRDB market basket percentage increase factor of 2.1 percent, reducing it by the mandated legislative adjustment of 1.25 percent (required by section 1881(b)(14)(F)(I)(i)), and reducing it further by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2017) of 0.5 percent. As is our general practice, if more recent data are subsequently available (for example, a more recent estimate of the market basket or MFP adjustment), we will use such data to determine the CY 2017 market basket update and MFP adjustment in the CY 2017 ESRD PPS final rule.

b. The Proposed CY 2017 ESRD PPS Wage Indices

i. Annual Update of the Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the use of the Office of Management and Budget's (OMB) Core-Based Statistical Areas (CBSAs)-based geographic area designations to define urban and rural areas and their corresponding wage index values. OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The latest bulletin, as well as subsequent bulletins, is available online at http://www.whitehouse.gov/omb/bulletins_index2003-2005.

For CY 2017, we would continue to use the same methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49117) for determining the wage indices for ESRD facilities. Specifically, we are updating the wage indices for CY 2017 to account for updated wage levels in areas in which ESRD facilities are located. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient prospective payment system. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The proposed CY 2017 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed CY 2017 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

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

We apply the wage index for Guam as established in the CY 2014 ESRD PPS final rule (78 FR 72172) (0.9611) to American Samoa and the Northern Mariana Islands. We apply the statewide urban average based on the average of all urban areas within the state (78 FR 72173) (0.8637) to Hinesville-Fort Stewart, Georgia. We note that if hospital data becomes available for these areas, we will use that data for the appropriate CBSAs instead of the proxy.

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

transition to 100 percent implementation of the ESRD PPS (75 FR 49116 through 49117; 76 FR 70240 through 70241), in the CY 2014 ESRD PPS final rule (78 FR 72173), we continued to apply the wage index floor and continued to reduce the floor by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), we finalized the continuation of the application of the wage index floor of 0.4000 to areas with wage index values below the floor, rather than reducing the floor by 0.05. We stated in that rule that we needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor. Also, in that rule a commenter provided several alternative wage indexes for Puerto Rico for the CY 2016 ESRD PPS final rule: (1) Utilize our policy for areas that do not have reliable hospital data by applying the wage index for Guam as we did in implementing the ESRD PPS in the Northern Marianas and American Samoa; (2) use the U.S. Virgin Islands as a proxy for Puerto Rico, given the geographic proximity and its ‘‘non-mainland’’ or ‘‘island’’ nature; or (3) reestablish the wage index floor in effect in 2010 when Puerto Rico became the only wage areas subject to the floor, that is, 0.65.

For the CY 2017 proposed rule, we analyzed ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and compared them to mainland facilities. Specifically, we analyzed CY 2013 claims and cost report data for 37 freestanding Puerto Rico facilities and compared it to 5,024 non-Puerto Rico freestanding facilities. We found that the freestanding facilities in Puerto Rico are bigger than facilities elsewhere in the United States. The Puerto Rico facilities produce roughly twice the number of treatments as other facilities and this larger size likely results in higher labor productivity. Finally,

dialysis patients in Puerto Rico are much more likely to be non-Medicare. We discuss the findings below in detail.

Total Composite Rate Cost and Operational Efficiency: Total composite rate cost per dialysis treatment is about 15 percent lower in Puerto Rico than elsewhere. This lower total cost reflects several production process differences: (1) Puerto Rico facilities make much higher use of equipment, as reflected in achieving about 50 percent more treatments per chair and (2) Approximately 30 percent of the freestanding Puerto Rico facilities indicated some operations during a third shift in comparison to only 12 percent of all other freestanding facilities in the United States. This higher rate of a third shift, on average, improves the rates of operational efficiency as some of these facilities more fully utilize equipment and decrease associated fixed costs per treatment.

Salary, Benefits, and Administrative Salaries: Salary and benefits for direct care staff includes costs for RNs, LPNs, nurse aides (NA), technicians, licensed social workers (LSWs), and registered dieticians (RDs). Although salaries and benefit expenses per chair are somewhat higher in Puerto Rico than those in other facilities, salaries and benefits expenses for direct care staff per treatment are about 19 percent lower because of the higher use rate of chairs. Including administrative salaries (including RN nurse managers), salaries and benefits per treatment are reported to be about 27 percent lower in Puerto Rico freestanding facilities when compared to other freestanding facilities.

Full-Time Employees (FTEs) per Treatment: Total direct care FTEs per treatment in Puerto Rico are about 12 percent less than elsewhere, but the data shows that Puerto Rico facilities employ a richer mix of staffing, as reflected in more than double the RNs per treatment in Puerto Rico than elsewhere. The data suggests that RNs are substituted for

technicians in Puerto Rico facilities. The calculated variable of salaries and benefits per direct care FTE are approximately 8 percent lower in Puerto Rico than elsewhere. This difference likely reflects the net of a richer mix of labor and somewhat lower wage rates per employee classification.

In addition to this analysis, we researched staffing requirements for ESRD facilities located in Puerto Rico and confirmed that under Puerto Rico law, ESRD facilities cannot hire technicians and must only hire RNs. This requirement supports the data findings above, specifically, that Puerto Rico facilities employ a richer mix of staffing, as reflected in more than double the RNs per treatment in Puerto Rico than elsewhere.

We believe that this information provides evidence that in furnishing renal dialysis services, Puerto Rico could potentially have an economic disadvantage that the rest of the country may not be experiencing. Although we have this information available, we still believe that we need to engage the industry for input on potential changes and to assist us in assessing the appropriateness of discontinuing the wage index floor. Therefore, we are proposing to continue to apply a wage index floor of 0.4000 to areas with wage index values below the floor for CY 2017 and soliciting comments on the use of a wage index floor for Puerto Rico going forward. Our review of the wage indices show that CBSAs in Puerto Rico continue to be the only areas with wage index values that would benefit from a wage index floor because they are so low. Because the wage index floor is only applicable to a small number of CBSAs, the impact to the base rate through the wage index budget neutrality factor would be insignificant. To the extent other geographical areas fall below the floor in CY 2017 or beyond, we believe they should have the benefit of the 0.4000 wage index floor as well.

For CY 2017, we are soliciting public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate course of action. We are not proposing to change the wage index floor for CBSAs in Puerto Rico, but we are requesting public comments in which stakeholders can provide useful input for consideration in future decision-making. Specifically, we are soliciting comment on the useful suggestions that were submitted in last year's final rule (80 FR 69007) and reiterated above. Along with comments we will continue to review wage index values and the appropriateness of a wage index floor in the future.

ii. Application of the Wage Index under the ESRD PPS

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2015 ESRD PPS final rule (79 FR 66136), we finalized a new labor-related share of 50.673 percent, which was based on the 2012-based ESRDB market basket finalized in that rule, and transitioned the new labor-related share over a 2-year period. Thus, for CY 2017, the labor-related share to which a facility's wage index would be applied is 50.673 percent.

c. CY2017 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities such as cancer. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy in our regulations at 42 CFR 413.237. The policy

provides the following ESRD outlier items and services are included in the ESRD PPS bundle: (i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) medical/surgical supplies, including syringes, used to administer ESRD-related drugs, that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (iv) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding oral-only drugs used in the treatment of ESRD.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis

service drugs which were or would have been covered under Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Our regulations at 42 CFR 413.237 specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed-dollar loss amount. In accordance with section 413.237(c) of our regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule, using 2007 data, we established the outlier percentage at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the fixed-dollar loss amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and fixed-dollar loss amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the

CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For the CY 2017 outlier policy, we would use the existing methodology for determining outlier payments by applying outlier services payment multipliers that were developed for the CY 2016 ESRD PPS final rule (80 FR 68993-68994, 69002). We used these outlier services payment multipliers to calculate the predicted outlier service MAP amounts and projected outlier payments for CY 2017.

For CY 2017, we propose that the outlier services MAP amounts and fixed-dollar loss amounts would be derived from claims data from CY 2015. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we propose the outlier thresholds for CY 2017 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2015. We recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and fixed-dollar loss amounts every year under the ESRD PPS. We continue to believe that since the implementation of the ESRD PPS, data for CY 2015 are reflective of relatively stable ESA use, in contrast with the relatively large initial declines in the use of both EPO and darbepoetin in the first 2 years of the ESRD PPS. In 2015, there were both decreases in the use of EPO and increases in the

use of darbepoetin based on estimates of average ESA utilization per session, suggesting a relative shift towards the use of darbepoetin between 2014 and 2015.

i. CY 2017 Update to the Outlier Services MAP Amounts and Fixed-Dollar Loss Amounts

For CY 2017, we are not proposing any change to the methodology used to compute the MAP or fixed-dollar loss amounts. Rather, we will continue to update the outlier services MAP amounts and fixed-dollar loss amounts to reflect the utilization of outlier services reported on 2015 claims. For this proposed rule, the outlier services MAP amounts and fixed dollar loss amounts were updated using 2015 claims data. The impact of this update is shown in Table 1, which compares the outlier services MAP amounts and fixed-dollar loss amounts used for the outlier policy in CY 2016 with the updated proposed estimates for this rule. The estimates for the proposed CY 2017 outlier policy, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2017 prices for outlier services.

TABLE 1--Outlier Policy: Impact of Using Updated Data to Define the Outlier Policy

	Column I Final outlier policy for CY 2016 (based on 2014 data price inflated to 2016)		Column II Proposed outlier policy for CY 2017 (based on 2015 data price inflated to 2017)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$40.20	$53.29	$40.49	$49.28
Adjustments				
Standardization for outlier services	0.9951	0.9729	1.0061	0.9786
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP	$39.20	$50.81	$39.92	$47.26

	Column I Final outlier policy for CY 2016 (based on 2014 data price inflated to 2016)		Column II Proposed outlier policy for CY 2017 (based on 2015 data price inflated to 2017)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
amount				
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$62.19	$86.97	$67.44	$83.00
Patient months qualifying for outlier payment	5.8%	6.5%	4.5%	6.7%

As demonstrated in Table 1, the estimated fixed-dollar loss amount per treatment that determines the CY 2017 outlier threshold amount for adults (Column II; $83.00) is lower than that used for the CY 2016 outlier policy (Column I; $86.97). The lower threshold is accompanied by a decline in the adjusted average MAP for outlier services from $50.81 to $47.26. For pediatric patients, there is an increase in the fixed dollar loss amount from $62.19 to $67.44. Unlike the adult patients, there was a slight increase in the adjusted average MAP for outlier services among pediatric patients, from $39.20 to $39.92.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2017 will be 6.7 percent for adult patients and 4.5 percent for pediatric patients, based on the 2015 claims data. The pediatric outlier MAP and fixed-dollar loss amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

ii. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081), in accordance with 42 CFR 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the

proportion of the estimated total payments under the ESRD PPS that are outlier payments. Based on the 2015 claims, outlier payments represented approximately 0.9 percent of total payments, slightly below the 1 percent target due to small overall declines in the use of outlier services. Recalibration of the thresholds using 2015 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2017. We believe the update to the outlier MAP and fixed-dollar loss amounts for CY 2017 will increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy. We note that recalibration of the fixed-dollar loss amounts in this proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would also increase for renal dialysis services eligible for outlier payments.

We note that many industry stakeholder associations and renal facilities have expressed concern that the outlier target percentage has not been achieved under the ESRD PPS and have asked that CMS eliminate the outlier policy. With regard to the suggestion that we eliminate the outlier adjustment altogether, we note that, under section 1881(b)(14)(D)(ii) of the Act, the ESRD PPS must include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management. We believe that the ESRD PPS is required to include an outlier adjustment in order to comply with section 1881(b)(14)(D)(ii) of the Act.

In addition, while we believe that the ESRD PPS base rate and other payment adjustments capture the cost for the average renal patient having certain characteristics, there may continue to be certain individual patients or certain subgroups of patients, such as patients with bacterial pneumonia or monoclonal gammopathy, which were eliminated as payment adjustments factors for CY2016, who receive more ESAs or other outlier services than the average patient. We believe that the inclusion of the 1 percent outlier policy helps to protect patient access to care by providing additional payment for patients requiring higher use of outlier services not otherwise captured in the payment adjustments made under the ESRD PPS.

We understand the industry's concern that payments under the outlier policy have not reached 1 percent of total ESRD PPS payments since the implementation of the payment system. As we explained in the CY 2015 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. As we stated above, based on the 2015 claims, outlier payments represented approximately 0.9 percent of total payments, slightly below the 1 percent target, which could indicate that ESRD facilities are getting better at reporting outlier services. We note that we would not increase the base rate to account for years where outlier payments were less than 1 percent of total ESRD PPS payments, nor would we reduce the base rate if the outlier payments exceed 1 percent of total ESRD PPS payments.

d. Proposed Impacts to the CY 2017 ESRD PPS Base Rate

i. 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.

ii. Annual Payment Rate Update for CY 2017

We are proposing an ESRD PPS base rate for CY 2017 of $231.04. This update reflects several factors, described in more detail below.

Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2017 projection for the ESRDB market basket is 2.1 percent. In CY 2017, this amount must be reduced by 1.25 percentage points as required by section 1881(b)(14)(F)(i)(I), as amended by section 217(b)(2)(A) of PAMA, which is calculated as 2.1 - 1.25 = 0.85 percent. This amount is then reduced by the

productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as required by section 1881(b)(14)(F)(i)(II) of the Act. The proposed multi-factor productivity adjustment for CY 2017 is 0.5 percent, thus yielding a proposed update to the base rate of 0.35 percent for CY 2017 (0.85 - 0.5 = 0.35 percent). Therefore, the proposed ESRD PPS base rate for CY 2017 before application of the wage index and training budget-neutrality adjustment factors would be $231.20 ($230.39 x 1.0035 = $231.20).

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2017, we are not proposing any changes to the methodology used to calculate this factor which is described in detail in CY 2014 ESRD PPS final rule (78 FR 72174). The CY 2017 proposed wage index budget-neutrality adjustment factor is 0.999552. Therefore, the proposed ESRD PPS base rate for CY 2017 before application of the training budget-neutrality adjustment factor would be $231.10 ($231.20 x 0.999552 = $231.10).

Home and Self-Dialysis Training Add-on Budget-Neutrality Adjustment Factor: Also, as discussed in section II.B.2 of this proposed rule, we are proposing an increase in the home dialysis training add-on in a budget-neutral manner. The home dialysis training add-on budget-neutrality factor ensures that the increase in the training add-on payment adjustment does not affect aggregate Medicare payments. Therefore, we are finalizing a home dialysis training add-on payment adjustment budget-neutrality adjustment factor of 0.999729, which will be applied directly to the CY 2017 ESRD PPS base rate. This application yields a CY 2017 ESRD PPS base rate of $231.04 ($231.10 × 0.999729 = $231.04).

In summary, we are proposing a CY 2017 ESRD PPS base rate of $231.04. This amount reflects a market basket increase of 0.35 percent, the CY 2017 wage index budget-

neutrality adjustment factor of 0.999552, and the home dialysis training add-on payment adjustment budget-neutrality adjustment of 0.999729.

III. Proposed Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

A. Background

On June 29, 2015, the Trade Protection Extension Act of 2015 (TPEA) (Pub. L. No. 114-27) was enacted. In the TPEA, the Congress amended the Act to include coverage and provide for payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act by including coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI. In addition, section 808(b) of TPEA amended section 1834 of the Act by adding a new subsection (r). Subsection (r)(1) of section 1834 of the Act provides that in the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or a provider of services paid under such section during a year (beginning with 2017) to an individual with acute kidney injury, the amount of payment under Part B for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. Section 1834(r)(2) defines "individual with acute kidney injury" to mean an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14). In this

rule, we are proposing payment and billing requirements as discussed below.

B. Proposed Payment Policy for Renal Dialysis Services Furnished to Individuals with AKI

1. Definition of "Individual with Acute Kidney Injury"

Consistent with section 1834(r)(2) of the Act, we propose to define an individual with AKI as an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14). Section 1881(b)(14) of the Act contains all of the provisions related to the ESRD PPS. We interpret the reference to section 1881(b)(14) of the Act to mean that we would pay renal dialysis facilities for renal dialysis services furnished to individuals with acute loss of kidney function when the services furnished to those individuals are not payable under section 1881(b)(14) because the individuals do not have ESRD. We propose to codify the statutory definition of individual with acute kidney injury at 42 CFR 413.371 and we solicit comments on this definition.

2. The Payment Rate for AKI Dialysis

Section 1834(r)(1) of the Act, as added by section 808(b) of TPEA, provides that the amount of payment for AKI services shall be the base rate for renal dialysis services determined for a year under section 1881(b)(14). We propose to interpret this provision to mean the ESRD PPS per treatment base rate as set forth in 42 CFR 413.220, which is updated annually by the market basket less the productivity adjustment as set forth in 42 CFR 413.196(d)(1), and adjusted by any other adjustment factor applied to the ESRD PPS base rate. This amount would be established on an annual basis through rulemaking and finalized in the CY ESRD PPS final rule. We recognize that there could be rulemaking years in which legislation or policy decisions could directly impact the ESRD PPS base rate because of changes to ESRD PPS policy that may not relate to the services furnished for AKI dialysis. For example, for CY 2017 we are applying a

training add-on budget neutrality adjustment factor to the otherwise applicable base rate. In those situations, we would still consider the ESRD PPS base rate as the payment rate for AKI dialysis. We believe that the statute was clear in that the payment rate for AKI dialysis shall be the ESRD PPS base rate determined for a year under section 1881(b)(14), which we interpret to mean the finalized ESRD PPS base rate and not to be some other determined amount. As described below, ESRD facilities will have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. For example, beneficiaries with AKI may require certain laboratory tests so that their practitioner can gauge organ function and accurately adjust the dialysis prescription that would be optimal for kidney recovery. These beneficiaries would require laboratory tests specific to their condition which would not be included in the ESRD PPS and thus, would be paid for separately. For instance, an individual with AKI might need to be tested for a biochemical indication of a urea cycle defect resulting in hyperammonemia. We propose to codify the AKI dialysis payment rate in our regulations at 42 CFR §413.372 and solicit comment on this proposal. This year's proposed ESRD PPS base rate is $231.04. Accordingly, we propose that the CY 2017 payment rate for renal dialysis services furnished by ESRD facilities for individuals with AKI will be $231.04.

3. Geographic Adjustment Factor

Section 1834(r)(1) of the Act further provides that the amount of payment for AKI dialysis services shall be the base rate for renal dialysis services determined for a year under section 1881(b)(14), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II). We interpret the reference to "any applicable geographic adjustment factor applied under section (D)(iv)(II)" of such section to mean the geographic

adjustment factor that is actually applied to the ESRD PPS base rate for a particular facility. Accordingly, we propose to apply the same wage index that is used under the ESRD PPS, that is, the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient prospective payment system that are unadjusted for occupational mix. The ESRD PPS wage index policy was finalized in the CY 2011 ESRD PPS final rule (75 FR 49117) and codified at 42 CFR §413.231. The AKI dialysis payment rate would be adjusted for wage index for a particular facility in the same way that the ESRD PPS base rate is adjusted for wage index for that facility. Specifically, we would apply the wage index to the labor-related share of the ESRD PPS base rate that we will utilize for AKI dialysis to compute the wage-adjusted per-treatment AKI dialysis payment rate. We propose that for CY 2017, the AKI dialysis payment rate would be the CY 2017 ESRD PPS base rate (established in the CY 2017 ESRD PPS final rule), adjusted by the ESRD facility's wage index. In proposed 42 CFR 413.372(a), we refer to the ESRD PPS wage index regulation at 42 CFR 413.231 as an adjustment we will apply to the ESRD PPS base rate.

4. Other Adjustments to the AKI Payment Rate

Section 1834(r)(1) also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14). For purposes of payment for AKI dialysis, we are not proposing to adjust the AKI payment rate by any other adjustments at this time. Therefore, for at least the first year of implementation of the AKI payment rate, we are not proposing to apply any of the optional payment adjustments under subparagraph (D) of section 1881(b)(14). We propose to codify our authority to adjust the AKI payment rate by any of the adjustments under section 1881(b)(14)(D) in our regulations at 42 CFR 413.373.

5. Renal Dialysis Services Included in the AKI Payment Rate

Section 1834(r)(1) provides that the AKI payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14). We propose that drugs, biologicals, laboratory services, and supplies that are considered to be renal dialysis services under the ESRD PPS as defined in 42 CFR §413.171, would be considered to be renal dialysis services for patients with AKI. As such, no separate payment would be made for renal dialysis drugs, biologicals, laboratory services, and supplies that are included in the ESRD PPS base rate when they are furnished by an ESRD facility to an individual with AKI. We propose to codify this policy in the regulations at 42 CFR 413.374(a).

However, we recognize that the utilization of items and services for beneficiaries with AKI receiving dialysis may differ from the utilization of these same services by ESRD beneficiaries. This is because we expect that individuals with AKI will only need dialysis for a finite number of days while they recover from kidney injury, while ESRD beneficiaries require dialysis indefinitely unless they receive a kidney transplant. We recognize that the intent of dialysis for patients with AKI is curative; therefore, we are proposing that we will pay for all hemodialysis treatments furnished to beneficiaries with AKI in a week, even if the number of treatments exceeds the three times-weekly limitation we apply to HD treatments furnished to beneficiaries with ESRD.

Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in 42 CFR 413.171, but that are related to their dialysis treatment as a result of their AKI and that an ESRD facility might furnish to a beneficiary with AKI, would be separately payable. In particular, an ESRD facility could seek separate payment

for drugs, biologicals, laboratory services, and supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting. Therefore, we are proposing to pay for these items and services separately when they are furnished to beneficiaries with AKI receiving dialysis in ESRD facilities. We propose to codify this policy at 42 CFR 413.374(b).

C. Applicability of ESRD PPS Policies to AKI Dialysis

1. Uncompleted Dialysis Treatment

Generally, we would pay for only one treatment per day across all settings. However, similar to the policy applied under the ESRD PPS for treatments for patients with ESRD, in the interest of fairness and in accordance with Chapter 8, section 10.2 of the Medicare Claims Processing Manual, if a dialysis treatment is started, that is, a patient is connected to the machine and a dialyzer and blood lines are used, but the treatment is not completed for some unforeseen, but valid reason, for example, a medical emergency when the patient must be rushed to an emergency room, both the ESRD facility and the hospital would be paid. We consider this to be a rare occurrence that must be fully documented to the A/B MAC's satisfaction.

2. Home and Self-Dialysis

We do not expect that beneficiaries with AKI will receive dialysis in their homes due to the duration of treatment and the unique needs of AKI. Specifically, it is our understanding that these patients require supervision by qualified staff during their dialysis and close monitoring through laboratory tests to ensure that they are receiving the necessary care to improve their condition and get off of dialysis. Therefore, we are proposing not to extend the home dialysis benefit to beneficiaries with AKI.

3. Vaccines and their Administration

Section 1881(b)(14)(B) of the Act specifically excludes vaccines covered under section 1861(s)(10) of the Act from the ESRD PPS. However, ESRD facilities are identified as an entity that can bill Medicare for vaccines and their administration. Therefore, we propose to allow ESRD facilities to furnish vaccines to beneficiaries with AKI and bill Medicare in accordance with billing requirements in Pub. 100-04, Chapter 18 Preventive and Screening Services, section 10.2 which is located on the CMS website: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf. We solicit comment on the proposal for ESRD facilities to administer vaccines to beneficiaries with AKI.

D. Monitoring of Beneficiaries with AKI Receiving Dialysis in ESRD Facilities

Because we are aware of the unique acute medical needs of the AKI population, we plan to closely monitor utilization of dialysis and all separately billable items and services furnished to individuals with AKI by ESRD facilities. For example, stakeholders have stated that beneficiaries with AKI will require frequent labs to monitor renal function or they will be at risk for developing chronic renal failure. Another recurrent concern is the flexibility necessary in providing dialysis sessions to beneficiaries with AKI. Stakeholders have told us that these patients may need frequent dialysis, but will also require days with no dialysis to test for kidney recovery. Consequently, we will closely monitor utilization of dialysis treatments and the drugs, labs and services provided to these beneficiaries.

We have met with both physician and provider associations with regard to the care of patients with AKI. Both have expressed concerns that physician oversight will be limited for these beneficiaries, based on current operational models used by ESRD facilities. They have encouraged CMS to support close monitoring of this patient population -- particularly with regard to lab values – in the interest of preventing these patients from becoming ESRD patients.

A close patient-physician relationship is critical for the successful outcome of the AKI patient.

E. AKI and the ESRD Conditions for Coverage

The ESRD Conditions for Coverage (CfCs) at 42 CFR Part 494 are health and safety standards that all Medicare-participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all ESRD patients receive safe and appropriate care.

We propose a technical change to 42 CFR 494.1(a), statutory basis, to incorporate the changes to ESRD facilities and treatment of AKI in the Act as enacted by section 808 of the Trade Protection Extension Act of 2015 (P. L. 114-27, June 29, 2015) (TPEA).

While the substance of the ESRD CfCs (comprehensively updated in 2008) does not directly address treatment of patients with AKI, we believe that the current ESRD facility requirements are sufficient to ensure that such patients are dialyzed safely. For example, infection control protocols would be the same for an ESRD patient receiving maintenance dialysis and an AKI patient. For the areas in which care and care planning may differ, such as frequency of certain patient assessments, we note that the CfCs set baseline standards and do not limit additional or more frequent services that may be necessary for AKI patients receiving temporary dialysis to restore kidney function.

Accordingly, we are not proposing changes to the CfCs specific to AKI at this time. However, we are soliciting comment from the dialysis community as to whether revisions to the CfCs might be appropriate for addressing treatment of AKI in ESRD facilities. Some of our specific questions include: Should we address AKI care directly in the ESRD CfCs? Should care planning for AKI patients be addressed differently than care planning for ESRD patients?

Are there other areas, such as medical records, that might be appropriate for AKI-related revisions? We do not intend to respond to comments related to potential CfC revisions for AKI in the final rule, but will consider them in future rulemaking.

F. ESRD Facility Billing for AKI Dialysis

For payment purposes, claims for beneficiaries with AKI would be identified through a specific condition code, an AKI diagnosis, an appropriate revenue code, and an appropriate Common Procedural Terminology code. These billing requirements would serve to verify that a patient has AKI and differentiate claims for AKI from claims for patients with ESRD. ESRD facilities are expected to report all items and services furnished to individuals with AKI and include comorbidity diagnoses on their claims for monitoring purposes. We anticipate that with exceptions for separately billable items and services, most of the claims policies laid out in Chapter 8 of the Medicare Claims Processing Manual will also apply to claims for dialysis furnished to AKI beneficiaries. All billing requirements will be implemented and furnished through sub-regulatory guidance.

G. Announcement of AKI Payment Rate in Future Years

In future years, we anticipate announcing the AKI payment rate in the annual ESRD PPS rule or in a **Federal Register** notice. We will adopt through notice and comment rulemaking any changes to our methodology for payment for AKI as well as any adjustments to the AKI payment rate other than the wage index. When we are not making methodological changes or adjusting (as opposed to updating) the payment rate, however, we will announce the update to the rate rather than subjecting it to public comment every year. We are proposing to announce the annual AKI payment rate in a notice published in the Federal Register or, alternatively, in the annual ESRD PPS rulemaking, and provide for that announcement at proposed 42 CFR 413.375.

We welcome comments on announcing the AKI payment rate in future years.

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

A. Background

Section 1881(h) of the Act requires the Secretary to establish an End-stage renal disease (ESRD) quality incentive program (QIP) by (1) selecting measures; (2) establishing the performance standards that apply to the individual measures; (3) specifying a performance period with respect to a year; (4) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (5) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score (TPS). This proposed rule discusses each of these elements and our proposals for their application to the ESRD QIP.

B. Proposed Changes to the Requirements for the Payment Year (PY) 2018 ESRD QIP

1. Proposal to Correct the Small Facility Adjuster (SFA) Policy for PY 2018

In the CY 2016 ESRD PPS Final Rule, we revised the calculation of the Small Facility Adjuster (SFA) (80 FR 69039). We are proposing to correct our description of the SFA for payment year (PY) 2017 and future years. Our original proposal pegged the SFA to the national mean, such that small facilities scoring below the national mean would receive an adjustment, but small facilities scoring above the national mean would not. Several commenters supported the overall objectives of the proposed SFA modification but were concerned that too few facilities would receive an adjustment under our proposed methodology. They recommended that rather than pegging the SFA to the national mean, we peg the SFA to the benchmark, which is the 90th percentile of national facility performance on a measure, such that facilities scoring below the benchmark would receive an adjustment, but those scoring above the benchmark

would not. In the process of updating the finalized policy to reflect public comment, we inadvertently neglected to update this sentence from our statement of finalized policy: "For the standardized ratio measures, such as the Standardized Readmission Ratio (SRR) and Standardized Transfusion Ratio (STrR) clinical measures, the national mean measure rate (that is, $\bar{P}$) is set to 1." (80 FR 69039). Setting the ratio measures at the national mean in the SFA equation would have been inconsistent with our desired policy position and would have been unresponsive to the commenter's point. It was also inconsistent with another part of our statement on the finalized SFA methodology and was more punitive for facilities because it did not provide an adjustment for a number of small facilities that may have been adversely affected by a small number of outlier patients. Therefore, we propose to correct the description of the SFA methodology such that, for the standardized ratio measures such as the SRR and STrR clinical measures, $\bar{P}$ is set to the benchmark, which is the 90^{th} percentile of national facility performance.

We seek comments on this proposal.

2. Proposed Changes to the Hypercalcemia Clinical Measure

During the measure maintenance process at National Quality Forum (NQF), two substantive changes were made to the Hypercalcemia clinical measure. First, plasma was added as an acceptable substrate in addition to serum calcium. Second, the denominator definition changed such that it now includes patients regardless of whether any serum calcium values were reported at the facility during the 3-month study period. Functionally, this means that a greater number of patient-months will be included in this measure, because patient-months will not be excluded from the measure calculations solely because a facility reports no calcium data for that patient during the entire three month study period.

We are proposing to update the measure's technical specifications for PY 2018 and future

years to include these two substantive changes to the Hypercalcemia clinical measure included in the ESRD QIP. These changes will positively impact data completeness in the ESRD QIP because facilities' blood tests typically use plasma calcium rather than serum calcium. Including patients with unreported calcium values in the measure calculations will encourage more complete reporting of this data. Additionally, these changes will ensure that the measure aligns with the NQF-endorsed measure and can continue to satisfy the requirements of the Protecting Access to Medicare Act (PAMA), which requires that the ESRD QIP include in its measure set measures (outcomes-based, to the extent feasible), that are specific to the conditions treated with oral-only drugs.

We seek comments on this proposal.

C. Proposed Requirements for the PY 2019 ESRD QIP

1. Proposed New Measures for the PY 2019 ESRD QIP

a. Proposed Reintroduction of the Expanded NHSN Dialysis Event Reporting Measure

We first adopted the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure for the PY 2014 ESRD QIP. For that program year, we required facilities to (1) enroll in the NHSN and complete any training required by the CDC; and (2) submit three or more consecutive months of dialysis event data to the NHSN (76 FR 70268 through 69). For PY 2015, we retained the requirement for facilities to enroll in the NHSN and complete any training required by the CDC, but expanded the reporting period to require facilities to report a full 12 months of dialysis event data (77 FR 67481 through 84). Beginning with PY 2016, we replaced the NHSN Dialysis Event Reporting Measure with the clinical version of the measure (78 FR 72204 through 07). As a result, facilities were scored for purposes of the ESRD QIP based on how many dialysis events they reported to the NHSN in accordance with the NHSN protocol.

We introduced the clinical version of the measure because we believed that the measure would hold facilities accountable for monitoring and preventing infections in the ESRD population. We continue to believe it is vitally important to hold facilities accountable for their actual clinical performance on this measure.

Since we introduced the NHSN Bloodstream Infection (BSI) Clinical Measure into the ESRD QIP, some stakeholders have expressed significant concerns about two distinct types of accidental or intentional under-reporting. First, these stakeholders believe that many facilities do not consistently report monthly dialysis event data for the full 12-month performance period. Second, these stakeholders believe that even with respect to the facilities that report monthly dialysis event data, many of those facilities do not consistently report all of the dialysis events that they should be reporting. (80 FR 69048). These public comments, as well as our thorough review of data reported for the PY 2015 NHSN Dialysis Event Reporting Measure and results from the PY 2014 NHSN data validation feasibility study, suggest that as many as 60-80 percent of dialysis events are under-reported.[2, 3]

We believe that there are delicate tradeoffs associated with incentivizing facilities to both report monthly dialysis event data and to accurately report such data. On the one hand, if we incentivize facilities to report monthly dialysis event data but do not hold them accountable for their performance, we believe that facilities will be more likely to accurately report all dialysis events. Complete and accurate reporting is critical to maintaining the integrity of the NHSN surveillance system, enables facilities to implement their own quality improvement initiatives,

2 Duc B. Nguyen, et al. Completeness of Methicillin-Resistant *Staphylococcus aureus* Bloodstream Infection Reporting From Outpatient Hemodialysis Facilities to the National Healthcare Safety network, 2013. Infection Control & Hospital Epidemiology, http://journals.cambridge.org/abstract_S0899823X15002652.
3 Nicola D. Thompson, Matthew Wise, Ruth Belflower, Meredith Kanago, Marion A Kainer, Chris Lovell and Priti R. Patel. Evaluation of Manual and Automated Bloodstream Infection Surveillance in Outpatient Dialysis Centers. Infection Control & Hospital Epidemiology, Available on CJO 2016 doi: 10.1017/ice.2015.336.

and enables the CDC to design and disseminate prevention strategies. Nevertheless, incentivizing full and accurate reporting without financial consequences for poor performance will not necessarily improve patient safety. On the other hand, if we incentivize facilities to achieve high clinical performance scores without also incentivizing them to accurately report monthly dialysis event data, we believe that facilities will be less likely to report complete and accurate monthly data, which could diminish the integrity of the NHSN surveillance system and the quality improvement efforts that it supports. Maintaining an incentive structure along these lines increases the financial consequences for not achieving high clinical scores, but jeopardizes the accuracy and completeness of the dialysis event data upon which those scores are based.

In light of these considerations, we believe that the best way to strike the proper balance between these competing interests is to propose to reintroduce the expanded NHSN Dialysis Event Reporting Measure, beginning with PY 2019, and to include both this measure and the NHSN BSI Clinical Measure in the ESRD QIP measure set.

In combination with other programmatic features described more fully below (see sections IV.C.2. and IV.C.8.), we believe this reporting measure will bolster incentives for facilities to report complete and accurate data to NHSN, while the clinical measure will preserve incentives to reduce the number of dialysis events. We believe that including both of these measures in the ESRD QIP measure set will ensure that we hold facilities accountable for the frequency with which they report data to the NHSN and will address validation concerns related to the two distinct types of under-reporting of data, described above.

, we propose that beginning with PY 2019, facilities must enroll in NHSN and complete any training required by the CDC related to reporting dialysis events via NHSN, and that they must report monthly dialysis event data on a quarterly basis to the NHSN. We also propose that

each quarter's data would be due 3 months after the end of the quarter. For example, data from January 1 through March 31, 2017 would need to be submitted to NHSN by June 30, 2017; data from April 1 through June 30, 2017 would need to be submitted by September 30, 2017; data from July 1 through September 30, 2017 would need to be submitted by December 31, 2017; and data from October 1 through December 31, 2017 would need to be submitted by March 31, 2018. For further information regarding NHSN's dialysis event reporting protocols, please see http://www.cdc.gov/nhsn/pdfs/pscmanual/8pscdialysiseventcurrent.pdf. These requirements are the same ones that previously applied to the expanded NHSN Dialysis Event Reporting Measure when that measure was included in the ESRD QIP (77 FR 67481 through 84).

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)(iii) 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 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. The proposed NHSN Dialysis Event Reporting Measure is not endorsed by the NQF, but for the reasons explained above, we believe that it is appropriate to assess facilities solely based on whether they actually report full and accurate monthly dialysis event data to the NHSN. Although we recognize that the NHSN BSI Clinical Measure is currently included in the ESRD QIP measure set and that this measure and the proposed NHSN Dialysis Event Reporting Measure would be calculated using the same set

of data, the two measures assess different outcomes. We believe that including both of these measures in the ESRD QIP measure set will collectively support our efforts to ensure that facilities report, and are scored based on, complete and accurate dialysis event data.

For the reasons stated above, we propose to reintroduce the NHSN Dialysis Event Reporting Measure to the ESRD QIP beginning with PY 2019.

We seek comments on this proposal.

b. Proposal for Scoring the Proposed NHSN Dialysis Event Reporting Measure

With respect to the proposed NHSN Dialysis Event Reporting measure, we are proposing to score facilities with a CCN Open Date on or before January 1, 2017. Using the methodology described below, we propose to assign the following scores for reporting different quantities of data:

Scoring Distribution for the Proposed NHSN Dialysis Event Reporting Measure:

Number of Reporting Months:

12 months = 10 points

6-11 months = 2 points

0-5 months = 0 points

We selected these scores for the following reasons: first, due to the seasonal variability of bloodstream infection rates, we want to incentivize facilities to report the full 12 months of data and reward reporting consistency over the course of the entire performance period. We therefore propose that facilities will receive 10 points for submitting twelve months of data. We recognize, however, that from the perspective of national prevention strategies and internal quality improvement initiatives, there is still some value in collecting fewer than 12 months of

data from facilities. We also need at least 6 months of data in order to calculate reliable scores on the NHSN BSI Clinical Measure. For these reasons, we propose that facilities will receive 2 points for reporting between 6 and 11 months of dialysis event data. Finally, in consultation with the CDC, we have determined that NHSN BSI Clinical Measure rates are not reliable when they are calculated using fewer than six months of data. For that reason, we propose that a facility will receive 0 points on the proposed NHSN Dialysis Event Reporting Measure if it reports fewer than six months of data.

The proposed scoring methodology for the proposed NHSN Dialysis Event Reporting Measure differs slightly from what we finalized for PY 2015. For that year of the program, facilities were awarded 0 points for reporting fewer than 6 months of data, 5 points for reporting 6 consecutive months, and 10 points for reporting all 12 months of data. We believe that it is appropriate to reduce the number of points facilities receive for reporting 6-11 months of data from 5 to 2 because by PY 2019, facilities will have had 3 more years of experience reporting data to NHSN than they had for PY 2015.

2. Proposed New Measure Topic Beginning with the PY 2019 ESRD QIP

a. Proposed NHSN BSI Measure Topic

For PY 2019 and future years of the program, we are proposing to create a new NHSN BSI Measure Topic. We propose that this measure topic consist of the following two measures:

(i) NHSN (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure

(ii) NHSN Dialysis Event Reporting Measure.

We believe it is appropriate to combine these two measures into one measure topic, because data from the reporting measure will be used to score both that measure and the clinical measure, and

combining both measures under the same measure topic will better enable us to precisely calibrate incentives for complete and accurate reporting and high clinical performance. The NHSN BSI Clinical Measure and the NHSN Dialysis Event Reporting Measure are mutually reinforcing because one measure encourages accurate reporting while the other uses the reported data to assess facility performance on preventing BSIs in their patients. Therefore, combining the reporting and clinical measures under the same measure topic will simplify the process of weighting each of the two measures, such that incentives from one measure can be simply reallocated to the other if new evidence suggests that the incentives are not properly balanced to optimize both reporting and prevention.

We seek comments on this proposal.

3. Proposal to Establish a New Safety Measure Domain

We currently use two domains in the ESRD QIP for purposes of scoring. The first of these domains, termed the Clinical Measure Domain, is defined as an aggregated metric of facility performance on the clinical measures and measure topics in the ESRD QIP, and we use subdomains within the Clinical Measure Domain for the purposes of calculating the Clinical Measure Domain score (79 FR 66213). We also have a Reporting Measure Domain, in which scores on reporting measures are weighted equally (79 FR 66218 through 66219).

In section IV.C.2 above, we describe the proposed NHSN BSI Measure Topic. We believe that this measure topic, consisting of both the proposed NHSN Dialysis Event Reporting Measure and the NHSN BSI Clinical Measure, is fundamentally different from the other measures and measure topics included in the ESRD QIP's measure set. The two measures included in this measure topic are inextricably linked because data from the reporting measure is used to calculate the clinical measure. No other reporting measures currently included in the

ESRD QIP's measure set are used for this purpose. As mentioned above, placing these two measures together in a single measure topic that is given a single measure topic score, creates the important linkage between the two measures and balances out the competing incentives involved: incentivizing complete and accurate reporting of data to NHSN while also incentivizing facilities to achieve high clinical scores on the clinical measure. Without complete and accurate data, the clinical measure will not produce meaningful results. The measure topic is also different from others included in the ESRD QIP's measure set because it is comprised of both a clinical measure and a reporting measure. It therefore does not appropriately belong in either the Reporting Measure Domain or the Clinical Measure Domain.

Because of these fundamental differences, we propose to remove the Safety Subdomain from the Clinical Measure Domain for PY 2019 and future payment years. We propose that the Safety Subdomain will instead be a new, third Domain, separate from and in addition to the existing Clinical and Reporting Measure Domains. Additionally, we propose that facilities will receive a Safety Measure Domain score in addition to their Reporting Measure Domain and Clinical Measure Domain scores. We describe our proposed scoring methodology more fully below in section IV.C.6, but we propose that these three Domain scores will be combined and weighted to produce a Total Performance Score (TPS) for each facility.

We seek comments on these proposals.

4. Proposal for Scoring the Proposed NHSN BSI Measure Topic

In light of the concerns we have discussed above, including the accidental or intentional underreporting of dialysis event data, we are proposing to assign significant weight to the proposed NHSN Dialysis Event Reporting Measure in the overall NHSN BSI Measure Topic score. However, our proposed weighting scheme also reflects our goal to incentivize strong

performance on the clinical measure. For these reasons, we propose that the NHSN Dialysis Event Reporting Measure be weighted at 40 percent of the measure topic score and the NHSN BSI Clinical Measure be weighted at 60 percent of the measure topic score. The formula below depicts how the NHSN BSI Measure Topic would be scored.

Proposed Formula to Derive NHSN BSI Measure Topic Score:

[NHSN Dialysis Event Reporting Measure Score * 0.4] + [NHSN BSI Clinical Measure Score*0.6] = Measure Topic Score

We seek comment on this proposal.

5. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Finalized for the PY 2019 ESRD QIP

In the calendar year (CY) 2016 ESRD PPS final rule, we finalized that for PY 2019, the performance standards, achievement thresholds, and benchmarks for the clinical measures would be set at the 50^{th}, 15^{th} and 90^{th} percentile, respectively, of national performance in CY 2015, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2019 program prior to the beginning of the performance period. (80 FR 69060). At this time, we do not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks because we do not yet have complete data from CY 2015. Nevertheless, we are able to estimate these numerical values based on the most recent data available. For the Vascular Access Type, Hypercalcemia, NHSN BSI and ICH CAHPS clinical measures, this data comes from the period of January through December 2015. For the SRR and STrR clinical measures, this data comes

from the period of January through December 2014. In Table 2, we have provided the estimated numerical values for all of the finalized PY 2019 ESRD QIP clinical measures. We will publish updated values for the clinical measures, using data from the first part of CY 2016, in the CY 2017 ESRD PPS final rule.

TABLE 2 – ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2019 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement Threshold	Benchmark	Performance Standard
Vascular Access Type			
%Fistula	53.72%	79.62%	66.04%
%Catheter	17.06%	2.89%	9.15%
Hypercalcemia	4.21%	0.32	1.85%
NHSN Bloodstream Infection SIR	1.812	0	0.861
Standardized Readmission Ratio	1.276	0.629	0.998
Standardized Transfusion Ratio	1.470	0.431	0.923
Comprehensive Dialysis Adequacy Measure Set	86.85%	97.19%	92.53%
ICH CAHPS: Nephrologists' Communication and Caring	56.41%	77.06%	65.89%
ICH CAHPS: Quality of Dialysis Center Care and Operations	52.88%	71.21%	60.75%
ICH CAHPS: Providing Information to Patients	72.09%	85.55%	78.59%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	48.84%	77.42%	62.26%
ICH CAHPS: Overall Rating of the Dialysis Facility	51.18%	80.58%	65.13%

In previous rulemaking, we have finalized policies to the effect that if final numerical values for the performance standard, achievement threshold, and/or benchmark were worse than they were for that measure in the previous year of the ESRD QIP, then we would substitute the

previous year's performance standard, achievement threshold, and/or benchmark for that measure. We finalized this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years. In light of recent discussions with CDC, we have determined that in certain cases it may be appropriate to re-baseline the NHSN BSI Clinical Measure, such that expected infection rates are calculated on the basis of a more recent year's data. In such cases, numerical values assigned to performance standards may appear to decline, even though they represent higher standards for infection prevention. For this reason, with the exception of the NHSN BSI Clinical Measure, we propose to substitute the PY 2018 performance standard, achievement threshold, and/or benchmark for any measure that has a final numerical value for a performance standard, achievement threshold, and/or benchmark that is worse than it was for that measure in the PY 2018 ESRD QIP. We also propose that the performance standards for the NHSN BSI Clinical Measure for PY 2019 will be used irrespective of what values were assigned to the performance standards for PY 2018.

We seek comments on this proposal.

6. Proposal for Weighting the Proposed Safety Measure Domain Within the TPS and Proposal to Change the Weighting of the Clinical Measure Domain for PY 2019

As discussed in Section IV.C.3 above, we are proposing to remove the Safety Subdomain from the Clinical Measure Domain and establish it as a third domain alongside the Clinical Measure and Reporting Measure Domains for the purposes of scoring facilities and determining Total Performance Scores.

In light of stakeholder comments we have received about the prevalence of under-reporting for the NHSN BSI Clinical Measure, as well as the tradeoffs (discussed more fully in section IV.C.1.a. above) between our desire to maintain strong incentives for facilities to report

bloodstream infections and to prevent those infections, and because the Safety Domain is comprised of a single measure topic, we believe it is necessary to reduce the weight of the Safety Measure Domain as a percentage of the TPS. However, we believe it is important to maintain as much consistency as possible in the ESRD QIP scoring methodology. Therefore, we are proposing to gradually reduce the weight of the Safety Measure Domain to 15 percent of the TPS in PY 2019, and then reduce it further in PY 2020, as proposed below. We further propose that the Clinical Measure Domain will be weighted at 75 percent of the TPS, and the Reporting Measure Domain will continue to be weighted at 10 percent of the TPS because we do not want to diminish the incentives to report data on the reporting measures.

In the CY 2015 ESRD PPS final rule, we finalized the criteria we will use to assign weights to measures in a facility's Clinical Measure Domain score (79 FR 66214 through 66216). Under these criteria, we take into consideration: (1) the number of measures and measure topics in a subdomain; (2) how much experience facilities have had with the measures; and (3) how well the measures align with CMS' highest priorities for quality improvement for patients with ESRD.

With respect to criterion 3, one of our top priorities for improving the quality of care furnished to ESRD patients includes increasing the number and significance of both outcome and patient experience of care measures because these measures track important patient outcomes, instead of focusing on the implementation and achievement of clinical processes that may not result in improved health for patients.[4] We believe that a shift toward outcome measures will establish a sounder connection between payment and clinical results that matter to patients. We similarly believe that it is important to prioritize measures of patient experience because high

4 CMS Quality Strategy, page 10, 2016. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.

performance on these measures improves clinical outcomes and patient retention. Accordingly, we believe that increasing the impact of outcome and patient experience of care measures in the ESRD QIP measure set will ensure that facilities that fail to perform well on these measures are much more likely to receive a payment reduction.

In light of the proposed addition of the Safety Measure Domain as well as the policy priorities discussed above, we are proposing to change the Clinical Measure Domain weighting for the PY 2019 ESRD QIP. Specifically, we are proposing to increase the weight of the Vascular Access Type, Dialysis Adequacy and Hypercalcemia measures by 1 percentage point each in the Clinical Measure Domain. This will result in a minor reduction of the weight that each of these measures receives as a percentage of the TPS, which is consistent with our policy to assign greater weight to outcome and experience of care measures. We are also proposing to apportion six percent of the Clinical Measure Domain to the SRR and ICH CAHPS measures, and to apportion the remaining five percent to the STrR measure. We believe this is appropriate because it distributes points as equally as possible among the outcome and experience of care measures, with a slight preference for SRR and ICH CAHPS because facilities will have had more experience with these measures than they will have had with STrR.

For the reasons discussed above, we propose to use the following weighting system in Table 3 below, for calculating a facility's Clinical Measure Domain score for PY 2019. For comparison, in Table 4, we have also provided the Measure Weights we originally finalized for PY 2019 in the CY 2016 ESRD PPS Final Rule (80 FR 69063).

Table 3: PROPOSED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2019 ESRD QIP

Measures/Measure Topics by Subdomain	**Measure Weight in the Clinical Measure Domain Score (Proposed for PY 2019)**	**Measure Weight as Percent of TPS (Proposed for PY 2019)**

Patient and Family Engagement/Care Coordination Subdomain	**42%**	
ICH CAHPS measure	26%	19.5%
SRR measure	16%	12%
Clinical Care Subdomain	**58%**	
STrR measure	12%	9%
Dialysis Adequacy measure	19%	14.25%
Vascular Access Type measure topic	19%	14.25%
Hypercalcemia measure	8%	6%

Note: For PY 2019, we are proposing that the Clinical Domain will make up 75% of a facility's Total Performance Score (TPS). The percentages listed in this Table represent the measure weight as a percent of the Clinical Domain Score.

Table 4: FINALIZED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2019 ESRD QIP (FINALIZED IN THE CY 2016 ESRD PPS FINAL RULE)

Measures/Measure Topics by Subdomain	**Measure Weight in the Clinical Measure Domain Score (Finalized for PY 2019)**	**Measure Weight as Percent of TPS (Finalized for PY 2019)**
Safety Subdomain	**20%**	
NHSN BSI Clinical Measure	20%	18%
Patient and Family Engagement/Care Coordination Subdomain	**30%**	
ICH CAHPS measure	20%	18%
SRR measure	10%	9%
Clinical Care Subdomain	**50%**	
STrR measure	7%	6.3%
Dialysis Adequacy measure	18%	16.2%
Vascular Access Type measure topic	18%	16.2%
Hypercalcemia measure	7%	6.3%

In the CY 2016 ESRD PPS Final Rule, we finalized a requirement that, to be eligible to receive a TPS, a facility had to be eligible for at least one reporting measure and at least one clinical measure (80 FR 69064). With the proposed addition of the Safety Measure Domain for PY 2019, we are proposing a change to this policy. Specifically, for PY 2019, we propose that to be eligible to receive a TPS, a facility must be eligible for at least one measure in the Clinical Measure Domain and at least one measure in the Reporting Measure Domain. As such, facilities do not need to receive a score on a measure in the Safety Measure Domain in order to be eligible to receive a TPS. The NHSN BSI Clinical Measure and the NHSN Dialysis Event Reporting Measure have the same eligibility requirements (specifically they require that a facility treated at least 11 eligible patients during the performance period). We are proposing this change in policy to avoid a situation in which a facility is eligible to receive a TPS when they only receive a score

for a single measure topic. We are not proposing any changes to the policy that a facility's TPS will be rounded to the nearest integer, with half of an integer being rounded up.

We seek comments on these proposals.

7. Example of the Proposed PY 2019 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the proposed scoring methodology for PY 2019. Figures 1 through 4 illustrate how to calculate the Clinical Measure Domain score, the Reporting Measure Domain score, the Safety Measure Domain score, and the TPS. Figure 5 illustrates the full proposed scoring methodology for PY 2019. Note that for this example, Facility A, a hypothetical facility, has performed very well.

Figure 1 illustrates the methodology used to calculate the Clinical Measure Domain score for Facility A.

FIGURE 1:

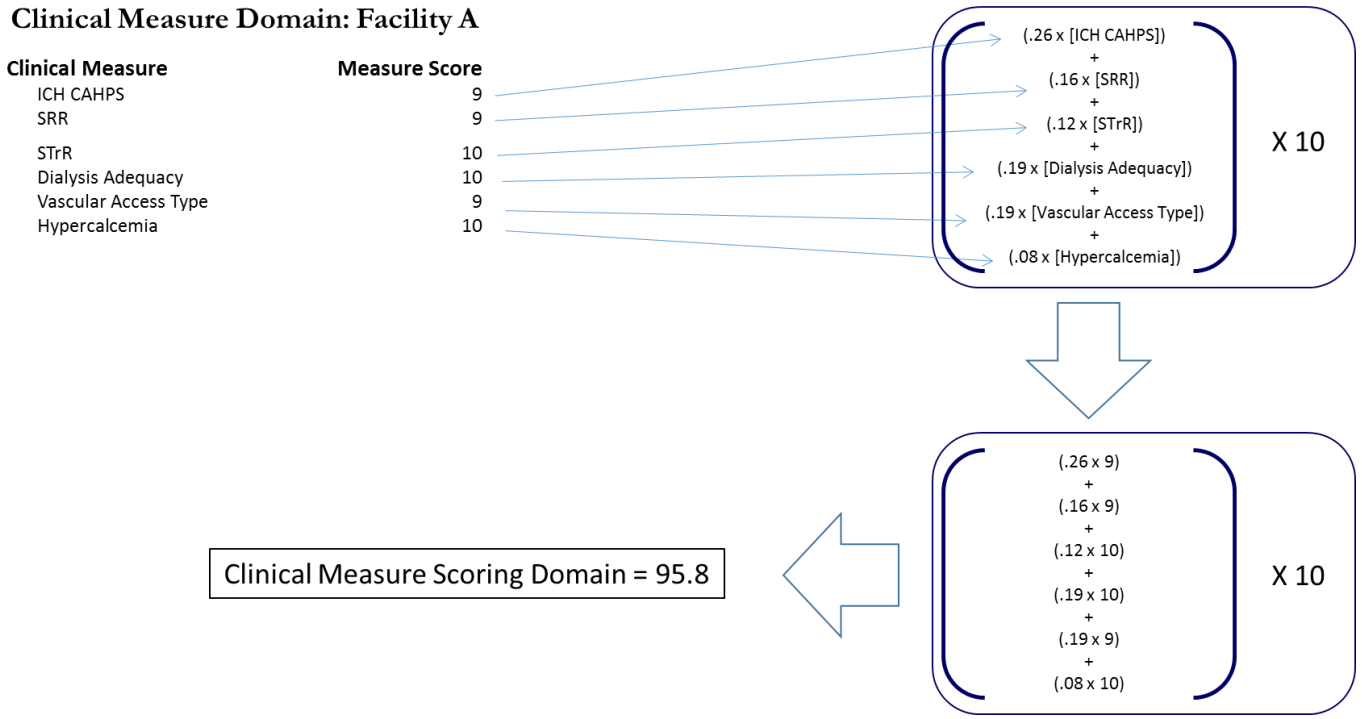


Figure 2 illustrates the general methodology for calculating the Reporting Measure Domain score for Facility A.

FIGURE 2:

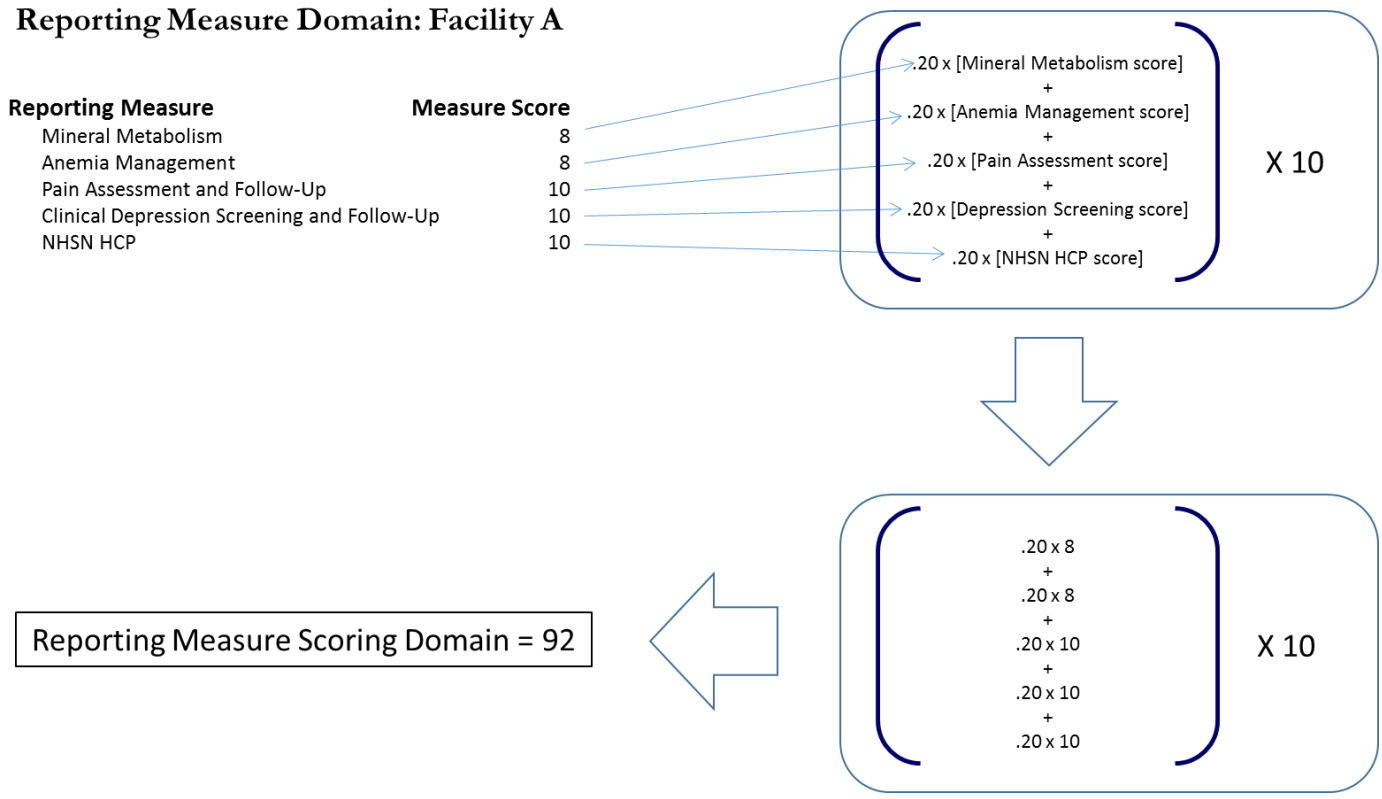


Figure 3 illustrates the methodology used for calculating the Safety Measure Domain score for Facility A.

FIGURE 3:

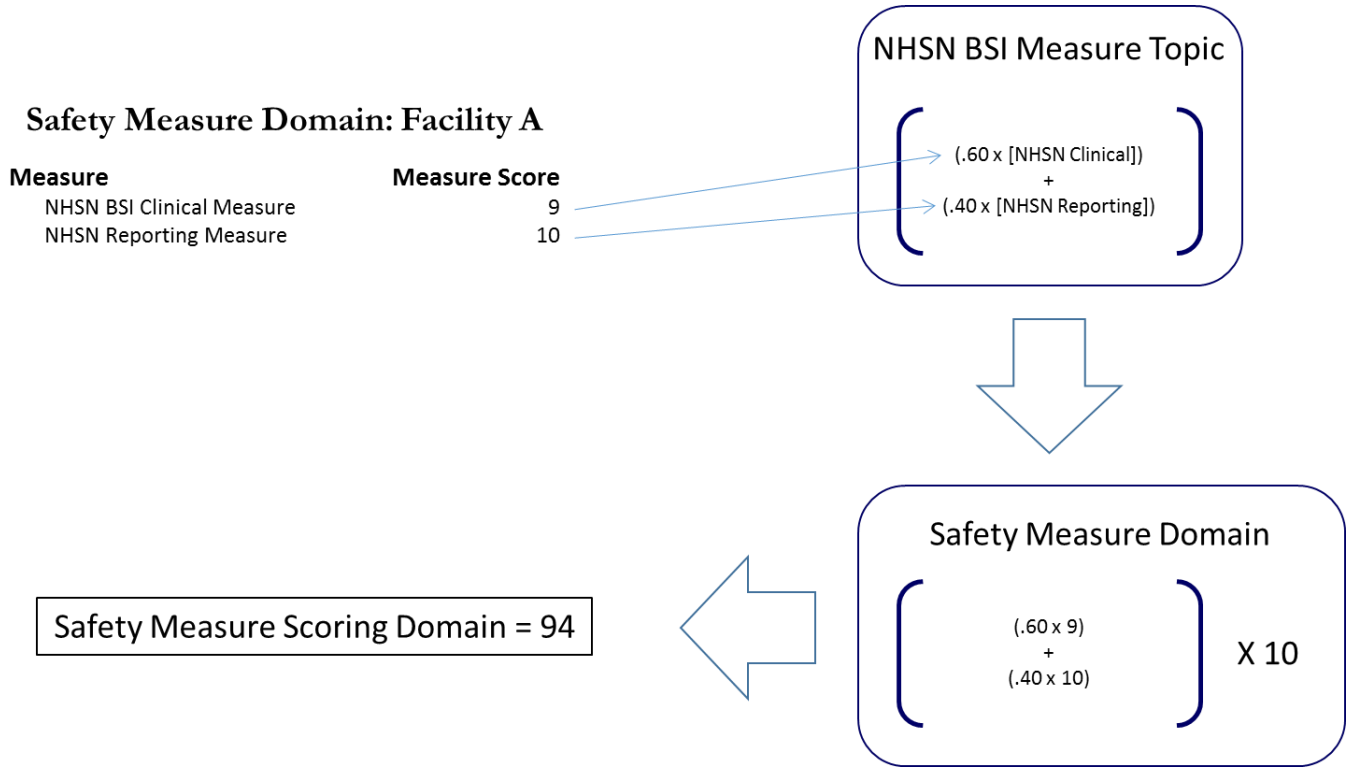


Figure 4 illustrates the methodology used to calculate the TPS for Facility A.

FIGURE 4:

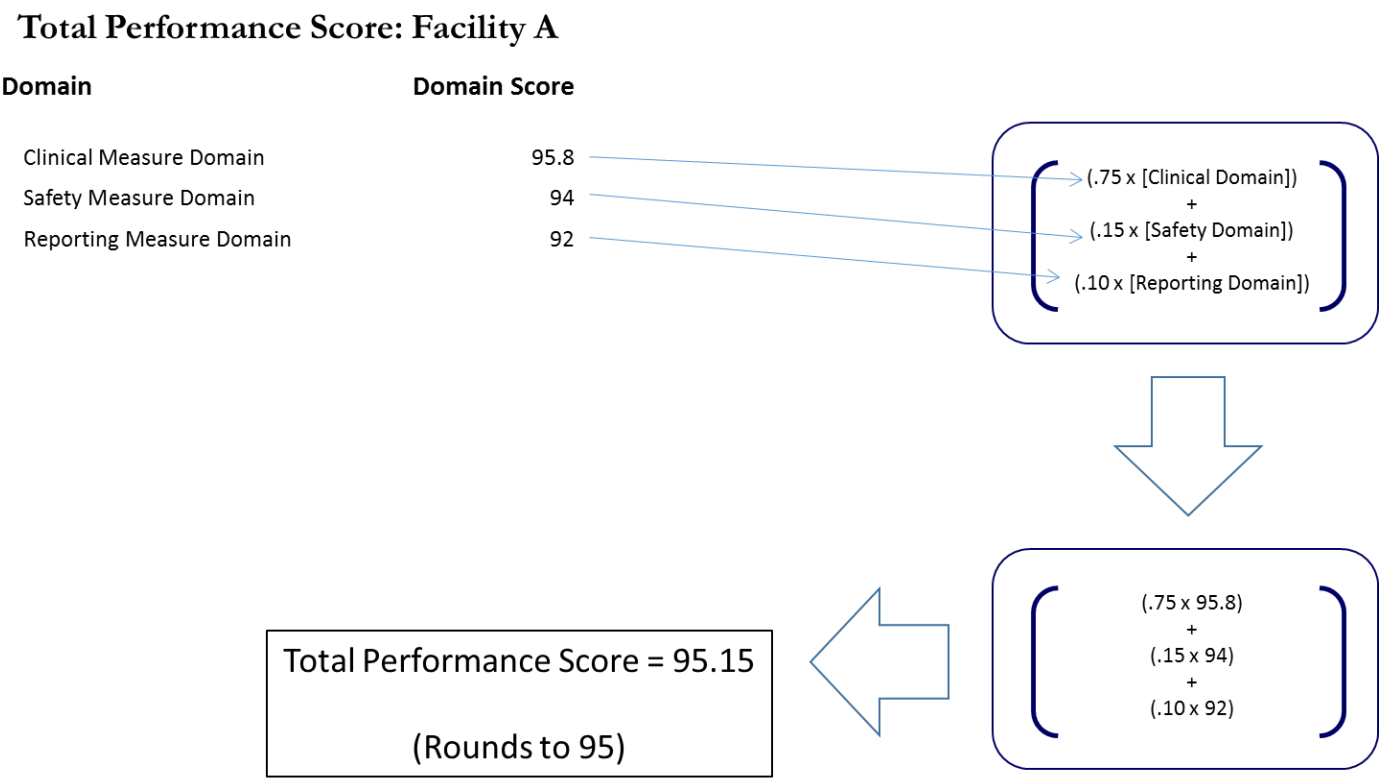
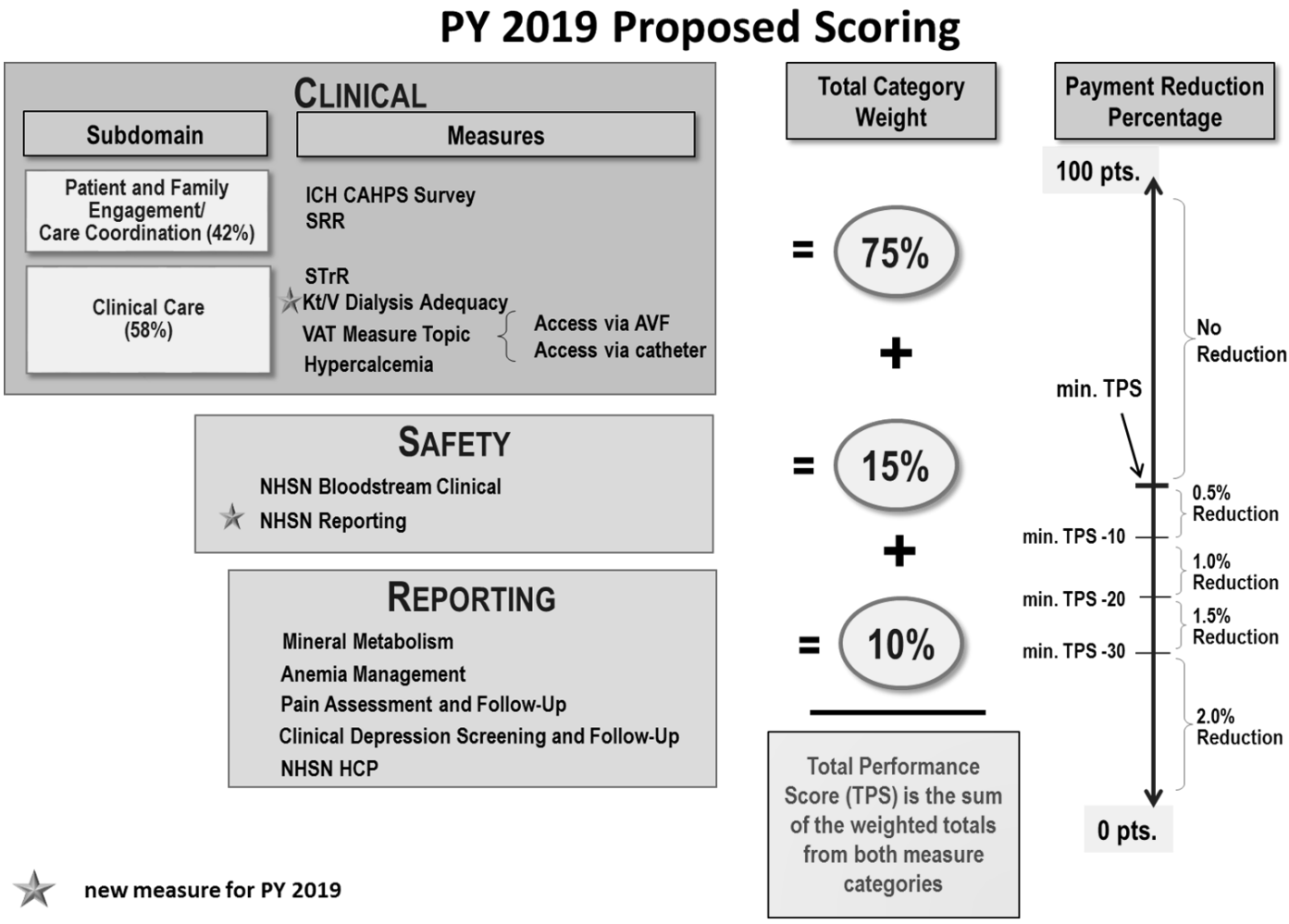


Figure 5 illustrates the full scoring methodology for PY 2019.

FIGURE 5:



8. Proposed Payment Reductions for the PY 2019 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the ESRD QIP scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2016 ESRD PPS final rule, we finalized our proposal for calculating the minimum TPS for PY 2019 and future payment years (80 FR 69067). Under our current policy, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (i) it performs at the performance standard for each clinical measure; and (ii) it receives the number of points for each

reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2017 reporting measures (80 FR 69067).

We were unable to calculate a minimum TPS for PY 2019 in the CY 2016 ESRD PPS final rule because we were not yet able to calculate the performance standards for each of the clinical measures. We therefore stated that we would publish the minimum TPS for the PY 2019 ESRD QIP in the CY 2017 ESRD PPS final rule (80 FR 69068).

Based on the estimated performance standards listed above, we estimate that a facility must meet or exceed a minimum TPS of 59 for PY 2019. For all of the clinical measures except the SRR and STrR, these data come from CY 2015. The data for the SRR and STrR clinical measures come from CY 2014 Medicare claims. For the ICH CAHPS clinical measure, we set the performance standard to zero for the purposes of determining this minimum TPS, because we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the PY 2019 performance period. We are proposing that a facility failing to meet the minimum TPS, as established in the CY 2017 ESRD PPS final rule, will receive a payment reduction based on the estimated TPS ranges indicated in Table 5 below.

TABLE 5 – ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2019 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total Performance Score	**Reduction**
100 – 59	0.0%
58 – 49	0.5%
48 – 39	1.0%
38 – 29	1.5%
28 – 0	2.0%

We seek comments on these proposals.

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 procured the services of a data validation contractor that was tasked with validating a national sample of facilities' records as reported to Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). For validation of CY 2014 data, our first priority was to develop a methodology for validating data submitted to CROWNWeb under the pilot data validation program. That methodology was fully developed and adopted through the rulemaking process. For the PY 2016 ESRD QIP (78 FR 72223 through 72224), we finalized a requirement to sample approximately 10 records from 300 randomly selected facilities; these facilities had 60 days to comply once they received requests for records. We continued this pilot for the PY 2017 and PY 2018 ESRD QIP, and propose to continue doing so for the PY 2019 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 2017. If a facility is randomly selected to participate in the pilot validation study but does not provide us with the requisite medical records within 60 calendar days of receiving a request, then we propose to deduct 10 points from the facility's TPS. Once we have developed and adopted a methodology for validating the CROWNWeb data, we intend to consider whether payment reductions under the ESRD QIP should be based, in part, on whether a facility has met our standards for data validation.

In the CY 2015 ESRD PPS final rule, we also finalized that there will be a feasibility study for validating data reported to the Centers for Disease Control and Prevention (CDC's) National Healthcare Safety Network (NHSN) Dialysis Event Module for the NHSN BSI Clinical Measure. Healthcare-Acquired Infections (HAI) are relatively rare, and we finalized that the feasibility study would target records with a higher probability of including a dialysis event,

because this would enrich the validation sample while reducing the burden on facilities. This methodology resembles the methodology we use in the Hospital Inpatient Quality Reporting Program to validate the central line-associated bloodstream infection measure, the catheter-associated urinary tract infection measure, and the surgical site infection measure (77 FR 53539 through 53553).

For the PY 2019 ESRD QIP, we propose to randomly select 35 facilities to participate in an NHSN dialysis event validation study by submitting 10 patient records covering two quarters of data reported in CY 2017. A CMS contractor will send these facilities requests for medical records for all patients with "candidate events" during the evaluation period; i.e., patients who had any positive blood cultures; received any intravenous antimicrobials; had any pus, redness, or increased swelling at a vascular access site; and/or were admitted to a hospital during the evaluation period. Facilities will have 30 calendar days to respond to the request for medical records based on candidate events either electronically or on paper. If the contractor determines that additional medical records are needed to reach the 10-record threshold from a facility to validate whether the facility accurately reported the dialysis events, then the contractor will send a request for additional, randomly selected patient records from the facility. The facility will have 30 calendar days from the date of the letter to respond to the request. With input from CDC, the CMS contractor will utilize a methodology for reviewing and validating records from candidate events and randomly selected patients, in order to determine whether the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event Protocol. If a facility is selected to participate in the validation study but does not provide CMS with the requisite lists of positive blood cultures within 30 calendar days of receiving a request, then we propose to deduct 10 points from the facility's TPS. Information from the validation study may

be used in future years of the program to inform our consideration of future policies that would incorporate NHSN data accuracy into the scoring process.

We recognize that facilities have previously had 60 days to respond to these requests. However, in the process of implementing the pilot validation study for CY 2015 data, we recognized that the validation contractor did not have enough time to initiate requests, receive responses, validate data reported to NHSN, and generate a comprehensive validation report before the end of the contract cycle. Although facilities will have less time, the 30-day response requirement is consistent with validation studies conducted in the Hospital IQR Program, and we believe that 30 days is a reasonable amount of time for facilities to obtain and transmit the requisite medical records.

We seek comments on this proposal.

D. Proposed Requirements for the PY 2020 ESRD QIP

1. Proposed Replacement of the Mineral Metabolism Reporting Measure Beginning with the PY 2020 Program Year

We consider a quality measure for removal or replacement if: (1) measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made (in other words, the measure is topped-out); (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public

reporting of a measure leads to negative or unintended consequences (77 FR 67475). In the CY 2015 ESRD PPS final rule, we adopted statistical criteria for determining whether a clinical measure is topped out, and also adopted a policy under which we could retain an otherwise topped-out measure if we determined that its continued inclusion in the ESRD QIP measure would address the unique needs of a specific subset of the ESRD population (79 FR 66174).

Subsequent to the publication of the CY 2016 ESRD PPS final rule, we evaluated the finalized PY 2019 ESRD QIP measures that would be continued in PY 2020 against all of these criteria. We determined that none of these measures met criterion (1), (2), (3), (4), (5) or (6). As part of this evaluation for criterion one, we performed a statistical analysis of the PY 2019 measures to determine whether any measures were "topped out." The full results of this analysis can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html and a summary of our topped-out analysis results appears in Table **6** below.

TABLE 6: PY 2020 CLINICAL MEASURES INCLUDING FACILITIES WITH AT LEAST 11 ELIGIBLE PATIENTS PER MEASURE

Measure	N	$75^{th}/25^{th}$ Percentile	$90^{th}/10^{th}$ Percentile	Std Error	Statistically Indistinguishable	Truncated Mean	Truncated SD	TCV	TCV's 0.10
Kt/V Delivered Dose above minimum	6210	96.0	98.0	0.093	**No**	92.5	4.20	0.05	**Yes**
Fistula Use	5906	73.2	79.6	0.148	**No**	65.7	8.88	0.14	**No**
Catheter Use	5921	5.43	2.89	0.093	**No**	90.1[1]	5.16	<0.01	**Yes**
Serum Calcium >10.2	6257	0.91	0.32	0.049	**No**	97.8[1]	1.48	<0.01	**Yes**
NHSN – SIR	5781	0.41	0.00	0.011	**No**	0.963	0.57	<0.01	**Yes**
SRR	5739	0.82	0.64	0.004	**No**	0.995	0.21	<0.01	**Yes**
STrR	5650	0.64	0.43	0.008	**No**	0.965	0.37	<0.01	**Yes**
SHR	6086	0.79	0.63	0.004	**No**	0.983	0.23	<0.01	**Yes**
ICH CAHPS									
Nephrologists communication and caring	3349	71.8	77.1	0.159	**No**	65.7	7.11	0.11	**No**
Quality of dialysis center care and	3349	66.2	71.2	0.134	**No**	60.9	6.20	0.10	**No**

Measure	N	75th/25th Percentile	90th/10th Percentile	Std Error	Statistically Indistinguishable	Truncated Mean	Truncated SD	TCV	TCV's 0.10
operations									
Providing information to patients	3349	82.4	85.6	0.101	**No**	78.4	4.61	0.06	**Yes**
Rating of Nephrologist	3349	69.9	76.6	0.204	**No**	62.0	9.29	0.15	**No**
Rating of dialysis facility staff	3349	70.9	77.4	0.215	**No**	62.0	9.92	0.16	**No**
Rating of dialysis center	3349	73.8	80.6	0.221	**No**	64.8	10.18	0.16	**No**

(1) Truncated mean for percentage is reversed (100% - truncated mean) for measures where lower score = better performance.

As the information in Table 6 indicates, none of these clinical measures are currently topped-out in the ESRD QIP. Accordingly, we are not proposing to remove any of these measures from the ESRD QIP for PY 2020 because they are topped out.

We consider the data sources we use to calculate our measures based on the reliability of the data, and we also try to use CROWNWeb data whenever possible. The Mineral Metabolism measure currently in the ESRD QIP measure set uses CROWNWeb data to determine how frequently facilities report serum phosphorus data, but it also uses Medicare claims data to exclude patients when they were treated at a facility fewer than seven times in a month. There is no evidence to suggest that the Mineral Metabolism reporting measure is leading to negative or unintended clinical consequences. However, we do not think it is optimal to use claims data to calculate the measure because that is inconsistent with our intention to increasingly use CROWNWeb as the data source for calculating measures in the ESRD QIP. There is also another available measure that can be calculated using only CROWNWeb data and that we believe is as reliable as the Mineral Metabolism Reporting Measure. The measure also excludes patients using criteria consistent with that used by other ESRD QIP measures. For these reasons, we are proposing to remove the Mineral Metabolism Reporting Measure from the ESRD QIP

measure set beginning with the PY 2020 program and to replace that measure with the proposed Serum Phosphorus Reporting measure, the specifications for which are described below in section IV.D.2.c.i.

We seek comments on this proposal.

2. Proposed Measures for the PY 2020 ESRD QIP

a. PY 2019 Measures Continuing for PY 2020 and Future Payment Years

We previously finalized 12 measures in the CY 2016 ESRD PPS final rule for the PY 2019 ESRD QIP, and these measures are summarized in Table 7 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 11 of these measures in the PY 2020 ESRD QIP. As noted above, we are proposing to replace the Mineral Metabolism Reporting Measure with the Serum Phosphorus Reporting Measure and we are proposing to reintroduce the NHSN Dialysis Event Reporting Measure into the ESRD QIP measure set beginning with PY 2019.

TABLE 7 – PY 2019 ESRD QIP MEASURES BEING CONTINUED IN PY 2020

NQF #	Measure Title and Description
0257	Vascular Access Type: AV Fistula, a clinical measure Percentage of patient-months on hemodialysis during the last hemodialysis treatment of the month using an autogenous AV fistula with two needles.
0256	Vascular Access Type: Catheter $\geq$ 90 days, a clinical measure Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A	National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
1454	Hypercalcemia, a clinical measure Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
N/A	Standardized Readmission Ratio, a clinical measure Standardized hospital readmissions ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned readmissions.
N/A	Standardized Transfusion Ratio, a clinical measure Risk-adjusted standardized transfusion ratio for all adult Medicare dialysis patients. Number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected

NQF #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Facility administers, using a third-party CMS-approved vendor, the ICH CAHPS survey twice in accordance with survey specifications and submits survey results to CMS.
N/A	Anemia Management Reporting, a reporting measure Number of months for which facility reports ESA dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient.
N/A	Pain Assessment and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period.
N/A	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient once before February 1 of the year following the performance period.
N/A	NHSN Healthcare Personnel Influenza Vaccination, a reporting measure Facility submits Healthcare Personnel Influenza Vaccination Summary Report to CDC's NHSN system, according to the specifications of the Healthcare Personnel Safety Component Protocol, by May 15 of the performance period.
N/A	Kt/V Dialysis Adequacy Comprehensive Clinical Measure Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
NA	NHSN Dialysis Event Reporting Measure (Proposed for PY 2019 in Section IV.C.1.a. of this Proposed Rule)

b. Proposed New Clinical Measures Beginning with the PY 2020 ESRD QIP

i. Proposed Standardized Hospitalization Ratio (SHR) Clinical Measure

Background

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year.[5] Hospitalizations account for approximately 40 percent of total Medicare expenditures for ESRD patients.[6] Measures of the frequency of hospitalization have the potential to help control escalating medical costs, play an important role in identifying potential problems, and help facilities provide cost-effective health care.

5 United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.
6 USRDS Annual Data Report (2015).

At the end of 2013 there were 661,648 patients being dialyzed, of which 117,162 were new (incident) ESRD patients.[7] In 2013, total Medicare costs for the ESRD program were $30.9 billion, a 1.6 percent increase from 2012.[8] Correspondingly, hospitalization costs for ESRD patients are very high with Medicare costs of over $10.3 billion in 2013.

Hospitalization measures have been in use in the Dialysis Facility Reports (formerly Unit-Specific Reports) since 1995. The Dialysis Facility Reports are used by the dialysis facilities and ESRD Networks for quality improvement, and by ESRD state surveyors for monitoring and surveillance. In particular, the Standardized Hospitalization Ratio (SHR) for Admissions is used in the CMS ESRD Core Survey Process, in conjunction with other standard criteria for prioritizing and selecting facilities to survey. In addition, the SHR has been found to be predictive of dialysis facility deficiency citations in the past (ESRD State Outcomes List). The SHR is also a measure that has been publicly reported since January 2013 on the Centers for Medicare and Medicaid Services (CMS) Dialysis Facility Compare website.

Overview of Measure

The SHR measure is an NQF-endorsed all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The Measures Application Partnership supports the direction of this measure for inclusion in the ESRD QIP.

We are proposing to adopt a modified version of the SHR currently endorsed by NQF (NQF #1463). We have submitted this modified measure to NQF for endorsement consideration as part of the standard maintenance process for NQF #1463. When we previously proposed the SHR for implementation in the QIP, we received public comments urging us to not rely solely on

7 USRDS Annual Data Report (2015).
8 United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

CMS Medical Evidence Form 2728 as the only source of patient comorbidity data in the risk-adjustment calculations for the SHR measure. These comments correctly stated that incident comorbidity data are collected for all ESRD patients on CMS Form 2728 when patients first become eligible to receive Medicare ESRD benefits, regardless of payer. Although CMS Form 2728 is intended to inform both facilities and us whether one or more comorbid conditions are present at the start of ESRD, "there is currently no mechanism for either correcting or updating patient comorbidity data on CMS' Medical Evidence Reporting Form 2728" (76 FR 70267). Commenters were concerned that risk-adjusting the SHR solely on the basis of comorbidity data from CMS Form 2728 would create access to care problems for patients, because patients typically develop additional comorbidities after they begin chronic dialysis, and facilities would have a disincentive to treat these patients if recent comorbidities were not included in the risk-adjustment calculations (77 FR 67495 through 67496).

In the CY 2013 ESRD PPS proposed rule, we noted that updated comorbidity data could be captured on the ESRD 72x claims form. Some public comments stated that, "reporting comorbidities on the 72x claim could be a huge administrative burden for facilities, including time associated with validating that the data they submit on these claims is valid" (77 FR 67496). In response to these comments, we stated that we would "continue to assess the best means available for risk-adjustment for both the SHR and Standardized Mortality Ratio (SMR) measures, taking both the benefits of the information and the burden to facilities into account, should we propose to adopt these measures in future rulemaking" (77 FR 67496). We proposed to adopt a Comorbidity Reporting Measure for the PY 2016 ESRD QIP. This measure would have allowed us to collect and analyze the updated comorbidity data "to develop risk adjustment methodologies for possible use in calculating the SHR and SMR measures" (78 FR 72208). We

chose not to finalize the comorbidity measure "as a result of the significant concerns expressed by commenters (78 FR 72209).

In response to the comments on the SHR when originally proposed, and subsequently the proposed comorbidity reporting measure, we have made revisions to the SHR specifications. The modified SHR that we are currently proposing to adopt beginning with the PY 2020 ESRD QIP includes a risk adjustment for 210 prevalent comorbidities in addition to the incident comorbidities from the CMS Medical Evidence Form 2728. The 210 prevalent comorbidities were identified through review by a Technical Expert Panel (TEP) first convened in late 2015. The details of how the 210 comorbidities were identified are described below. We propose to identify these prevalent comorbidities for purposes of risk adjusting the measure using available Medicare claims data. We believe this approach allows us to address commenters' concerns about increased reporting burden, while also resulting in a more robust risk-adjustment methodology.

Our understanding is that the 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/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=79434). Under this approach, patient comorbidities should only be included in risk-adjustment calculations if the following criteria are met: (1) risk adjustment should be based on patient factors that influence the measured outcome and are present at the start of care; (2) measures should not be adjusted for factors related to disparities in care or the quality of care; (3) risk adjustment factors

must be substantially related to the outcome being measured; and (4) risk adjustment factors should not reflect the quality of care furnished by the provider/facility being evaluated. As indicated in the "Inclusion and Exclusion Criteria" subsection below, as well as in the NQF-endorsed measure specifications, the proposed SHR clinical measure includes dialysis patients starting on day 91 of ESRD treatment. Accordingly, we believe that consistent with NQF Measure Evaluation Criterion 2b4, it is appropriate to risk adjust the proposed SHR measure on the basis of incident patient comorbidity data collected on CMS Form 2728 because these comorbidities are definitively present at the start of care (that is, on day 91 of ESRD treatment). The 210 prevalent comorbidities now included for adjustment were also selected with these criteria in mind. Specifically, in developing its recommendations, the TEP was asked to apply the same criteria that the NQF uses to assign risk-adjusters under the approach described above.

Reflecting these criteria, the TEP evaluated a list of prevalent comorbidities derived through the following process. First, the ESRD Hierarchical Comorbidity Conditions (ESRD-HCCs) were used as a starting point to identify ICD-9 diagnosis codes that could be used for risk adjustment. Those individual ICD-9 conditions that comprised the respective ESRD HCCs, with a prevalence of at least 0.1 percent in the patient population, were then selected for analysis to determine their statistical relationship to mortality or hospitalization. This step resulted in 555 diagnoses for comorbidities (out of over 3000 ICD-9 diagnosis codes in the ESRD-HCCs). Next, an adaptive lasso variable selection method was applied to these 555 diagnoses to identify those with a statistically significant relationship to mortality and/or hospitalization ($p<0.05$). This process identified 242 diagnoses. The TEP members then scored each of these diagnoses as follows:

1. Very likely the result of dialysis facility care.
2. Likely the result of dialysis facility care.
3. May or may not be the result of dialysis facility care.
4. Unlikely to be the result of dialysis facility care.
5. Very likely not the result of dialysis facility care.

This scoring exercise aimed at identifying a set of prevalent comorbidities are not likely the result of facility care and therefore potentially are risk adjusters for SHR and SMR. The TEP concluded that comorbidities scored as "unlikely" or "very unlikely the result of facility care" by at least half of TEP members (simple majority) were appropriate for inclusion as risk-adjusters. This process resulted in 210 conditions as risk adjustors. The TEP recommended incorporation of these adjustors in the risk model for the SHR, and CMS concurred.

Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iv) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (that entity currently is NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed, so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We have given due consideration to endorsed measures, including the endorsed SHR (NQF #1463), 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 a hospitalization measure (NQF #1463), our analyses suggest that incorporating prevalent comorbidities results in a more robust and reliable measure of hospitalization.

We have analyzed the measure's reliability, the results of which are provided below and in greater detail in the SHR Measure Methodology report, available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html. The Inter-Unit Reliability (IUR) was calculated for the proposed SHR 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). 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 good 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.

Overall, we found that IURs for the 1-year SHRs have a range of 0.70 through 0.72 across the years 2010, 2011, 2012 and 2013, which indicates that two-thirds of the variation in the 1-year SHR can be attributed to the between-facility differences and one-third to within-facility variation.

Table 9: IUR for 1-year SHR, Overall and by Facility Size, 2010-2013

	2010		2011		2012		2013	
Facility Size (Number of patients)	**IUR**	**N**	**IUR**	**N**	**IUR**	**N**	**IUR**	**N**
All	0.72	5407	0.71	5583	0.70	5709	0.70	5864
Small (<=50)	0.54	1864	0.51	1921	0.48	1977	0.46	2028
Medium (51–87)	0.65	1702	0.63	1785	0.58	1825	0.57	1930
Large (>=88)	0.81	1841	0.81	1877	0.81	1907	0.82	1906

We also tested the SHR for measure validity, assessing its association with established quality metrics in the ESRD dialysis population. The SHR measure is correlated with the SMR for each

individual year from 2010 through 2013, where Spearman's correlation coefficient ranged from 0.27 to 0.30, with all four correlations being highly significant ($p<0.0001$). Also for each year from 2011 through 2013, the SHR was correlated with the Standardized Readmission Ratio (SRR) (Spearman's rho=0.54, 0.50, 0.48; $p<0.0001$).

In addition, SHR is negatively correlated in each of the 4-years with the measure assessing percentage of patients in the facility with an AV Fistula (Spearman's rho= -0.12, -0.15, -0.12, -0.13). Thus higher values of SHR are associated with lower usage of AV Fistulas. Further, SHR is positively correlated with catheter use >= 90 days (Spearman's rho=0.21, 0.21, 0.18, 0.16), indicating that higher values of SHR are associated with increased use of catheters. These correlations are all highly significant ($p<0.001$). For each year of 2010 through 2013, the SHR is also found to be negatively correlated with the percent of hemodialysis patients with Kt/V>=1.2, again in the direction expected (Spearman's rho= -0.11, -0.13, -0.10,-0.11; $p<0.0001$). Lower SHRs are associated with a higher percentage of patients receiving adequate dialysis dose.

Data Sources

Data are derived from an extensive national ESRD patient database, which is largely derived from the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN), which includes Renal Management Information System (REMIS), and the Standard Information Management System database, the Enrollment Database, Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network, the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, the Dialysis Facility Compare and the Social Security Death Master File. The database is comprehensive for Medicare Parts A and B patients. Non-

Medicare patients are included in all sources except for the Medicare payment records. Standard Information Management System/CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on hospitalizations and patient comorbidities are obtained from Medicare Inpatient Claims Standard Analysis Files.

Outcome

The outcome for this measure is the number of inpatient hospital admissions among eligible chronic dialysis patients under the care of the dialysis facility during the 1-year reporting period.

Measure Eligible Population

The measure eligible population includes adult and pediatric Medicare ESRD patients who have reached day 91 of ESRD treatment and who received dialysis within the 1-year period.

Inclusion and Exclusion Criteria

Patients are included in the measure after the first 90 days of treatment. For each patient, we identify the dialysis provider at each point in time. Starting with day 91 of ESRD treatment, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to his or her current facility on day 91 of ESRD treatment if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to the facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility.

Patients are removed from facilities 3 days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

Risk Adjustment

The SHR measure estimates expected hospitalizations calculated from a Cox model that adjusts for patient risk factors and demographic characteristics. This model accounts for clustering of patients in particular facilities and allows for an estimate of the performance of each individual facility, while applying the risk adjustment model to obtain the expected number of hospitalizations for each facility. The model does not adjust for sociodemographic status. We understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding dialysis facilities to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2-years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the Improving Medicare Post-Acute Care Transformation Act. We will closely examine the findings of the Assistant Secretary for Planning and Evaluation reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Calculating the SHR Measure

The SHR measure is calculated as the ratio of the number of observed hospitalizations to the number of expected hospitalizations. A ratio greater than one means that facilities have more hospitalizations than would be expected for an average facility with a similar patient-mix; a ratio less than one means the facility has fewer hospitalizations than would be expected for an average facility with a similar patient-mix.

The SHR uses expected hospital admissions calculated from a Cox model as extended to handle repeated events, with piecewise constant baseline rates. The model is fit in two stages. The stage 1 model is first fitted to the national data with piecewise constant baseline rates applied to each facility. Hospitalization rates are adjusted for patient age, sex, diabetes, duration of ESRD, nursing home status, BMI at incidence, comorbidity index at incidence, and calendar year. This model allows the baseline hospitalization rates to vary between facilities then applies the regression coefficients equally to all facilities. This approach is robust to possible differences between facilities in the patient mix being treated. The second stage then uses a risk adjustment factor from the first stage as an offset. The stage 2 model then calculates the national baseline hospitalization rate. The predicted value from stage 1 and the baseline rate from stage 2 are then used to calculate the expected number of hospital days for each patient over the period

during which the patient is seen to be at risk.

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

We seek comments on our proposal to adopt the SHR measure for the ESRD QIP beginning with PY 2020.

c. Proposed New Reporting Measures Beginning with the PY 2020 ESRD QIP

i. Proposed Serum Phosphorus Reporting Measure

As mentioned above, for PY 2020 we are proposing to adopt a new Proposed Serum Phosphorus Reporting Measure. Section 1881(h)(2)(A)(iii) of the Act states that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures of bone mineral metabolism. Abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced Chronic Kidney Disease (CKD). Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Overt symptoms of these abnormalities often manifest in only the most extreme states of calcium-phosphorus dysregulation, which is why we believe that routine blood testing of calcium and phosphorus is necessary to detect abnormalities.

The proposed Serum Phosphorus Reporting Measure is based on a serum phosphorus measure that is endorsed by the NQF (NQF #0255), which evaluates the extent to which facilities monitor and report patient phosphorus levels. In addition, and as explained above, the proposed Serum Phosphorus Reporting Measure is collected using CROWNWeb data and excludes

patients using criteria consistent with other ESRD QIP measures. The Measure Applications Partnership expressed full support for this measure.

For PY 2020 and future payment years, we propose that facilities must report serum or plasma phosphorus data to CROWNWeb at least once per month for each qualifying patient. Qualifying patients for this proposed measure are defined as patients 18 years of age or older, who have a completed CMS Medical Evidence Form 2728, who have not received a transplant with a functioning graft, and who are assigned to the same facility for at least the full calendar month (for example, if a patient is admitted to a facility during the middle of the month, the facility will not be required to report for that patient for that month). We further propose that facilities will be granted a one-month period following the calendar month to enter this data. For example, we would require a facility to report Serum Phosphorus rates for January 2018 on or before February 28, 2018. Facilities would be scored on whether they successfully report the required data within the timeframe provided, not on the values reported. Technical specifications for the Serum Phosphorus reporting measure can be found at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html .

We seek comments on this proposal.

ii. Proposed Ultrafiltration Rate Reporting Measure

The ultrafiltration rate measures the rapidity with which fluid (ml) is removed during dialysis per unit (kg) of body weight in unit (hour) time. A patient's ultrafiltration rate is under the control of the dialysis facility and is monitored throughout a patient's hemodialysis session. Studies suggest that higher ultrafiltration rates are associated with higher mortality and higher

odds of an "unstable" dialysis session,[9] and that rapid rates of fluid removal at dialysis can precipitate events such as intradialytic hypotension, subclinical yet significantly decreased organ perfusion, and in some cases myocardial damage and heart failure.

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 that require reporting of relevant ultrafiltration data currently exist, we are proposing to adopt the Ultrafiltration Rate reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

The proposed Ultrafiltration Rate reporting measure is based upon the NQF-endorsed Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hr) (NQF #2701). This measure assesses the percentage of patient-months for patients with an ultrafiltration rate greater than or equal to 13 ml/kg/hr. The Measure Applications Partnership expressed full support for this measure.

For PY 2020 and future payment years, we propose that facilities must report the following data to CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/V draw submitted to CROWNWeb for that clinical month, for each qualifying patient (defined below):

- HD Kt/V Date
- Post-Dialysis Weight
- Pre-Dialysis Weight
- Delivered Minutes of BUN Hemodialysis
- Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month

Qualifying patients for this proposed measure are defined as patients 18 years of age or older,

9 Flythe SE, Kimmel SE, Brunelli SM. Rapid fluid removal during dialysis is associated with cardiovascular morbidity and mortality. Kidney International (2011) Jan; 79(2):250-7. Flythe JE, Curhan GC, Brunelli SM. Disentangling the ultrafiltration rate—mortality association: The respective roles of session length and weight gain. Clin J Am Soc Nephrol. 2013 Jul;8(7):1151-61. Movilli, E et al. "Association between high ultrafiltration rates and mortality in uraemic patients on regular hemodialysis. A 5-year prospective observational multicenter study." Nephrology Dialysis Transplantation 22.12(2007): 3547-3552.

who have a completed CMS Medical Evidence Form 2728, who have not received a transplant with a functioning graft, who are on in-center hemodialysis, and who are assigned to the same facility for at least the full calendar month (for example, if a patient is admitted to a facility during the middle of the month, the facility will not be required to report for that patient for that month). We further propose that facilities will be granted a one-month period following the calendar month to enter this data. For example, we would require a facility to report ultrafiltration rates for January 2018 on or before February 28, 2018. Facilities would be scored on whether they successfully report the required data within the timeframe provided, not on the values reported. Technical specifications for the Ultrafiltration Rate reporting measure can be found at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

We seek comments on this proposal.

3. Proposed Performance Period for the PY 2020 ESRD QIP

We are proposing to establish CY 2018 as the performance period for the PY 2020 ESRD QIP for all but the NHSN Healthcare Personnel Influenza Vaccination reporting measure because it is consistent with the performance periods we have historically used for these measures and accounts for seasonal variations that might affect a facility's measure score.

We are proposing that the performance period for the NHSN Healthcare Personnel Influenza Vaccination reporting measure will be from October 1, 2016 through March 31, 2017, because this period spans the length of the 2016-2017 influenza season.

We seek comments on these proposals.

4. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2020 ESRD QIP

Section 1881(h)(4)(A) of the Act provides that "the Secretary shall establish performance standards with respect to measures selected . . . for a performance period with respect to a year." Section 1881(h)(4)(B) of the Act further provides that the "performance standards . . . shall include levels of achievement and improvement, as determined appropriate by the Secretary." We use the performance standards to establish the minimum score a facility must achieve to avoid a Medicare payment reduction. We use achievement thresholds and benchmarks to calculate scores on the clinical measures.

a. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2020 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we are proposing for PY 2020 to set the performance standards, achievement thresholds, and benchmarks for the clinical measures at the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2016, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2020 program prior to the beginning of the performance period. We continue to believe these standards will provide an incentive for facilities to continuously improve their performance, while not reducing incentives to facilities that score at or above the national performance rate for the clinical measures.

We seek comments on these proposals.

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Proposed for the PY 2020 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures, because we do not yet have data from

CY 2016 or the first portion of CY 2017. We will publish values for the clinical measures, using data from CY 2016 and the first portion of CY 2017, in the CY 2018 ESRD PPS final rule.

c. Proposed Performance Standards for the PY 2020 Reporting Measures

In the CY 2014 ESRD PPS final rule, we finalized performance standards for the Anemia Management and Mineral Metabolism reporting measures (78 FR 72213). We are not proposing any changes to these policies for the PY 2020 ESRD QIP.

In the CY 2016 ESRD PPS final rule, we finalized performance standards for the Screening for Clinical Depression and Follow-Up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures (79 FR 66209). We are not proposing any changes to these policies.

For the proposed Ultrafiltration Rate Reporting Measure, we propose to set the performance standard as successfully reporting the following data to CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/V draw for that clinical month, for each qualifying patient (1) HD Kt/V Date; (2) Post-Dialysis Weight; (3) Pre-Dialysis Weight; (4) Delivered Minutes of BUN Hemodialysis; and (5) Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month. This information must be submitted for each qualifying patient in CROWNWeb on a monthly basis, for each month of the reporting period.

For the proposed Serum Phosphorus Reporting measure, we propose to set the performance standard as successfully reporting a serum phosphorus value for each qualifying patient in CROWNWeb on a monthly basis, for each month of the reporting period.

For the proposed NHSN Dialysis Event Reporting measure, we propose to set the performance standard as successfully reporting 12 months of data from CY 2018.

We seek comments on these proposals.

5. Proposal for Scoring the PY 2020 ESRD QIP

a. Scoring Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). Under this methodology, facilities receive points along an achievement range based on their performance during the performance period for each measure, which we define as a scale between the achievement threshold and the benchmark. In determining a facility's achievement score for each clinical measure under the PY 2020 ESRD QIP, we propose to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. The facility's achievement score would be calculated by comparing its performance on the measure during CY 2018 (the proposed performance period) to the achievement threshold and benchmark (the 15^{th} and 90^{th} percentiles of national performance on the measure in CY 2016).

We seek comment on this proposal.

b. Scoring Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). In determining a facility's improvement score for each measure under the PY 2020 ESRD QIP, we propose to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. Under this methodology, facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We propose to define the improvement threshold as the facility's performance on the measure during CY 2017. The facility's improvement score would be calculated by comparing its performance on the measure

during CY 2018 (the proposed performance period) to the improvement threshold and benchmark.

We seek comment on this proposal.

c. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through 66210). We are not proposing any changes to this policy. Under this methodology, facilities will receive an achievement score and an improvement score for each of the three composite measures and three global ratings in the ICH CAHPS survey instrument. A facility's ICH CAHPS score will be based on the higher of the facility's achievement or improvement score for each of the composite measures and global ratings, and the resulting scores on each of the composite measures and global ratings will be averaged together to yield an overall score on the ICH CAHPS clinical measure. For PY 2020, the facility's achievement score would be calculated by comparing where its performance on each of the three composite measures and three global ratings during CY 2018 falls relative to the achievement threshold and benchmark for that measure and rating based on CY 2016 data. The facility's improvement score would be calculated by comparing its performance on each of the three composite measures and three global ratings during CY 2018 to its performance rates on these items during CY 2017.

We seek comments on this proposal.

d. Proposal for Calculating Facility Performance on Reporting Measures

In the CY 2013 ESRD PPS final rule, we finalized policies for scoring performance on the Anemia Management and Mineral Metabolism reporting measures in the ESRD QIP (77 FR 67506). We are not proposing any changes to these policies for the PY 2020 ESRD QIP.

In the CY 2015 ESRD PPS final rule, we finalized policies for scoring performance on the Clinical Depression Screening and Follow-Up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures (79 FR 66210 through 66211). We are not proposing any changes to these policies.

With respect to the proposed Ultrafiltration Rate and Serum Phosphorus reporting measures, we are proposing to score facilities with a CMS Certification Number (CCN) Open Date before July 1, 2018 using the same formula previously finalized for the Mineral Metabolism and Anemia Management reporting measures (77 FR 67506):

$$\left[\frac{(\#\text{ months successfully reporting data})}{(\#\text{ eligible months})} \times 12 \right] - 2$$

As with the Anemia Management and Mineral Metabolism reporting measures, we would round the result of this formula (with half rounded up) to generate a measure score from 0-10.

We seek comments on these proposals.

6. Proposal for Weighting the Clinical Measure Domain, and Weighting the Total Performance Score

a. Proposal for Weighting the Clinical Measure Domain for PY 2020

In light of the proposed removal of the Safety Subdomain from the Clinical Measure Domain, our policy priorities for quality improvement for patients with ESRD discussed in Section IV.C.6 above, and the criteria finalized in the CY 2015 ESRD PPS Final Rule used to assign weights to measures in a facility's Clinical Measure Domain score (79 FR 66214 through 66216), we propose to weight the following measures in the following subdomains of the proposed clinical measure domain as follows (see Table 10, below):

TABLE 10: PROPOSED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2020 ESRD QIP

Measures/Measure Topics by Subdomain	Measure Weight in the Clinical Domain Score (Proposed for PY 2020)	Measure Weight as Percent of TPS (Proposed for PY 2020)
Patient and Family Engagement/Care Coordination Subdomain	**40%**	
ICH CAHPS measure	25%	20%
SRR Measure	15%	12%
Clinical Care Subdomain	**60%**	
STrR measure	11%	8.8%
Dialysis Adequacy measure	18%	18.8%
Vascular Access Type measure topic	18%	18.8%
Hypercalcemia measure	2%	1.6%
(Proposed) SHR measure	11%	8.8%

Note: We propose that the Clinical Domain make up 80% of a facility's Total Performance Score (TPS) for PY 2020. The percentages listed in this Table represent the measure weight as a percent of the Clinical Domain Score.

Specifically, we are proposing to reduce the weight of the Safety Measure Domain in light of validation concerns discussed above in the context of the proposal to reintroduce the NHSN Dialysis Event Reporting Measure (see Section (IV)(1)(a) above). For PY 2020 we are proposing to reduce the weight of the Safety Measure Domain from 15 percent to 10 percent. In future years of the program, we may consider increasing the weight of the NHSN BSI Clinical Measure and/or the NHSN BSI Measure Topic once we see that facilities are completely and accurately reporting to NHSN and once we have analyzed the data from the proposed increased NHSN Data Validation Study. In order to accommodate the reduction of the weight of the Safety Measure Domain, we are proposing to increase the weight of the Clinical Measure Domain to 80 percent, and to keep the weight of the Reporting Measure Domain at 10 percent.

We are also proposing to weight the proposed SHR Clinical Measure at 11 percent of a facility's Clinical Measure Domain score. Facilities have had significant experience with SHR

via public reporting on Dialysis Facility Compare, and reducing hospitalizations is a top policy goal for CMS. Further, increasing the emphasis on outcome measures is an additional policy goal of CMS, for reasons discussed above. For these reasons, we believe it is appropriate to weight the proposed SHR Clinical Measure at 11 percent of a facility's Clinical Measure Domain score.

Next, we are proposing to decrease the weight of the Hypercalcemia clinical measure within the Clinical Care Subdomain to 2 percent of a facility's clinical domain score. We are proposing to do so at this time to accommodate the weight assigned to the proposed SHR measure. The Hypercalcemia clinical measure was recently re-endorsed at NQF with a reserved status because there was very little room for improvement and facility scores on the measure are very high overall. Although this is true, the Hypercalcemia clinical measure does not meet the criterion for being topped out in the ESRD QIP (as described in Section IV.D.1. above). Therefore, despite its limited value for assessing facility performance, we decided not to propose to remove the Hypercalcemia clinical measure from the ESRD QIP measure set, but rather to significantly reduce its weight in the clinical subdomain because it provides some indication of the quality of care furnished to patients by facilities.

Finally, to accommodate the proposed addition of the SHR Clinical Measure beginning in PY 2020 and the proposed reduction in weight of the Hypercalcemia measure, we are proposing to reduce the weights of the following measures by 1 percentage point each from what we have proposed for PY 2019, within the Clinical Measure Domain: ICH CAHPS, SRR, STrR, Dialysis Adequacy, and Vascular Access Type. As illustrated in Table 10, these minor reductions in the weights of these measures in the Clinical Measure Domain would be counterbalanced by the increase in the overall percent of the TPS that we are proposing to make to the Clinical Measure

Domain, such that the proposed weights for these measures as a percentage of the TPS will remain as constant as possible from PY 2019 to PY 2020. Accordingly, this proposal would generally maintain the percentage of the TPS assigned to these measures.

We seek comments on these proposals.

b. Weighting the Total Performance Score

We continue to believe that while the reporting measures are valuable, the clinical measures evaluate actual patient care and therefore justify a higher combined weight (78 FR 72217). We are proposing to reduce the weight of the Safety Measure Domain from 15 percent of a facility's TPS for PY 2019 to 10 percent of a facility's TPS for PY 2020. As noted in Section IV.C.1.a. above, we are gradually reducing the weight of this Safety Measure Domain over the course of 2 years because we believe it is important to reduce the weight of the Domain in light validation concerns, but it is important to maintain as much consistency as possible in the QIP Scoring Methodology from year to year.

For the same reasons discussed above, in Section IV.C.6., we propose that for PY 2020, to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in the Clinical Measure Domain and at least one measure in the Reporting Measure Domain.

We seek comments on these proposals.

7. Example of the Proposed PY 2020 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the proposed scoring methodology for PY 2020. Figures 6-9 illustrate how to calculate the Clinical Measure Domain score, the Reporting Measure Domain score, the Safety Measure Domain score, and the TPS. Figure 10 illustrates the full proposed scoring methodology for PY 2020. Note that for this example, Facility A, a hypothetical facility, has performed very well. Figure 6 illustrates the methodology

used to calculate the Clinical Measure Domain score for Facility A.

FIGURE 6:

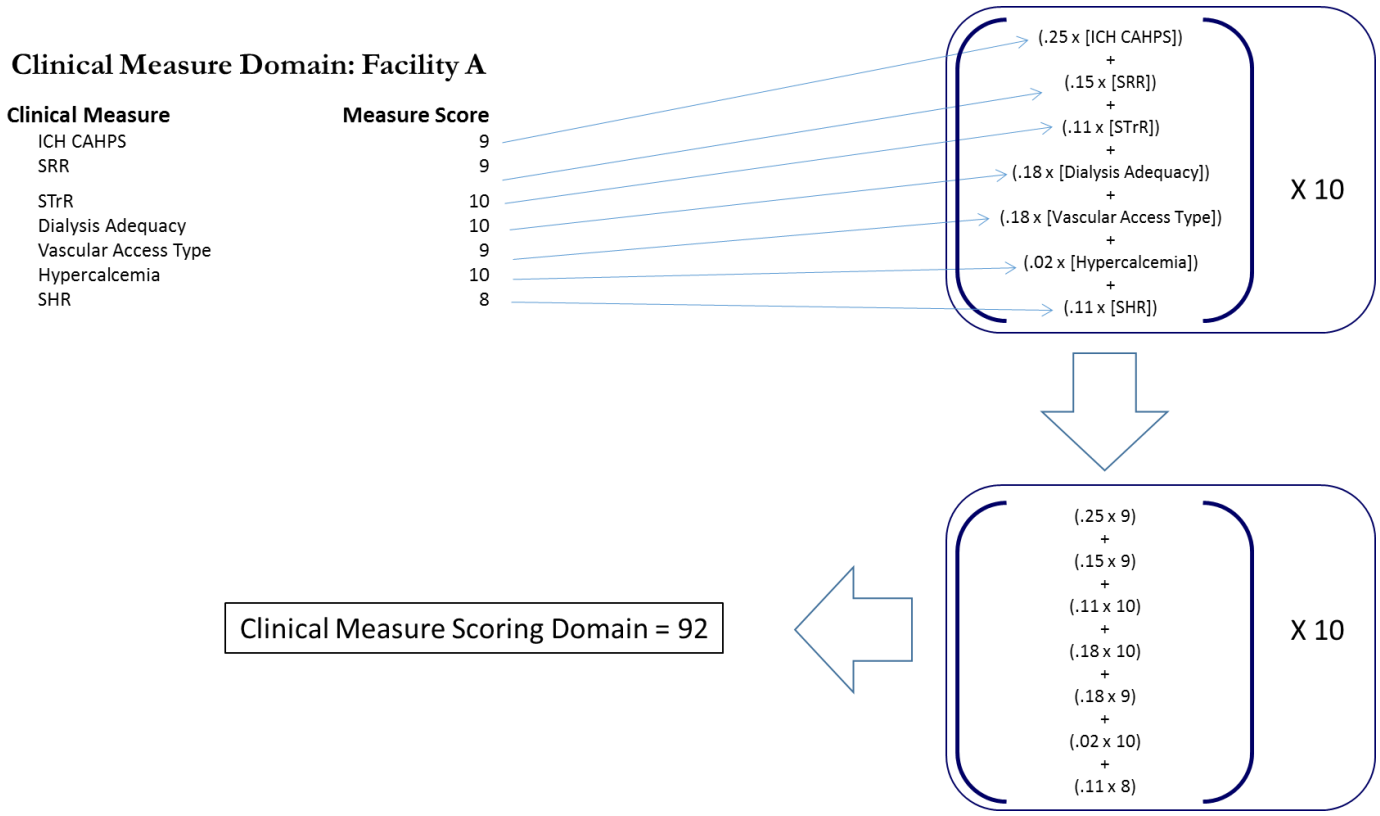


Figure 7 illustrates the general methodology for calculating the Reporting Measure Domain score for Facility A.

FIGURE 7:

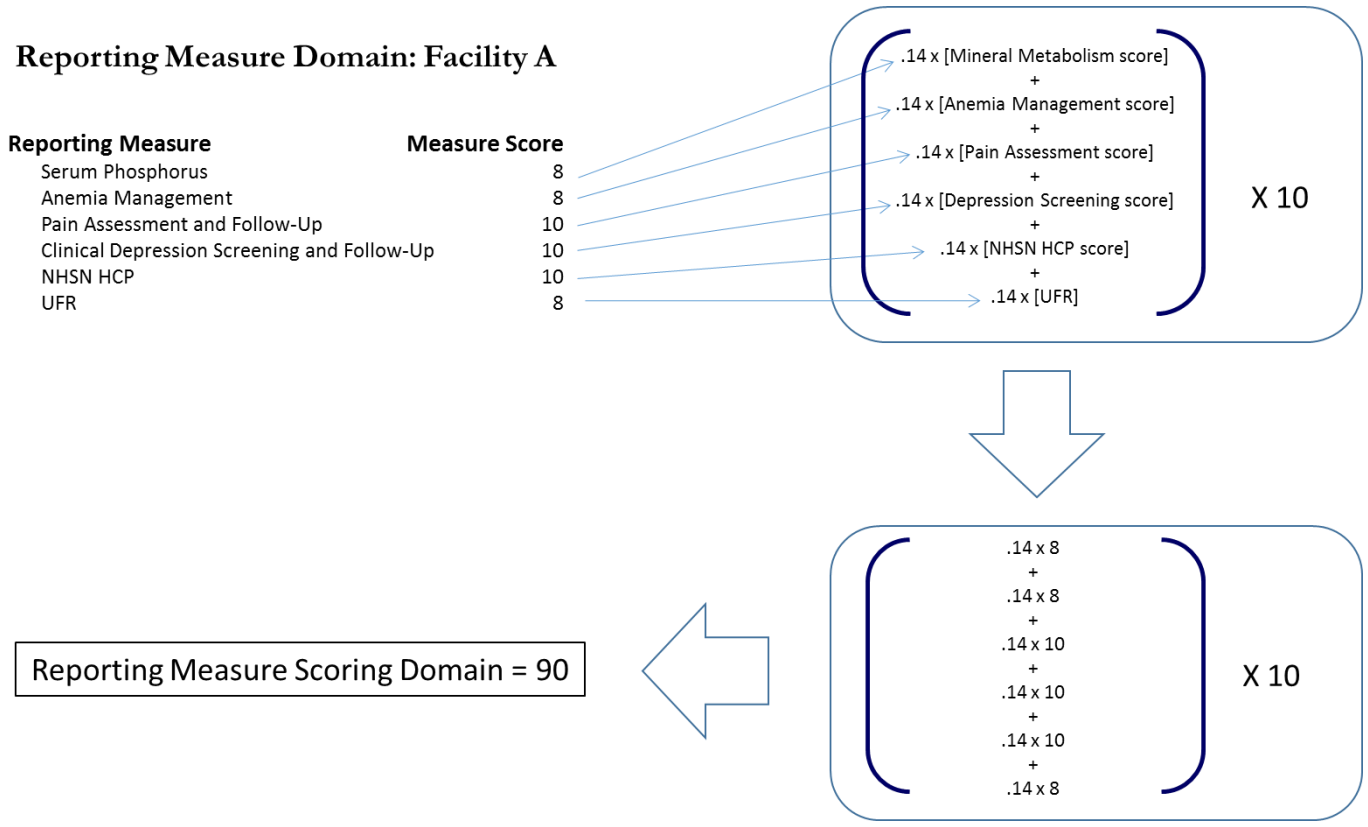


Figure 8 illustrates the methodology used for calculating the Safety Measure Domain score for Facility A.

FIGURE 8:

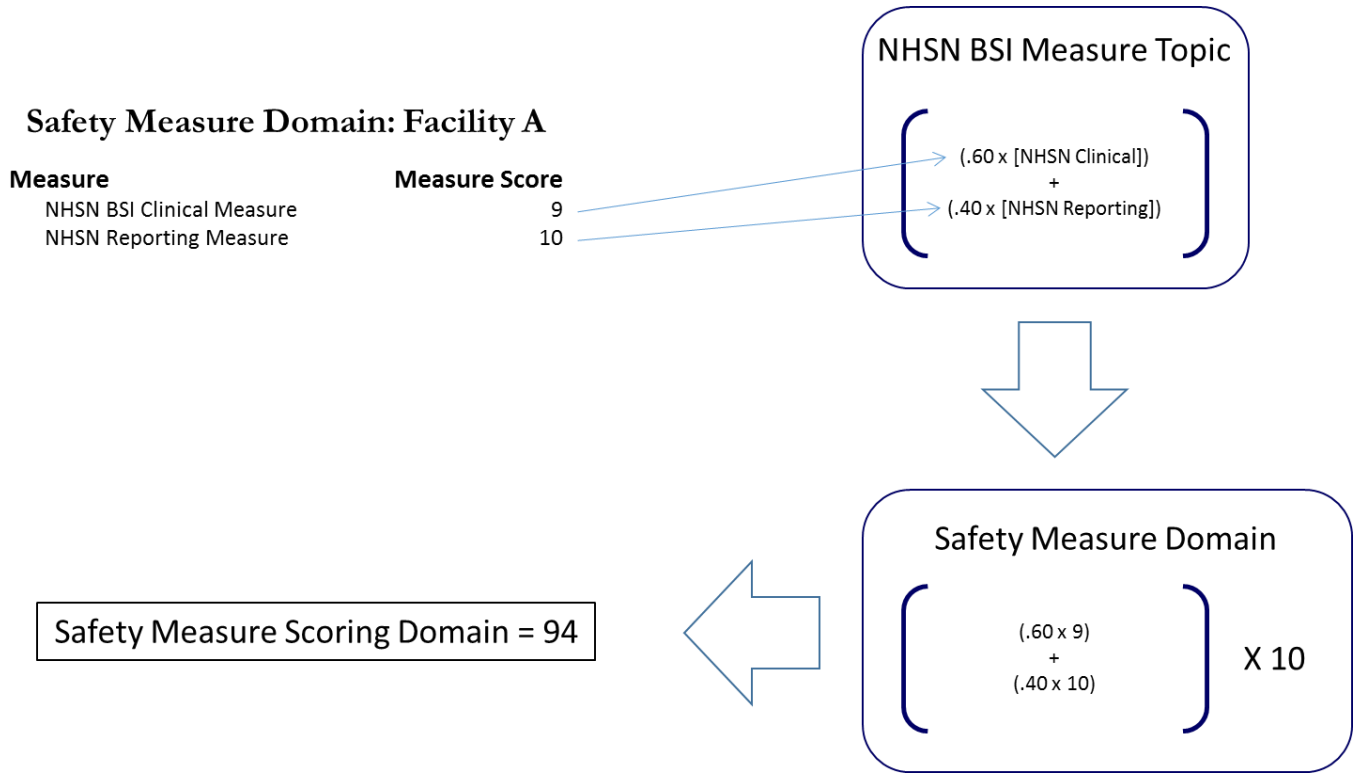


Figure 9 illustrates the methodology used to calculate the TPS for Facility A.

FIGURE 9:

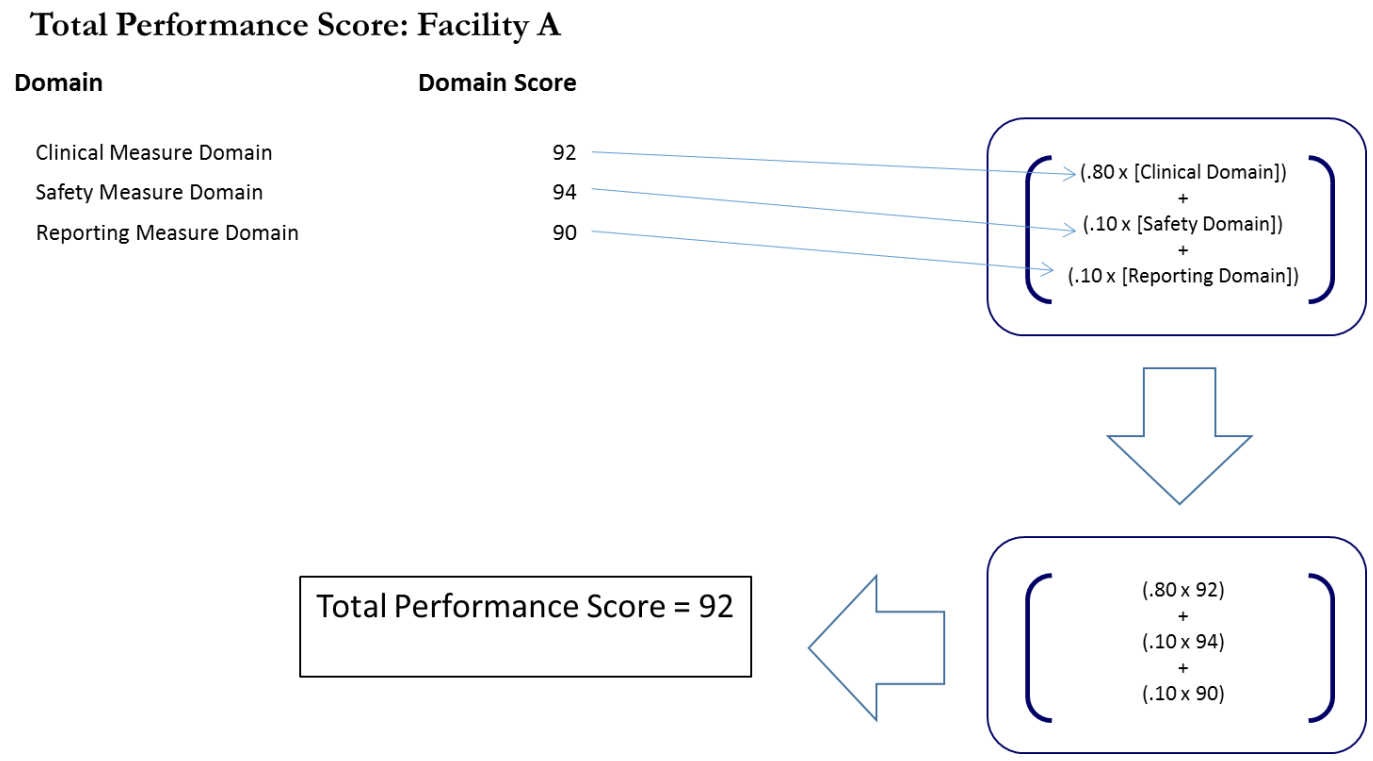
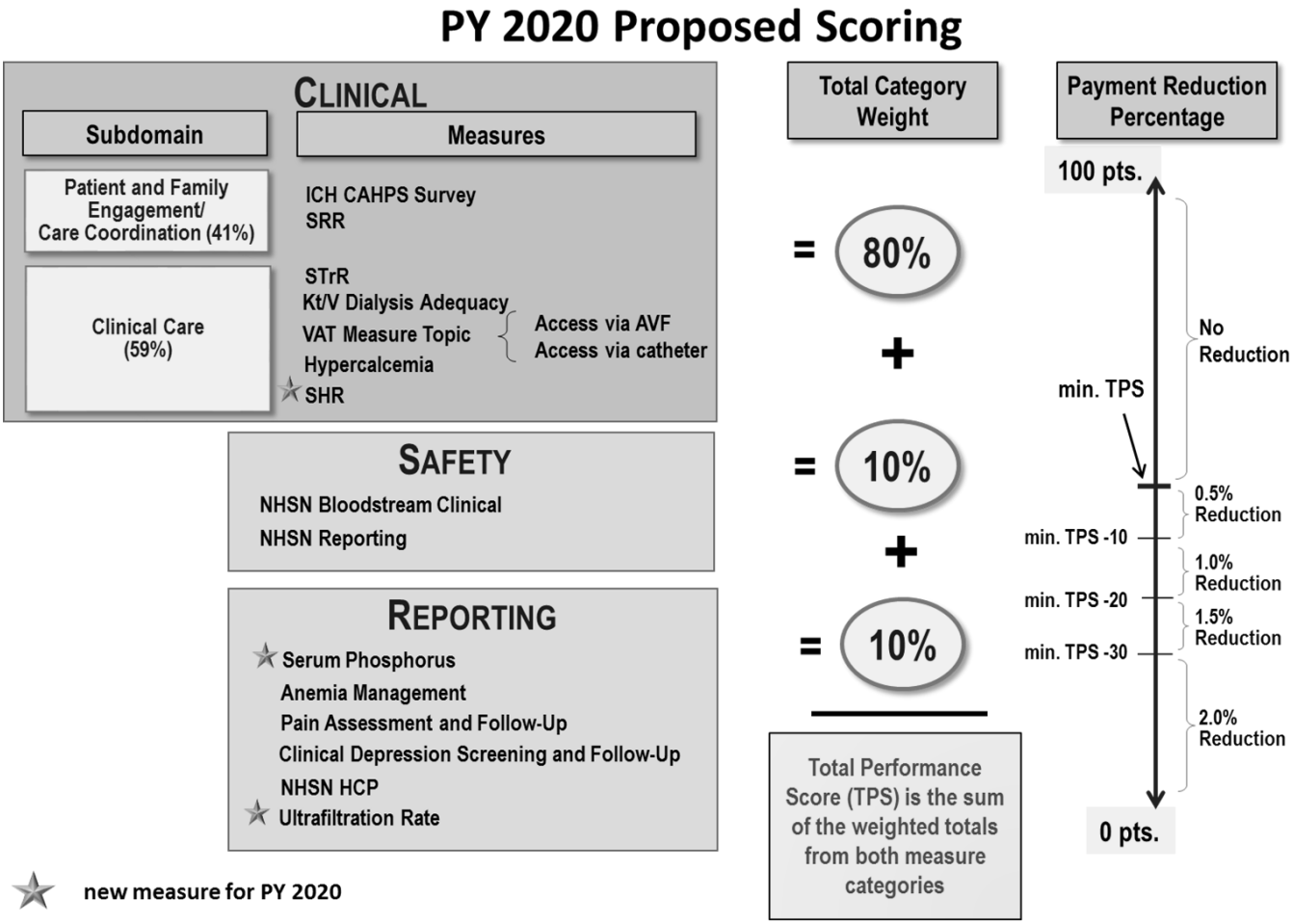


Figure 10 illustrates the full scoring methodology for PY 2020.

FIGURE 10:



8. Proposed Minimum Data for Scoring Measures for the PY 2020 ESRD QIP

Our policy is to score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period. With the exception of the Standardized Readmission Ratio, Standardized Hospitalization Ratio, Standardized Transfusion Ratio, and ICH CAHPS clinical measures, a facility must treat at least 11 qualifying cases during the performance period in order to be scored on a clinical or reporting measure. A facility must have at least 11 index discharges to be eligible to receive a score on the SRR clinical measure, 10 patient-years at risk to be eligible to receive a score on the STrR clinical measure, and 5 patient-years at risk to be eligible to receive a score on the SHR clinical measure. In order to receive a score on the ICH CAHPS clinical measure, a facility must have treated at

least 30 survey-eligible patients during the eligibility period and receive 30 completed surveys during the performance period. We are not proposing to change these minimum data policies for the measures that we have proposed to continue including in the PY 2019 ESRD QIP measure set.

For the proposed Ultrafiltration Rate and Serum Phosphorus Reporting Measures, we also propose that facilities with at least 11 qualifying patients will receive a score on the measure. We believe that setting the case minimum at 11 for these reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly burden or penalize small facilities. We further believe that setting the case minimum at 11 is appropriate because this aligns with case minimum policy for the vast majority of the reporting measures in the ESRD QIP.

Under our current policy, we begin counting the number of months for which a facility is open on the first day of the month after the facility's CMS Certification Number (CCN) Open Date. Only facilities with a CCN Open Date before July 1, 2018 would be eligible to be scored on the Anemia Management, Mineral Metabolism, Pain Assessment and Follow-Up, Clinical Depression Screening and Follow-Up reporting measures, and only facilities with a CCN Open Date before January 1, 2018 would be eligible to be scored on the NHSN Bloodstream Infection Clinical Measure, ICH CAHPS Clinical Measure, and NHSN Healthcare Personnel Influenza Vaccination reporting measure. We further propose that, consistent with our CCN Open Date policy for other reporting measures, facilities with a CCN Open Date after July 1, 2018, would not be eligible to receive a score on the Ultrafiltration Rate Reporting Measure because of the difficulties these facilities may face in meeting the requirements of this measure due to the short period of time left in the performance period.

We seek comments on these proposals.

Table 11 displays the proposed patient minimum requirements for each of the measures, as well as the proposed CCN Open Dates after which a facility would not be eligible to receive a score on a reporting measure.

TABLE 11 – PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2020 ESRD QIP

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11 – 25 qualifying patients
Vascular Access Type: Catheter (Clinical)	11 qualifying patients	N/A	11 – 25 qualifying patients
Vascular Access Type: Fistula (Clinical)	11 qualifying patients	N/A	11 – 25 qualifying patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11 – 25 qualifying patients
NHSN Bloodstream Infection (Clinical)	11 qualifying patients	On or before January 1, 2018	11 – 25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	On or before January 1, 2018	N/A
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
SHR (Clinical)	5 patient-years at risk	N/A	5-14 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.	On or before January 1, 2018	N/A

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
Anemia Management (Reporting)	11 qualifying patients	Before July 1, 2018	N/A
Serum Phosphorus (Reporting)	11 qualifying patients	Before July 1, 2018	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before July 1, 2018	N/A
Pain Assessment and Follow-Up (Reporting)	11 qualifying patients	Before July 1, 2017	N/A
NHSN Healthcare Personnel Influenza Vaccination (Reporting)	N/A	Before January 1, 2018	N/A
Ultrafiltration Rate (Reporting)	11 qualifying patients	Before July 1, 2018	N/A

9. Proposed Payment Reductions for the PY 2020 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. We propose that, for the PY 2020 ESRD QIP, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if:

- It performed at the performance standard for each clinical measure; and
- It received the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2018 reporting measures.

We note this proposed policy for PY 2020 is identical to the policy finalized for PY 2019.

We recognize that we are not proposing a policy regarding the inclusion of measures for which we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the performance period in the PY 2019 minimum

TPS. We have not proposed such a policy because no measures in the proposed PY 2020 measure set meet this criterion. However, should we choose to adopt a clinical measure in future rulemaking without the baseline data required to calculate a performance standard before the beginning of the performance period, we will propose a criterion accounting for that measure in the minimum TPS for the applicable payment year at that time.

The PY 2018 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 2020 (that is, CY 2018). Because we have not yet calculated final measure scores, we are unable to determine the 50th percentile of facility performance on the PY 2018 reporting measures. We will publish that value in the CY 2018 ESRD PPS final rule once we have calculated final measure scores for the PY 2018 program.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2014 ESRD PPS final rule (78 FR 72223 through 72224), we finalized a payment reduction scale for PY 2016 and future payment years: for every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction on its ESRD PPS payments for PY 2016 and future payment years, with a maximum reduction of 2.0 percent. We are not proposing any changes to this policy for the PY 2020 ESRD QIP.

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate a proposed minimum TPS at this time. We will publish the minimum TPS, based on data from CY 2016 and the first part of CY 2017, in the CY 2018 ESRD PPS final rule.

We seek comments on this proposal.

E. Future Policies and Measures Under Consideration

As we continue to refine the ESRD QIP's policies and measures, we are evaluating different methods of ensuring that facilities strive for continuous improvement in their delivery of care to patients with ESRD. We also seek to refine our scoring methodology in an effort to make it easier for facilities and the ESRD community to understand. For future rulemaking, we are considering several policies and measures, and we are seeking comments on each of these policies and measures.

As discussed in Section III.D.3.a.i above, we are proposing to adopt the Standardized Hospitalization Ratio (SHR) Clinical measure and calculate performance rates for that measure in accordance with NQF-endorsed, Measures Application Partnership reviewed specifications. Similarly, performance rates for the SRR and STrR will continue to be calculated in accordance with NQF-endorsed, Measures Application Partnership reviewed specifications. Stakeholders have expressed that for most standardized ratio measures, rates are easier to understand than ratios. (The exception is the NHSN BSI Clinical Measure, which is intentionally expressed as a ratio, and cannot be transformed into a rate without distorting the underlying results.) For future years of the QIP, we are considering a proposal to express the ratios as rates instead, for the SRR and STrR measures. Specifically, we would not propose any changes to the manner in which performance rates themselves are calculated, but would propose to calculate rates by multiplying the facility's ratio for each of these measures by the national raw rate of events (also known as the median), which is specific to the measure each year. We are also considering reporting national performance standards and individual facility performance rates as rates, as opposed to ratios, for these measures. Similarly, we are considering a proposal to use rates, as opposed to ratios, when calculating facility improvement scores for these measures.

In PY 2019, we proposed to adopt a patient-level influenza immunization reporting measure that could be used to calculate a future clinical measure based on either "ESRD Vaccination—Full-Season Influenza Vaccination" (MAP #XDEFM) or NQF #0226: "Influenza Immunization in the ESRD Population (Facility Level)." We continue to believe that it is important to include a clinical measure on patient-level influenza vaccination in the ESRD QIP. However, at this time we are not proposing to add a patient-level influenza immunization reporting measure into the ESRD QIP. Nevertheless, data elements were recently amended in CROWNWeb to support data collection for either of the two potential clinical measures on patient-level influenza (that is, MAP # XDEFM and NQF #0226). We will continue to collect these data and conduct detailed analyses to determine whether either of these clinical measures would be appropriate for future inclusion in the ESRD QIP. We are seeking comments on these issues, including whether data for a patient-level influenza immunization clinical measure should be collected through CROWNWeb or through NHSN.

As part of our effort to continuously improve the ESRD QIP, we are also working on developing additional, robust measures that provide valid assessments of the quality of care furnished to ESRD patients by ESRD facilities. Some measures we are considering developing for future inclusion in the ESRD QIP measure set include a Standardized Mortality Ratio (SMR) measure, a measure examining utilization of hospital Emergency Departments, a measure examining medication reconciliation efforts, and a measure examining kidney transplants in patients with ESRD.

We seek comments on these measures and policies that we are considering for adoption in the ESRD QIP in the future.

V. DMEPOS Competitive Bidding Program

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 the CBP in CBAs throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs, mandated by section 1847(a) of the Act, are collectively referred to as the "Medicare DMEPOS Competitive Bidding Program." The 2007 DMEPOS competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other Issues published in the April 10, 2007 **Federal Register** (72 FR 17992)), established 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 DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services.

Section 1847(a)(1)(G) of the Act, added by section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) (MACRA), now requires a bid surety bond for bidding entities.

Section 1847(a)(1)(G) of the Act, as added by section 522(a) of MACRA, provides that, with respect to rounds of competitions under section 1847 beginning not earlier than January 1, 2017 and not later than January 1, 2019, a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, in the range of $50,000 to $100,000 in a form specified by the Secretary consistent with subparagraph (H) of section 1847(a)(1), and (2) provided the Secretary with proof of having obtained the bid surety bond for each CBA in which the entity submits its bid(s). Section 1847(a)(1)(H)(i) provides that in the event that a bidding entity is offered a contract for any product category for a CBA, and its

composite bid for such product category and area was at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amount(s) for the product category and CBA, and the entity does not accept the contract offered, the bid surety bond(s) for the applicable CBAs will be forfeited and CMS will collect on the bid surety bond(s). In instances where a bidding entity does not meet the bid forfeiture conditions for any product category for a CBA as specified in section 1847(a)(1)(H)(i) of the Act, then the bid surety bond liability submitted by the entity for the CBA will be returned to the bidding entity within 90 days of the public announcement of the contract suppliers for such area.

Section 522 of MACRA further amended Section 1847(b)(2)(A) of the Act by adding clause (v) to the conditions that a bidding entity must meet in order for the Secretary to award a contract to any entity under a competition conducted in a CBA to furnish items and services. New clause (v) of section 1847(b)(2)(A) of the Act adds the requirement that the bidding entity must meet applicable State licensure requirements in order to be eligible for a DMEPOS CBP contract award. We note, however, that this does not reflect a change in policy as CMS already requires contract suppliers to meet applicable State licensure requirements in order to be eligible for a contract award.

B. Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Action

This rule proposes to extend our current appeals process for contract terminations to all breach of contract actions that CMS might take. We propose to effectuate this change by expanding the breach of contract actions to which our current appeals process at §414.423 applies to include all of the breach of contract actions specified in §414.422(g)(2) and not just §414.422(g)(2)(iii), which currently describes CMS' ability to terminate a supplier's contract. Any deviation from contract requirements, including a failure to comply with governmental

agency or licensing organization requirements, constitutes a breach of contract under our regulations at §414.422(g)(1). Pursuant to §414.422(g)(2), CMS may take one or more actions in the event that a contract supplier breaches its contract , including, for example, terminating or suspending the contract supplier's contract. We have determined that there are certain actions specified in §414.422(g)(2) that are not breach of contract actions, such as requiring a contract supplier to submit a corrective action plan and revoking a supplier's billing number under the DMEPOS CBP. We are proposing to remove these two actions from§414.422(g)(2) . If CMS determines a contract supplier to be in breach of its contract, it will provide a notice of breach of contract to the supplier. Currently, the notice states that a supplier has the right to request a hearing by a Competitive Bidding Implementation Contractor ("CBIC") hearing officer to appeal the termination, but does not specify that there is also a formal process for appealing any of the other breach of contract actions that CMS may take in §414.422(g)(2). As such, we propose revisions to §414.422, Terms of Contracts, and §414.423, Appeals Process for Termination of Competitive Bidding Contract, to extend the appeals process to any breach of contract actions that CMS may take pursuant to the revised §414.422(g)(2).

C. Provisions of the Proposed Regulations

1. Bid Surety Bond Requirement

At §414.402, we propose adding a definition for "bidding entity" to mean the entity whose legal business name is identified in the "Form A: Business Organization Information" section of the bid.

At §414.412, "Submission of bids under a competitive bidding program," we propose to add a new paragraph (h) that would allow CMS to implement section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, to state that an entity may not submit a bid for a CBA

unless, as of the deadline for bid submission, the entity has obtained a bid surety bond for the CBA. Proposed §414.412(h)(1) would specify that the bond must be obtained from an authorized surety. An authorized surety is a surety that has been issued a Certificate of Authority by the U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.

At proposed §414.412(h)(2) "Bid Surety Bond requirements," we propose a bid surety bond contain the following information: (1) the name of the bidding entity as the principal/obligor; (2) The name and National Association of Insurance Commissioners number of the authorized surety; (3) CMS as the named obligee; (4) The conditions of the bond as specified in this proposed rule at (h)(3); (5) The CBA covered by the bond; (6) The bond number; (7) The date of issuance; and (8) The bid bond value of $100,000.

Section 1847(a)(1)(G) of the Act permits CMS to determine the amount of the bond within a range of $50,000 to $100,000. Given the importance of this provision, we have determined that it is appropriate to require bidding entities to obtain bid surety bonds in an amount of $100,000 for each CBA in which they submit a bid. This requirement is intended to ensure that bidding entities accept a contract offer(s) when their composite bid(s) is at or below the median composite bid rate used in the calculation of the single payment amounts. We also believe that setting the bid surety bond amount at $100,000 will provide an additional level of assurance that all bidding entities submit substantiated bids. The CBP has historically had a contract acceptance rate exceeding 90 percent, and we believe that this acceptance rate will increase with the promulgation of this regulation. We are considering whether a lower bid surety bond amount would be appropriate for a particular subset of suppliers, for example, small

suppliers as defined by §414.402, and are specifically soliciting comments on whether to establish a lower bid surety bond amount for certain types of suppliers.

Proposed 414.412(h)(3) specifies conditions for forfeiture of the bid surety bond and return of the bond liability. Pursuant to section 1847(a)(1)(H) of the Act, when (1) a bidding entity is offered a contract for any product category in a CBA, (2) the entity's composite bid is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for the product category and CBA, and (3) the entity does not accept the contract offer, then the entity's bid surety bond for that CBA will be forfeited and CMS will collect on it. When the bidding entity does not meet these forfeiture conditions, the bid bond liability will be returned within 90 days of the public announcement of the contract suppliers for the CBA. The proposed provision requires CMS to notify a bidding entity when it does not meet the bid forfeiture conditions and as a result CMS will not collect on the bid surety bond.

We propose that bidding entities that provide a falsified bid surety bond would be prohibited from participation in the current round of the CBP in which they submitted a bid and from bidding in the next round of the CBP. Additionally, offending suppliers would be referred to the Office of Inspector General and Department of Justice for further investigation. We also propose that if we find that a bidding entity has accepted a contract offer and then breached the contract in order to avoid bid surety bond forfeiture, the breach would result in a termination of the contract and preclusion from the next round of competition in the CBP. These proposed penalties would be included in our regulations at §414.412(h)(4).

2. State Licensure Requirement

We propose to revise §414.414(b)(3), "Conditions for awarding contracts," to align with 1847(b)(2)(A) of the Act as amended by section 522(b) of MACRA. The amendment to the Act

states that "[t]he Secretary may not award a contract to any entity under the competition conducted in an [*sic*] competitive acquisition area . . . to furnish such items or services unless the Secretary finds . . . [t]he entity meets applicable State licensure requirements." The regulation at §414.414 (b)(3) currently states that "[e]ach supplier must have all State and local licenses required to perform the services identified in the request for bids." Therefore, we are proposing to revise 414.414(b)(3)to align with the language of section 1847(b)(2)(A) of the Act as revised by MACRA, to state that a contract will not be awarded to a bidding entity unless the entity meets applicable State licensure requirements. We note, however, that this does not reflect a change in policy as CMS already has a regulation in place to require suppliers to meet applicable State and local licensure requirements.

3. Procedure on Appeals Process for a Breach of Contract of DMEPOS Competitive Bidding Contract Action(s)

We believe suppliers should have the option to appeal all breach of contract actions. As a result, we propose to revise §414.423, Appeals Process for Termination of Competitive Bidding Contract, to expand the appeals process for suppliers who have been sent a notice of a breach of contract stating that CMS intends to take one or more of the actions described in §414.422(g)(2) as a result of the breach. While we recognize that we have the authority to take one or more breach of contract actions specified in §414.422(g)(2), we currently only have an appeals process for one of those actions, specifically, contract termination. Therefore, the proposed revisions will expand §414.423 to allow appeal rights for each breach of contract action specified in §414.422(g)(2). If a supplier's notice of breach of contract includes more than one breach of contract action and the supplier chooses to appeal, CMS will make separate decisions for each breach of contract action after reviewing the hearing officer's recommendation. Proposed

revisions are made in §414.422(g)(2) to remove the breach of contract actions of (1) requiring a contract supplier to submit a corrective action plan; and (2) revoking the supplier number of the contract supplier. We are proposing to remove §414.423(g)(2)(i) because a corrective action plan is a part of the formal appeals process outlined in §414.423, rather than an action CMS imposes on contract suppliers that it considers to be in breach. We are also proposing to remove the supplier number revocation action at §414.422(g)(2)(v) because the DMEPOS CBP does not have the authority to revoke a DMEPOS supplier's Medicare billing number. Furthermore, we are proposing to revise this section to state that CMS will specify in the notice of breach of contract which actions they are taking as a result of the breach of contract.

Proposed revisions are made throughout §414.423 to extend the appeals process to any breach of contract actions described in §414.422(g)(2) that we might take as a result of the breach, rather than just contract termination actions. We are also proposing to remove the references to termination throughout 414.423and instead to cross-reference all of the breach of contract actions in §414.422(g)(2).

In revisions to §414.423(a), we are proposing to delete the language indicating that termination decisions made under this section are final and binding as this reference is not inclusive of all breach of contract actions, and the finality of a decision is correctly addressed in paragraph (k)(4) of this section.

In the revisions to §414.423(b)(1), we propose to delete the phrase "either in part or in whole" because 414.422(g)(1) specifies that any deviation from contract requirements constitutes a breach of contract. In addition, we propose to remove the requirement that the breach of contract notice to the supplier be delivered by certified mail from §414.423(b)(1) to allow CMS the flexibility to use other secure methods for notifying suppliers. We are also proposing

changes to §414.423 (b)(2)(i) and (b)(2)(ii). The revised §414.423(b)(2)(i) states that the notice of breach of contract will include the details of the breach of contract, while §414.423(b)(2)(ii) requires CMS to include the action(s) that it is taking as a result of the breach of contract and the timeframes associated with the each breach of contract action in the notice. For example, when a notice of breach of contract includes preclusion, the effective date of the preclusion will be the date specified in the letter and the timeframe of the preclusion will specify the round of the CBP from which the supplier is precluded. We have also added language to (b)(2)(vi) to specify that the effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless a timely hearing request has been filed or a CAP has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.

We are proposing to revise §414.423(c)(2)(ii) to specify that the subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant to §414.423(c)(1)(i). Section 414.423(e)(3) will be revised to clarify that CMS retains the option to offer the supplier an opportunity to submit another CAP, if CMS deems appropriate, in situations where CMS has already accepted a prior CAP.

Proposed revisions to §414.423(f)(5) explain that in the event the supplier fails to timely request a hearing, the breach of contract action(s) specified in the notice of breach of contract will take effect 45 days from the date of the notice of breach of contract. Proposed revisions to §414.423(g)(3) will be made to clarify that the scheduling notice must be sent to all parties, not just the supplier.

We are proposing to revise §414.423(j) to clarify that the hearing officer will issue separate recommendations for each breach of contract action in situations where there is more than one breach of contract action presented at the hearing.

In §414.423(k), we are proposing to specify that CMS will make separate decisions for each recommendation when the hearing officer issues multiple recommendations. In addition, we are proposing revisions to this paragraph to expand CMS' final determination process, clarifying that the notice of CMS' decision will be sent to the supplier and the hearing officer and will indicate whether any breach of contract actions included in the notice of breach of contract still apply and will be effectuated, and will indicate the effective date of the breach of contract action, if applicable. We propose to expand on §414.423(l), effect of breach of contract action(s), to specify effects of all contract actions described in §414.422(g)(2). We propose to add §414.423(l)(1), effect of contract suspension, to outline the supplier's requirements regarding furnishing items and reimbursement for the duration of the contract suspension, as well as the details regarding the supplier's obligation to notify beneficiaries. We are also proposing to add §414.423(l)(3), effect of preclusion, to specify that a supplier who is precluded will not be allowed to participate in a specific round of the CBP, which will be identified in the original notice of breach of contract. Additionally, we propose to add §414.423(l)(4), effect of other remedies allowed by law, to state if CMS decides to impose other remedies under §414.422(g)(2)(iv), the details of the remedies will be included in the notice of breach of contract. Proposed §414.423(l) also specifies the steps suppliers must take to notify beneficiaries after CMS takes the contract action(s) described in §414.422(g)(2). Lastly, we have removed language from §414.423(l)(2), effect of contract termination, to avoid confusion as to which supplier is providing notice to the beneficiary.

VI. Methodology for Adjusting DMEPOS Fee Schedule Amounts for Similar Items with Different Features 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 PEN and for DME prosthetic devices, prosthetics, orthotics, and surgical dressings, was provided in the July 11, 2014 proposed rule at 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. Methodologies for Adjusting Payment Amounts using Information from the DMEPOS Competitive Bidding Program

Below is a summary of the three general methodologies used in adjusting payment amounts for DMEPOS items in areas that are not CBAs for the items using information from the DMEPOS CBP. Also summarized are the processes for updating adjusted fee schedule amounts and for addressing the impact of unbalanced bidding on SPAs when adjusting payment amounts using information from the DMEPOS CBPs. We issued a final rule (Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule) on November 6, 2014 (hereinafter, the CY 2015 final rule) in which we adopted these methodologies (79 FR 66223-66233). We also issued program instructions on these methodologies in Transmittal #3350, (Change Request # 9239), issued on September 11, 2015 and Transmittal #3416, (Change Request # 9431) issued on November 23, 2015. The CBP product categories, HCPCS codes and single payment amounts (SPAs) included in the CBPs are available on the Competitive Bidding Implementation Contractor (CBIC) website: http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home.

Section 1834(a)(1)(F)(ii) of the Act provides the Secretary with the authority to use 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. Also, Section 1842(s)(3)(B) of the Act provides authority for making adjustments to the fee schedule amounts for enteral nutrients, equipment, and supplies (enteral nutrition) based on information from CBPs. Section 1834(a)(1)(F)(ii) 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 re-competed. 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. Also, Section 1834(a)(1)(G) of the Act 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."

a. Adjusted Fee Schedule Amounts for Areas within the Contiguous United States

Pursuant to §414.210(g)(1), CMS determines a regional price for DME items or services for each state in the contiguous United States and the District of Columbia equal to the un-weighted average of the single payment amounts (SPAs) for an item or service for CBAs that are fully or partially located in the same region that contains the state or the District of Columbia. CMS uses the regional prices to determine a national average price equal to the un-weighted average of the regional prices. The regional SPAs (RSPAs) cannot be greater than 110 percent of the national average price (national ceiling) or less than 90 percent of the national average

price (national floor). This methodology applies to enteral nutrition and most DME items furnished in the contiguous United States (that is, items that are included in more than 10 CBAs).

The fee schedule amounts for areas defined as rural areas for the purposes of the CBP are adjusted to 110 percent of the national average price described above. The regulations at §414.202 define a rural area to mean, 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 CBA 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.

b. Adjusted Fee Schedule Amounts for Areas Outside the Contiguous United States

Pursuant to §414.210(g)(2), in areas outside the contiguous United States (that is, noncontiguous areas such as Alaska, Guam, and Hawaii), the fee schedule amounts are reduced to the greater of the average of SPAs for the item or service for CBAs outside the contiguous United States (currently only applicable to Honolulu, Hawaii) or the national ceiling amounts calculated for an item or service based on RSPAs for CBAs within the contiguous United States.

c. Adjusted Fee Schedule Amounts for Items Included in 10 or Fewer CBAs

Pursuant to §414.210(g)(3), for DME items included in ten or fewer CBAs, the fee schedule amounts for the items are reduced to 110 percent of the un-weighted average of the SPAs from the ten or fewer CBAs. This methodology applies to all areas within and outside the contiguous United States.

d. Updating Adjusted Fee Schedule Amounts

Section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information from the

CBP to adjust the DMEPOS payment amounts for items furnished on or after January 1, 2016, and section 1834(a)(1)(F)(iii) requires the Secretary to continue to make such adjustments as additional covered items are phased in or information is updated as competitive bidding contracts are recompeted. In accordance with §414.210(g)(8), the adjusted fee schedule amounts are revised when an SPA for an item or service is updated following one or more new competitions and as other items are added to CBPs. DMEPOS schedule amounts that are adjusted using SPAs will not be subject to the annual DMEPOS covered item update and will only be updated when SPAs from the CBP are updated. Updates to the SPAs may occur at the end of a contract period as contracts are recompeted, as additional items are added to the CBP, or as new CBAs are added. In cases where adjustments to the fee schedule amounts are made using any of the methodologies described above, and the adjustments are based solely on the SPAs from CBPs that are no longer in effect, the SPAs are updated before being used to adjust the fee schedule amounts. The SPAs are adjusted based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) over the course of time described in §414.210(g)(4). For example, if the adjustments were to be effective January 1, 2017, the SPAs from CBPs no longer in effect would be updated based on the percentage change in the CPI-U from the mid-point of the last year the SPAs were in effect to June 30, 2016, the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustment, if the adjustments continue to be based solely on the SPAs that are no longer in effect, the SPAs will be updated every 12 months using the CPI-U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

e. Methodology for Avoiding HCPCS Price Inversions When Adjusting Fee Schedule Amounts using Information from the DMEPOS Competitive Bidding Program

In our CY 2015 final rule (79 FR 66263), we adopted a methodology to address unbalanced bidding, which is a situation that results in price inversions under CBPs. We added §414.210(g)(6) for certain limited situations where bidding for similar but different enteral infusion pumps and standard power wheelchairs resulted in the SPAs for higher utilized items with additional features (for example, an enteral infusion pump with an alarm or a Group 2 power wheelchair) being less than the SPAs for lower utilized items without those additional features (for example, an enteral infusion pump without an alarm or Group 1 power wheelchair). A Group 2 power wheelchair is faster, travels further, and climbs higher obstacles than a Group 1 power wheelchair. Under CBPs, when similar items with different features are included in the same product category, the code with higher utilization at the time of the competition receives a higher weight and the bid for this item has a greater impact on the supplier's composite bid as well as the competitiveness of the supplier's overall bid for the product category (PC) within the CBP as compared to the bid for the less frequently utilized item. If, at the time the competition takes place under the CBP, the item with the additional features is priced higher and over time is utilized more than the other similar items without these features, it could result in unbalanced bidding, which in turn causes the item without the additional features to receive a higher single payment amount under the CBP than the item with the additional features. This situation results in a price inversion, where the higher weighted and higher priced item at the time of the competition becomes the lower priced item in the CBP following the competition. Unbalanced bidding can occur when a bidder has a higher incentive to submit a lower bid for one item than another due to the fact that the item has a higher weight and therefore a greater effect on the supplier's composite bid for the product category than the other item. Our current regulation at §414.210(g)(6) for adjusting DMEPOS fee schedule amounts paid in non-CBAs using

information from CBPs includes methodologies to address price inversions for power wheelchairs and enteral infusion pumps only. This rule limits SPAs for items without additional features (for example, an enteral infusion pump without an alarm) to the SPAs for items with the additional features (for example, an enteral infusion pump with an alarm) prior to using these SPAs to adjust fee schedule amounts.

For example, if most of the utilization or allowed services for standard power wheelchairs are for higher paying Group 2 wheelchairs than Group 1 wheelchairs at the time the competition occurs, the bids for the Group 2 wheelchairs have a greater impact on the supplier's composite bid and chances of being offered a contract. Therefore the supplier has a much greater incentive to make a lower bid for the Group 2 wheelchairs relative to the fee schedule payment than they do for the Group 1 wheelchairs. If, for example, Medicare is paying $450 per month for a Group 2 wheelchair at the time of the competition and a Group 2 wheelchair has a high weight, while Medicare is paying $350 per month for the Group 1 version of the same wheelchair at the time of the competition and the Group 1 wheelchair has a very low weight, the bids for the two items could be unbalanced or inverted whereby the bid submitted for the Group 2 wheelchair is $250 (44 percent below the fee schedule amount for the item) while the bid submitted for the Group 1 wheelchair is $300 (14 percent below the fee schedule amount for the item). A price inversion therefore results where Medicare previously paid $450 for one item and now pays $250, and previously paid $350 for another item for which it now pays $300. The item weight under the CBP results in Medicare paying more for a Group 1 power wheelchair than a higher-performing Group 2 power wheelchair.

In the CY 2015 proposed rule published on July 11, 2014 in the Federal Register (79 FR 40208) (hereinafter, CY 2015 proposed rule), we referred to an additional feature that one item

has and another item does not have as a "hierarchal" feature, meaning that one item provides an additional, incremental service that the other item does not provide (79 FR 40287). For example, code B9002 in the HCPCS describes an enteral infusion pump with an alarm, while code B9000 describes an enteral infusion pump without an alarm. Code B9002 describes an item that provides an additional service (an alarm) and the alarm was referred to as a hierarchal feature, meaning the item with the alarm provides an item and service above what the item without the alarm provides. Commenters believed the term "hierarchal feature" should be better defined (79 FR 66231). We agreed and finalized the rule only for the specific scenarios addressed in the proposed rule, namely, enteral infusion pumps and standard power wheelchairs. The final regulation at 42 CFR 414.210(g)(6)(i) specifically requires that in situations where a SPA for an enteral infusion pump without alarm is greater than the SPA in the same CBA for an enteral infusion pump with alarm, the SPA for the enteral infusion pump without alarm is adjusted to equal the SPA for the enteral infusion pump with alarm prior to applying the payment adjustment methodologies for these items in non-CBAs. We also adopted regulations at 42 CFR 414.210(g)(6)(ii) through (v) to address bid inversion for standard power wheelchairs. In the CY 2015 final rule at 79 FR 66231, we stated that we would consider whether to add a definition of hierarchal feature, or to apply the rule we proposed to other items not identified in the final rule through future notice and comment rulemaking.

B. Current Issues

We performed a review of all HCPCS codes in the CBPs in order to comply with our commitment to consider whether to apply the regulation at §414.210(g)(6) to other cases of price inversion that resulted from unbalanced bidding that were not identified or addressed in the CY 2015 final rule (79 FR 66231). We found a significant number of price inversions resulting from

the 2016 DMEPOS CBP Round 2 Recompete for contract periods beginning July 1, 2016. The items affected included transcutaneous electrical nerve stimulation (TENS) devices, walkers, hospital beds, power wheelchairs, group 2 support surfaces (mattresses and overlays), enteral infusion pumps, and seat lift mechanisms. As a result of our review, we are proposing a rule that will expand the provisions of §414.210(g)(6) to address these and other price inversions.

To perform our review, we examined instances within the HCPCS where there are multiple codes for an item (for example, a walker) that are distinguished by the addition of features (for example, folding walker versus rigid walker or wheels versus no wheels) which may experience price inversions. Our review included all groupings of similar items with different features within each of the product categories. We have included the HCPCS codes describing groupings of similar items that would be subject to this proposed rule and the features associated with each code below:

ENTERAL INFUSION PUMPS	
B9000	Pump without alarm
B9002	Pump with alarm
HOSPITAL BEDS	
E0250	Fixed Height With Mattress & Side Rails
E0251	Fixed Height With Side Rails
E0255	Variable Height With Mattress & Side Rails
E0256	Variable Height With Side Rails
E0260	Semi-Electric With Mattress & Side Rails
E0261	Semi-Electric With Side Rails
E0290	Fixed Height With Mattress
E0291	Fixed Height
E0292	Variable Height With Mattress
E0293	Variable Height
E0294	Semi-Electric With Mattress
E0295	Semi-Electric
E0301	Heavy Duty Extra Wide With Side Rails
E0302	Extra Heavy Duty Extra Wide With Side Rails

E0303	Heavy Duty Extra Wide With Mattress & Side Rails
E0304	Extra Heavy Duty Extra Wide With Mattress & Side Rails
MATTRESSES AND OVERLAYS	
E0277	Powered mattress
E0371	Powered overlay
E0372	Non-powered overlay
E0373	Non-powered mattress
POWER WHEELCHAIRS	
K0813	Group 1 Sling Seat, Portable
K0814	Group 1 Captains Chair, Portable
K0815	Group 1 Sling Seat
K0816	Group 1 Captains Chair, Standard Weight
K0820	Group 2 Sling Seat, Portable
K0821	Group 2 Captains Chair, Portable
K0822	Group 2 Sling Seat, Standard Weight
K0823	Group 2 Captains Chair, Standard Weight
SEAT LIFT MECHANISMS	
E0627	Electric
E0628	Electric
E0629	Non-electric
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICES	
E0720	Two leads
E0730	Four leads
WALKERS	
E0130	Rigid
E0135	Folding
E0141	Rigid With Wheels
E0143	Folding With Wheels

As shown in Table 12 below, under the 2015 DMEPOS fee schedule, Medicare pays more for walkers with wheels than walkers without wheels. The same is true for walkers that fold as compared to walkers that do not fold. Walkers that are rigid and do not fold are very

rarely used and have extremely low utilization, and a walker that folds and has wheels is used much more frequently than a walker that folds but does not have wheels.

TABLE 12 –Average of 2015 DMEPOS Fee Schedule Amounts for Purchase of Walkers

Code	Item	Average 2015 Fee Schedule Amount[1]	2014 Allowed Services
E0130	Rigid Walker without Wheels	$64.97	59
E0135	Folding Walker without Wheels	$78.97	5,053
E0141	Rigid Walker with Wheels	$107.89	455
E0143	Folding Walker with Wheels	$111.69	95,939

[1] Average of 2015 fee schedule amounts for all areas

Under the DMEPOS CBP, because the folding walker without wheels (E0135) is used more frequently than the rigid walker without wheels (E0130), code E0135 receives a higher weight than code E0130. In addition, under the 2015 fee schedule, Medicare pays more for code E0135 than code E0130. Weights are assigned to individual items (HCPCS codes) within a product category (for example, standard mobility equipment) under the DMEPOS CBP for the purpose of calculating a composite bid for each supplier submitting bids for that product category in a CBA. The weights are based on the beneficiary utilization rate using national data when compared to other items in the same product category. The beneficiary utilization rate of an item captures the total allowed services for the item from Medicare claims submitted for the item on a national basis. A supplier's bid for each item in the product category is multiplied by the weight assigned to the item, and the sum of these calculations equals the supplier's composite bid. Contracts are offered to eligible suppliers with the lowest composite bids. Therefore, the higher the weight for an item in a product category, the more the bid for that item will affect the supplier's composite bid and chances of being offered a contract for that product category. Conversely, the lower the weight for an item in a product category, the less the bid for that item

will affect the supplier's composite bid and chances of being offered a contract for that product category.

Similarly, because the folding walker with wheels (E0143) is used more frequently than the rigid walker with wheels (E0141), and more frequently than the walkers without wheels (E0130 and E0135), it receives a higher weight under the DMEPOS CBP than all three codes for the less expensive, less frequently utilized codes with fewer features: E0130, E0135, and E0141. Under the 2015 fee schedule, Medicare pays more for code E0143 than codes E0130 (rigid walkers without wheels), E0135 (folding walkers without wheels) or E0141 (rigid walkers with wheels). Under the Round 2 Recompete, the fact that code E0143 (folding walkers with wheels) received a far greater weight than the other walkers that either did not fold, did not have wheels, or had neither feature resulted in price inversions as illustrated in Table 13 below. The first price inversion involves a rigid walker without wheels (E0130). A rigid walker without wheels has lower fee schedule amounts on average and a lower weight than a folding walker without wheels (E0135), yet under competitive bidding, it has a greater SPA than the folding walker. The second price inversion involves a rigid walker with wheels (E0141), which has lower fee schedule amounts on average and a lower weight than a folding walker with wheels (E0143), but has a greater SPA than the folding walker with wheels under competitive bidding. The third price inversion involves a rigid walker without wheels (E0130), which has a greater SPA than a folding walker with wheels despite having lower fee schedule amounts on average and a lower weight than the folding walker with wheels (E0143).

TABLE 13 – Round 2 (2016) Price Inversions for Purchase of Walkers

Code	Item	2015 Fee[1]	Avg SPA[2]
E0130	Rigid Walker without Wheels	$64.97	$47.23
E0135	Folding Walker without Wheels	$78.97	$43.05
E0141	Rigid Walker with Wheels	$107.89	$75.03

E0143	Folding Walker with Wheels	$111.69	$45.92

[1] Average of 2015 fee schedule amounts for all areas
[2] Average of Round 2 2016 SPAs

In all cases, Medicare pays higher payment for walkers with wheels than walkers without wheels under the fee schedule. This differential in payment amounts is significant because it reflects the fact that the walker with wheels has a feature that likely resulted in higher fee schedule amounts for this item, making it more costly than the same type of walker without the addition of wheels. Rather than defining the ability of a walker to fold or the presence of wheels as a "hierarchal" feature, it can simply be noted that under the fee schedule, Medicare pays more for walkers with the ability to fold than walkers without the ability to fold and that Medicare pays more for walkers with wheels than for walkers without wheels. If the items with additional features are more expensive and are also utilized more than the items without the features, a price inversion can result in a CBA due to the item weights and how they factor into the composite bids, as described above. Therefore, we propose to adopt a definition of price inversion in our regulations at 414.402 as any situation where the following occurs : (a) one item in a product category includes a feature that another, similar item in the same product category does not have (for example, wheels, an alarm, or Group 2 performance); (b) the average of the 2015 fee schedule amounts for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and (c) the SPA for the item with the feature is lower than the SPA for the item without that feature. We propose to classify this circumstance as a price inversion under competitive bidding that would be adjusted prior to revising the fee schedule amounts for the items. For this adjustment, we considered two methodologies.

The first methodology we considered for addressing price inversions (method 1) uses the

methodologies at 42 CFR 414.210(g)(6) and limits the SPA for the code without the feature to the SPA for the code with the feature before the SPA is used to adjust the fee schedule amounts for the item. For example, under the Round 2 Recompete, the SPA for code E0141 for the South Haven-Olive Branch, MS CBA is $106.52. Code E0143 describes the same type of walker, but code E0143 walkers fold, while code E0141 walkers are rigid and do not fold. However, under the Round 2 Recompete, the SPA for code E0143 (wheeled walkers that fold) for the South Haven-Olive Branch, MS CBA is $44.00, or $62.52 less than the SPA for E0141 (wheeled walkers that do not fold). The average of the 2015 fee schedule amounts for codes E0141 and E0143 are $107.89 and $111.69, respectively. Altogether, since (a) one walker in a product category includes a feature that another, similar walker in the same product category does not have (in this situation, the ability to fold); (b) the average of the 2015 fee schedule amounts for the folding walker (E0143) is higher than the average of the 2015 fee schedule amounts for the rigid walker (EO141); and (c) the SPA for the folding walker ($44.50) is lower than the SPA for the rigid walker ($106.52), these items would meet the proposed definition of a price inversion under the DMEPOS CBP. Under method 1, the SPA of $106.52 for code E0141 in this CBA would be adjusted to the SPA of $44.00 for code E0143 in this CBA, so that $44.00, rather than $106.52, would be used for this CBA in computing the regional price for code E0141 described in §414.210(g)(1)(i) under the methodology used to adjust the fee schedule amounts for code E0141. To further illustrate how method 1 would work, the 2016 SPAs for codes E0130, E0135, E0141, and E0143 for the Akron, Ohio CBA, and the amounts they would be adjusted to before applying the fee schedule adjustment methodologies are listed in Table 14 below.

TABLE 14 – Adjustment of 2016 SPAs for Purchase of Walkers for Akron, OH to Eliminate Price Inversions with Method 1

Code	Item	2015 Fee[1]	2016 SPA	Adjusted Amount[2]

E0130	Rigid Walker without Wheels	$64.97	$50.85	$44.88
E0135	Folding Walker without Wheels	$78.97	$44.88	n/a
E0141	Rigid Walker with Wheels	$107.89	$84.82	$48.62
E0143	Folding Walker with Wheels	$111.69	$48.62	n/a

[1] Average of 2015 fee schedule amounts for all areas

[2] The SPA would be adjusted to this amount before making adjustments to the fee schedule

The method 1 approach is currently used for enteral infusion pumps and standard power wheelchairs at §414.210(g)(6), and each price inversion correction is made for a set of two items, as described in the regulation. For example, §414.210(g)(6)(ii) states: "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." If method 1 is finalized, we would indicate that additional price inversions involving additional sets of two items to which this rule would be applied would be identified in a table in the preamble of the final rule. An example of such a table is provided below in Table 15 using codes for walkers, seat lift mechanisms, and TENS devices:

TABLE 15 –Additional Price Inversions Subject to 42 CFR §414.210(g)(6)

Item	Code Without Feature(s)	Code With Feature(s)	Feature(s)	Adjustment
Walker	E0130	E0135	Folding	E0130 SPA adjusted not to exceed (NTE) SPA for E0135
Walker	E0141	E0143	Folding	E0141 SPA adjusted NTE SPA for E0143
Walker	E0130	E0143	Folding, Wheels	E0130 SPA adjusted NTE SPA for E0143
Walker	E0135	E0143	Wheels	E0135 SPA adjusted NTE SPA for E0143
Seat Lift	E0629	E0627[1]	Powered	E0629 SPA adjusted NTE

Item	Code Without Feature(s)	Code With Feature(s)	Feature(s)	Adjustment
				SPA for E0627
Seat Lift	E0629	E0628[1]	Powered	E0629 SPA adjusted NTE SPA for E0628
TENS	E0720	E0730	Two Additional Leads	E0720 SPA adjusted NTE SPA for E0730

[1] Codes E0627 and E0628 both describe powered electric seat lift mechanisms. Code E0627 describes powered seat lift mechanisms incorporated into non-covered seat lift chairs.

The second methodology we considered and are proposing (method 2) would limit the SPAs in situations where price inversions occur so that the SPAs for all of the similar items, both with and without certain features, are limited to the weighted average of the SPAs for the items based on the item weights assigned under competitive bidding. This approach would factor in the supplier bids for the lower volume and higher volume items. This would establish one payment for similar types of items that incorporates the volume and weights for items furnished prior to the unbalanced bidding and resulting price inversions. To illustrate how method 2 would work, the 2016 SPAs for codes E0130, E0135, E0141, and E0143 for the Vancouver, WA CBA, and the amounts they would be adjusted to before applying the fee schedule adjustment methodologies using the weights from Round 2 Recompete are listed in Table 16 below.

TABLE 16 – Adjustment of 2016 SPAs for Purchase of Walkers for Vancouver, WA to Eliminate Price Inversions Method 2

Code	Item	2015 Fee[1]	2016 SPA	Round 2 Recompete Item Weight	Adjusted Amount[2]
E0130	Rigid Walker without Wheels	$64.97	$51.62	0.1%	$45.53
E0135	Folding Walker without Wheels	$78.97	$47.65	4.8%	$45.53
E0141	Rigid Walker with Wheels	$107.89	$81.62	0.5%	$45.53
E0143	Folding Walker with Wheels	$111.69	$45.22	94.6%	$45.53

[1] Average of 2015 fee schedule amounts for all areas

[2] The SPA would be adjusted to this amount before making adjustments to the fee schedule

The item weights from the Round 2 Recompete for the four walker codes in this subcategory of walkers in the table above are 0.1 percent for E0130, 4.8 percent for E0135, 0.5 percent for

E0141, and 94.6 percent for E0143. The weighted average of the SPA for the four walker codes would be $45.53 ($51.62 × 0.001 + $47.65 × 0.048 + $81.62 × 0.005 + $45.22 × 0.946). This weighted average SPA would be used to adjust the fee schedule amounts for these four codes rather than simply limiting the SPAs for E0135 and E0143 in Table 16 above. This method uses item weights in a product category to adjust the SPA before making adjustments to the fee schedule amount. In accordance with the proposed definition of a price inversion, (a) E0135 and E0143 include features that other, similar walkers in the same product category do not (the ability to fold); (b) the average of the 2015 fee schedule amounts for the folding walkers (E0135 & E0143) are higher than the average of the 2015 fee schedule amounts for the rigid walkers (E0130 & E0141); and (c) the 2016 SPAs for the folding walkers were less than the SPAs for the respective rigid walkers. Therefore, the SPA for code E0130 is higher than the SPA for code E0135, the SPAs for codes E0141 and E0143 were inverted such that the SPA for code E0141 is higher than the SPA for code E0143, and the SPAs for codes E0135 and E0143 were inverted such that the SPA for code E0135 is higher than the SPA for code E0143. Under proposed method 2, these three price inversions would be addressed so that the SPAs for all of the similar items described by codes E0130, E0135, E0141, and E0143 in this CBA would be adjusted to the weighted average of the SPAs for these codes for similar items in this CBA. As a result, the adjusted SPA of $45.53 rather than $51.62, $47.65, $81.62, and $45.22, would be used to compute the regional price for codes E0130, E0135, E0141, and E0143, respectively, using method 2 to adjust the fee schedule amounts for these items and in accordance with §414.210(g)(1)(i).

Although we believe that both method 1 and method 2 would correct inverted SPAs, method 1 simply limits the amount paid for the item without a feature(s) to the item with the

feature(s), while method 2 factors in the SPAs for all of the items. Therefore, if the cost of an item without a feature was actually more than the cost of an item with a feature (for example, for volume discounts for the item with the feature drives the price down below the price for the item without the feature), method 1 would not allow the higher cost of the item without the feature to be factored into the payment made to the suppliers of the items. Therefore, we are proposing to use method 2 because it takes into account the supplier bids for all of the similar items into account in establishing the payment amounts used to adjust fees; and therefore, factors in contemporary information relative to bids and supplier information for various items with different features and costs. The SPAs established based on supplier bids for all of the similar items are used to calculate the weighted average. If, for some reason, the market costs for an item without a feature are actually higher than the market costs for an item with the feature, due to economies of scale, supply and demand, or other economic factors, these costs are accounted for in the weighted average of the SPAs established for each of the similar items. Under method 1, the SPA for the lower weight item without a feature is limited to the SPA for the higher weight item with the feature, and so potential cost inversions driven by market forces or supplier costs are not accounted for in establishing the adjusted payment amounts. However, we are soliciting comments on both method 2, which we are proposing, and method 1, which we are considering.

Other examples of price inversions resulting from the Round 2 Recompete are listed in Table 17 below. This is not an exhaustive list of price inversions that have resulted under the CBPs and to which the proposed rule would apply.

TABLE 17 - Examples of Round 2 Recompete SPA Price Inversions for Items with Additional Feature(s), by CBA

Higher Priced Item under 2015 Fee Schedule	Lower Priced Item under 2015 Fee Schedule	Number of CBAs out of 117 with Price Inversion
Folding Walker with Wheels (E0143)	Rigid Walker with Wheels (E0141)	117 CBAs in which E0143 now priced lower than E0141

Powered Group 2 Support Surface Mattress (E0277)	Non-powered Group 2 Support Surface Mattress (E0373)	117 CBAs in which E0277 now priced lower than E0373
Enteral Pump with Alarm (B9002)	Enteral Pump without Alarm (B9000)	112 CBAs in which B9002 now priced lower than B9000
Group 2 Power Wheelchair (K0823)	Group 1 Power Wheelchair (K0816)	103 CBAs in which K0823 now priced lower than K0816
Four lead TENS (E0730)	Two lead TENS (E0720)	93 CBAs in which E0730 now priced lower than E0720

In summary, we propose to expand use of the methodology at §414.210(g)(6) to other situations where price inversions occur under CBPs. First, we propose to revise 42 CFR 414.402 to add the definition of price inversion as any situation where the following occurs:

- One item (HCPCS code) in a grouping of similar items (for example, walkers, enteral infusion pumps or power wheelchairs) in a product category includes a feature that another, similar item in the same product category does not have (for example, wheels, alarm, or Group 2 performance);
- The average of the 2015 fee schedule amounts (or initial, unadjusted fee schedule amounts for subsequent years for new items) for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and
- The SPA in any year after and including 2016 for the code with the feature is lower than the SPA for the code without that feature.

Second, we propose to revise §414.210(g)(6) to specify that, in situations where price inversions occur under a CBP, the SPAs for the items would be adjusted before applying the fee schedule adjustment methodologies under §414.210(g). We are proposing that the adjustments to the SPAs would be made using method 2 described above. We are proposing changes to the regulation text at 414.210(g)(6) to reflect use of method 2 to adjust the SPAs for all of the similar items where price inversions have occurred, both with and without certain features, so that they

are limited to the weighted average of the SPAs for the items in the product category in the CBA before applying the fee schedule adjustment methodologies under §414.210(g). We propose to apply this rule to price inversions as defined in this proposed rule for the groupings of similar items listed in the Table 18 below. For the purpose of calculating the weighted average at proposed §414.210(g)(6)(iii), we are proposing to add a definition of "total nationwide allowed services" at §414.202, to mean the total number of services allowed for an item furnished in all states, territories, and the District of Columbia where Medicare beneficiaries reside and can receive covered DMEPOS items and services. We are proposing to define the weight for each code in a grouping of similar items at §414.210(g)(6)(iii) for purposes of calculating the weighted average as the proportion of the total nationwide allowed services for the code for claims with dates of service in calendar year 2012 relative to the total nationwide allowed services for each of the other codes in the grouping of similar items for claims with dates of service in calendar year 2012. We are proposing to use data from calendar year 2012 because this is the most recent calendar year that includes data for items furnished before implementation of Round 2 of the CBP and the beginning of the price inversions. The weights reflect the frequency that covered items in a grouping of similar items were furnished in calendar year 2012 on a national basis relative to other items in the grouping.

TABLE 18 – Groupings of Similar Items

Grouping of Similar Items	**HCPCS Codes[1]**
Enteral Infusion Pumps	B9000, B9002
Hospital Beds	E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, E0304
Mattresses and Overlays	E0277, E0371, E0372, E0373
Power Wheelchairs	K0813, K0814, K0815, K0816, K0820, K0821, K0822, K0823

Grouping of Similar Items	HCPCS Codes[1]
Seat Lift Mechanisms	E0627, E0628, E0629
TENS Devices	E0720, E0730
Walkers	E0130, E0135, E0141, E0143

[1] The descriptions for each HCPCS code are available at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html

We are soliciting comments on this section.

VII. Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items with Different Features under the DMEPOS Competitive Bidding Program

A. Background on the DMEPOS Competitive Bidding Programs

Medicare pays for most DMEPOS furnished after January 1, 1989, pursuant to fee schedule methodologies set forth in sections 1834 and 1842 of the Social Security Act (the Act). Specifically, subsections (a) and (h) of section 1834 and subsection (s) of section 1842 of the Act provide that Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or a fee schedule amount for the item. The regulations implementing these provisions are located at 42 CFR Part 414, Subparts C and D.

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. Section 1847(b)(5) of the Act directs the Secretary to base the single payment amount (SPA) for each item or service in each CBA on the bids submitted and accepted in the CBP. For competitively bid items, the SPAs have replaced

the fee schedule payment methodology. Section 1847(b)(5) of the Act provides that Medicare payment for these competitively bid items and services is made on an assignment-related basis and is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act. Section 1847(b)(2)(A)(iii) of the Act prohibits the Secretary from awarding a contract to an entity in a CBA unless the Secretary finds that the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. This requirement guarantees savings to both the Medicare program and its beneficiaries.

We implemented CBPs in 9 Round 1 metropolitan statistical areas on January 1, 2011, and an additional 91 Round 2 metropolitan statistical areas on July 1, 2013. Bids are submitted during a 60-day bidding period allowing suppliers adequate time to prepare and submit their bids. We then evaluated each submission and awarded contracts to qualified suppliers in accordance with the requirements of section 1847(b)(2) of the Act ,§414.414, which specifies conditions for awarding contracts, and §414.416, which specifies how single payment amounts are established.

B. Definitions of Item, Item Weight, Product Category and Composite Bid

"Item" is defined in our regulations at 414.402 as a product included in a CBP that is identified by a HCPCS code, which may be specified for competitive bidding, or a combination of codes and/or modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category. A product category is a grouping of similar items that are used to treat a similar medical condition. Pursuant to § 414.414(e)(3), CMS evaluates bids for items within a product category by establishing a composite bid for each supplier and network that submitted a bid for the product

category. A composite bid is the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers. Because suppliers bid for multiple items of similar equipment within a product category, the lowest bid for each item will not always be submitted by the same supplier. Evaluating single bids for individual items would not determine which suppliers should be selected to be contract suppliers because different suppliers may submit the lowest bids for different items. We established this provision (72 FR 18040) for using a composite bid as a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category. This allows us to determine which suppliers can offer the lowest expected costs to Medicare for all items in a product category.

To compute the composite bid for a product category, we multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items. The weight of an item is based on the utilization of the individual item compared to other items within that product category based on historic Medicare claims. The sum of each supplier's weighted bids for every item in a product category is the supplier's composite bid for that product category. When an item receives a very low weight within its product category, suppliers have little incentive to bid lower for this item because the bids have a minimal effect on the composite bid of the suppliers, whereas the bids for higher weighted items have a significant effect on the supplier's composite bid. This results in price inversions, as discussed further below.

C. Current Issues

As explained in section VI above, price inversions may occur when items that are similar in terms of the general purpose they serve (for example, walkers), but have different

features (for example, wheels, folding capability, etc.), fall within the same product category and have different item weights, therefore having varying degrees of influence on a supplier's composite bid. An item in a product category that is rented and/or purchased by beneficiaries more often than another similar item(s) in the product category has a higher item weight than the other similar item(s) in the product category, and typically will have a higher fee schedule amount at the time the competition takes place than the other similar item(s) in the product category. In a price inversion, an SPA is established for the higher volume item with the higher fee schedule amount that is lower than the SPA(s) established for the other similar item(s) that had lower fee schedule amounts at the time the competition took place. For example, prior to the implementation of the Round 2 CBPs in July 2013, the 2013 rental fee schedule amounts in Akron, Ohio for the infrequently furnished Group 1 power wheelchair (K0816) and portable Group 2 power wheelchair (K0821) were significantly lower than the 2013 rental fee schedule amount for the heavily utilized Group 2 power wheelchair (K0823). Table 19 below shows these fee schedule amounts and also includes national data for calendar year 2012 indicating the percentage of claims for all standard power wheelchairs furnished in 2012 attributed to each code.

TABLE 19 - 2013 Rental Fee Schedule Amounts and 2012 Utilization Rates for Certain Power Wheelchairs in Akron, Ohio CBA

Code	2013 Fee	Akron, OH – Fee Schedule	Percent of Standard Power Wheelchair Utilization in 2012 (National)
K0816	$471.38	Group 1 Power Wheelchair	0.16%
K0821	$463.01	Group 2 Portable Power Wheelchair	0.09%
K0823	$563.26	Group 2 Power Wheelchair	81.7%

Because codes K0816 and K0821 had comparatively low utilization and received very low weights within the product category, suppliers had little incentive to bid lower for these items

than for K0823, since the bids for K0816 and K0821 had a minimal effect on the suppliers' composite bids, while the bids for K0823 had a significant effect on the suppliers' composite bids. This resulted in the price inversions described in the Table 20 below, whereby the payment rate for code K0816 was 16 percent lower than the SPA for code K0823 before competitive bidding, but 39 percent higher than the SPA for code K0823 after competitive bidding. Similarly, the payment rate for code K0821 was 18 percent lower than the SPA for code K0823 before competitive bidding, but 43 percent higher than the SPA for code K0823 after competitive bidding.

TABLE 20 - Price Inversions for Certain Power Wheelchairs in Akron, Ohio CBA

Code	2013 SPA	Akron, OH – Competitive Bidding	Percent of Standard Power Wheelchair Utilization in 2015 (National)
K0816	$374.55	Group 1 Power Wheelchair	7.2%
K0821	$387.31	Group 2 Portable Power Wheelchair	4.1%
K0823	$270.00	Group 2 Power Wheelchair	65.9%

The 2012 and 2015 utilization percentages above are the national data for all areas, including areas that are not CBAs. As the tables above show, some utilization of standard power wheelchairs shifted from Group 2 non-portable power wheelchairs to less durable and lower performing Group 1 and Group 2 portable power wheelchairs. This results in the beneficiaries receiving items without additional features at a higher SPA price than items with these additional features. It also undermines the purpose of the CBP and savings intended by the Act and implementation of the program.

The true magnitude of the problem of price inversions is best illustrated by data for power wheelchairs furnished in the Round 2 CBAs. Under the Round 2 competitions and contracts that took effect on July 1, 2013, code K0816 received a very low item weight based on

the low utilization rate for this item whereas code K0823 received a very high item weight. The average rental fee schedule amount of $471.38 for code K0816 in 2013 decreased to an average SPA of $344.32 under the CBP, a 27 percent decrease. In comparison, the average reduction in the rental payment amount for code K0823 under Round 2 2013 was 49 percent; from an average rental fee schedule amount in 2013 of $563.26 to an average SPA of $287.05.

After the SPAs took effect in the Round 2 CBAs, we found trends indicating increased expenditures or total allowed charges for code K0816 in the Round 2 CBAs, but a decrease in expenditures or total allowed charges for code K0823 in the Round 2 CBAs. Also, under the Round 2 competition, total allowed charges from July 2013 through December 2015 (2.5 years) for K0816 increased by 1,159 percent as compared to the total allowed charges from January 2011 through June 2013 (2.5 years). By comparison, total allowed charges for K0823 for these same time periods and areas decreased by 86 percent. This inversion in both charges and utilization was more pronounced in certain CBAs than others. In the Atlanta-Sandy Springs-Marietta, Georgia CBA, allowed charges for K0816 (SPA = $361.59) increased by 10,239 percent from $8,010 to $828,995, while allowed charges for K0823 (SPA = $281.89) decreased by 87 percent from $11,051,027 to $1,477,062. We found the same phenomenon for hospital beds where utilization of non-electric hospital beds (code E0250) increased by 214 percent in the Round 2 CBAs while utilization of semi-electric beds (code E0260) decreased by 63 percent. Therefore, the data shows that due to unbalanced bidding in various CBAs, item utilization is shifting from certain items to others, and Medicare is now paying more for these items under the CBP than it was before the CBP was implemented for these items in these CBAs. This is an unacceptable outcome because it results in the beneficiary receiving an item with less functionality (for example, a manual hospital bed rather than a semi-electric hospital bed) at a

higher cost for both the Medicare program and the beneficiary than the item with more functionality.

D. Proposed Revisions

To avoid the aforementioned price inversions, we are proposing in §414.412(d)(2), that in situations where we find that a product category includes a grouping of two or more similar items with different features, that we would utilize an alternative to the current bidding methodology that CMS may apply for certain items within product categories for which previous competitions resulted in price inversions. Under this alternative bidding methodology, we will designate one item as the lead item for the grouping for bidding purposes. The item in the grouping with the highest allowed services during a specified base period, as detailed below, will be considered the lead item of the grouping. For purposes of this proposed rule, the lead item bidding method described below only applies to a subset of similar items with different features identified in this rule, as opposed to an entire product category. The supplier's bid for the lead item would be used as the basis for calculating the SPAs for the similar items within that grouping. That is, we would automatically calculate the SPAs for any similar item in the grouping based on the ratio of the average of the similar item's fee schedule amounts for all areas nationwide in 2015, to the average of the lead item's fee schedule amounts for all areas nationwide in 2015. In §414.412(d)(2), we are proposing to use the fee schedule amounts for 2015 for the purpose of determining the relative difference in fee schedule payments for similar items because we believe they reflect the relative difference in cost for the items under the fee schedule prior to any adjustments being made to the amounts based on information from the CBPs. We found price inversions for groupings of similar items within the following categories: standard power wheelchairs, walkers, hospital beds, enteral infusion pumps, TENS devices,

support surface mattresses and overlays and seat lift mechanisms. These groupings of similar items are a subset of similar items with different features identified in this rule, as opposed to entire product categories.

Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping of similar items with different features (for example, standard power wheelchairs); however, rather than submitting bids for each individual HCPCS code for each item, a supplier would make one bid that should take into account the cost of furnishing all of the similar items. For example, a $300 bid for K0823 would automatically establish the payment amounts for all the other power wheelchairs in the grouping, so that K0816 would be .84 times $300, and K0829 would be 1.58 times $300 (as shown in the Table 21 below). The supplier may have to adjust its initial K0823 bid before deciding on a final bid, depending on the utilization of the lower volume items in the grouping, and its targeted total revenue for the grouping according to its item weights. The supplier would also be educated at the time of bidding that the SPAs for the other similar items would be based on its bid for the lead item, and the supplier is therefore submitting bids for all of these items when bidding on the lead item. Thus, to avoid cases of price inversions, the supplier is submitting a bid for an item (for example, standard power wheelchair), and for lead item bidding purposes, an "item" is a product that is identified by a combination of codes, as described in §414.402. We also believe that the proposed lead item-focused bidding method would greatly reduce the burden on suppliers of formulating and submitting multiple bids for similar items because it would require less time to enter their bids and would reduce the chances of keying errors when submitting bids. The items subject to this proposed rule would include a broader set of items than those subject to the proposed rule under section VI above. Namely all codes for walkers, hospital beds, and standard power wheelchairs

would be subject to this proposed rule and not just those codes for walkers, hospital beds, and standard power wheelchairs where price inversions have already occurred. The lead item bidding method is intended to prevent future price inversions for a grouping of similar items, including codes for items (for example, total electric hospital beds) where price inversions have not occurred thus far, but where we believe price inversions would be likely based on information about the fee schedule amounts and the utilization of these items. By applying the lead item bidding method to all hospital beds, including total electric hospital beds, this prevents price inversions from occurring for all hospital beds. We also believe it is a more efficient method for implementing CBPs and pricing.

To identify the lead item, we propose using allowed services from calendar year 2012 for the first time this bidding method is used for specific items in specific CBAs. We did not observe price inversions under the Round 1 competitions and contracts that were in effect from January 2011 through December 2013. The price inversions began with the Round 2 competitions and contracts that began on July 1, 2013; therefore, we propose using data for allowed services from calendar year 2012 to ensure that the effects of price inversions do not impact the utilization of the various items that is used to identify the lead item. Once this bidding method has been used in all competitions for an item (for example, standard power wheelchairs), we propose that the lead item would be identified for future competitions based on allowed services for the items at the time the subsequent competitions take place rather than the allowed services from calendar year 2012. For example, using allowed services from calendar year 2012 is necessary to identify the lead items initially since utilization of items for years subsequent to 2012 could be affected by the price inversions that began with the Round 2 competitions and contracts on July 1, 2013. Once the lead item bidding method is implemented

for a grouping of similar items, and the price inversions are eliminated, utilization of items for years subsequent to the point at which the price inversions are eliminated can be used for the purpose of identifying the lead item because they would not be affected by price inversions. This proposed rule would also help to prevent price inversions in adjusted fee schedule amounts using competitive bidding SPAs. We propose to announce which items would be subject to this bidding method at the start of each competition in each CBA where this bidding method is used.

The following tables 21, 22, and 23 show how the lead item for three groupings of similar items (standard power wheelchairs, walkers, and hospital beds, respectively) would be identified using 2012 allowed services and how the SPAs would be established based on the method described above. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping of similar items. In the charts below, the lead items identified would be the lead items in initial competitions where the lead item bidding method is used. The first proposed category for lead item bidding is standard power wheelchairs.

TABLE 21 – Lead Item Bidding for Standard Power Wheelchairs and Relative Difference in Fees

HCPCS	Features	Allowed Services for 2012	Average of 2015 Rental Fees	Fee Relative to Lead Item
K0823 (lead item)	Group 2 Captains Chair, Standard Weight	1,108,971	$578.51	1.00
K0825	Group 2 Captains Chair, Heavy Duty	122,422	$637.40	1.10
K0822	Group 2 Sling Seat, Standard Weight	99,597	$574.73	0.99
K0824	Group 2 Sling Seat, Heavy Duty	10,609	$696.23	1.20
K0827	Group 2 Captains Chair, Very Heavy Duty	6,683	$766.42	1.32
K0814	Group 1 Captains Chair, Portable	6,287	$443.98	0.77
K0816	Group 1 Captains Chair, Standard Weight	2,176	$484.14	0.84
K0826	Group 2 Sling Seat, Very Heavy Duty	1,063	$901.38	1.56
K0821	Group 2 Captains Chair, Portable	1,048	$475.55	0.82
K0813	Group 1 Sling Seat, Portable	771	$346.83	0.60
K0815	Group 1 Sling Seat	545	$505.52	0.87
K0828	Group 2 Sling Seat, Extra Heavy Duty	114	$993.20	1.72
K0829	Group 2 Captains Chair, Extra Heavy Duty	105	$912.06	1.58
K0820	Group 2 Sling Seat, Portable	46	$370.46	0.64

Rather than submitting 14 individual bids for each of the 14 items, the supplier would submit one bid for the lead item. The SPA for lead item K0823 would be based on the median of the bids for this code, following the rules laid out in §414.416(b) and for calculating rental amounts pursuant to §414.408(h)(2). The SPAs for the other items would be based on the relative difference in fees for the other items as compared to the lead item. For example, if the SPA for code K0823 is $300.00, the SPA for code K0825 would be equal to $330.00, or $300.00 multiplied by 1.1. Similarly, if the SPA for code K0823 is $300.00, the SPA for code K0816 would be equal to $252.00, or $300.00 multiplied by 0.84. Suppliers submitting bids would be educated in advance that their bid for code K0823 is a bid for all 14 codes and bidding suppliers would factor this into their decision on what amount to submit as their bid for the lead item. This would avoid price inversions and would carry over the relative difference in item weight that establishes Medicare payment amounts for standard power wheelchairs under the fee schedule into the CBPs. The second proposed category for lead item bidding is walkers as shown in Table 22 below. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping.

TABLE 22 – Lead Item Bidding for Walkers and Relative Difference in Fees

HCPCS	Features	Allowed Services for 2012	Average of 2015 Purchase Fees	Fee Relative to Lead Item
E0143 (lead item)	Folding With Wheels	958,112	$111.69	1.00
E0135	Folding	56,399	$78.97	0.71
E0149	Heavy Duty With Wheels	23,144	$214.34	1.92
E0141	Rigid With Wheels	6,319	$107.89	0.97
E0148	Heavy Duty	4,366	$122.02	1.09
E0147	Heavy Duty With Braking & Variable Wheel Resistance	4,066	$551.98	4.94
E0140	With Trunk Support	1,483	$346.38	3.10
E0144	Enclosed With Wheels & Seat	1,275	$305.95	2.74
E0130	Rigid	788	$64.97	0.58

Rather than submitting 9 individual bids for each of the 9 items, the supplier would submit one bid for the lead item. The SPA for lead item E0143 would be based on the median of the bids for this code, following the rules laid out in §414.416(b) and for calculating rental and purchase amounts per §414.408(f) and (h)(7). We propose to include a new section 414.416(b)(3) that would include the lead item bidding method. The SPAs for the other items would be based on the relative difference in fees for the item compared to the lead item, following the rules for inexpensive or routinely purchased items at §414.408(f) and (h)(7), and, for E0144, following the rules for capped rental items at §414.408(h)(1). For example, if the SPA for purchase for code E0143 is $80.00, Medicare payment for rental of E0143 would be $8.00 per month in accordance with §414.408(h)(7), and the SPA for purchase of E0143 used would be $60.00. The SPAs for code E0135 would be equal to $56.80 ($80.00 multiplied by 0.71), for purchase of a new E0135 walker, $5.68 per month for rental of E0135, and $42.60 for purchase of a used E0135 walker. The SPAs for rental of code E0144 would be equal to $21.92 ($8.00 multiplied by 2.74) for rental months 1 through 3, and $16.44 for rental months 4 through 13. Suppliers submitting bids would be educated in advance that their bid for code E0143 is a bid for all 9 codes and bidding suppliers would factor this into their decision on what amount to submit as their bid for the lead item. This would avoid price inversions and would carry over the relative difference in item weights that establish Medicare payment amounts for walkers under the fee schedule into the CBPs.

The third proposed category for lead item bidding is hospital beds as shown in the Table 23. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping.

TABLE 23 – Lead Item Bidding for Hospital Beds and Relative Difference in Fees

HCPCS	Features	Allowed Services for 2012	Average of 2015 Rental Fees	Fee Relative to Lead Item
E0260 (lead item)	Semi-Electric With Mattress & Side Rails	2,201,430	$134.38	1.00
E0261	Semi-Electric With Side Rails	109,727	$124.20	0.92
E0303	Heavy Duty Extra Wide With Mattress & Side Rails	47,795	$284.67	2.12
E0265	Total Electric With Mattress & Side Rails	37,584	$185.75	1.38
E0255	Variable Height With Mattress & Side Rails	25,003	$108.10	0.80
E0250	Fixed Height With Mattress & Side Rails	15,075	$88.95	0.66
E0295	Semi-Electric	15,056	$113.78	0.85
E0294	Semi-Electric With Mattress	9,446	$119.93	0.89
E0301	Heavy Duty Extra Wide With Side Rails	6,075	$252.96	1.88
E0256	Variable Height With Side Rails	4,135	$76.53	0.57
E0304	Extra Heavy Duty Extra Wide With Mattress & Side Rails	2,448	$737.98	5.49
E0266	Total Electric With Side Rails	1,969	$166.51	1.24
E0251	Fixed Height With Side Rails	1,463	$68.26	0.51
E0297	Total Electric	957	$129.68	0.97
E0296	Total Electric With Mattress	955	$148.29	1.10
E0302	Extra Heavy Duty Extra Wide With Side Rails	732	$685.28	5.10
E0292	Variable Height With Mattress	305	$76.97	0.57
E0293	Variable Height	189	$65.29	0.49
E0290	Fixed Height With Mattress	64	$67.29	0.50
E0291	Fixed Height	7	$48.85	0.36

Rather than submitting 20 individual bids for each of the 20 items, the supplier would submit one bid for the lead item. The SPA for lead item E0260 would be based on the median of the bids for this code, following the rules laid out in §414.416(b) and for calculating rental amounts per §414.408(h)(1). The SPAs for the other items would be based on the relative difference in the average of the 2015 fee schedule amounts for the item compared to the lead item. For example, if the SPA for code E0260 is $75.00, the SPA for code E0261 would be equal to $69.00, or $75.00 multiplied by 0.92. Suppliers submitting bids would be educated in advance that their bid for code E0260 is a bid for all 20 codes and bidding suppliers would factor this into their decision on what amount to submit as their bid for the lead item.

The fourth through seventh proposed categories for lead item bidding are as are shown in Table 24, Table 25 and Table 26 below. Under our proposal, when bidding for the lead item, a

supplier is bidding to furnish the entire grouping.

TABLE 24 – Lead Item Bidding for Enteral Infusion Pumps and Relative Difference in Fees

HCPCS	Features	Allowed Services for 2012	Average of 2015 Rental Fees	Fee Relative to Lead Item
B9002 (lead item)	Pump with alarm	265,890	$121.70	1.00
B9000	Pump without alarm	935	$115.47	0.95

TABLE 25 – Lead Item Bidding for TENS Devices and Relative Difference in Fees

HCPCS	Features	Allowed Services for 2012	Average of 2015 Rental Fees	Fee Relative to Lead Item
E0730 (lead item)	4 lead	267,428	$402.70	1.00
E0720	2 lead	46,238	$388.83	0.97

TABLE 26 – Lead Item Bidding for Support Surface Mattress/Overlay and Relative Difference in Fees

HCPCS	Features	Allowed Services for 2012	Average of 2015 Rental Fees	Fee Relative to Lead Item
E0277 (lead item)	Powered mattress	139,240	$663.22	1.00
E0372	Powered air mattress overlay	2,076	$505.82	0.76
E0371	Nonpower mattress overlay	1,444	$416.85	0.63
E0373	Nonpowered mattress	716	$576.84	0.87

TABLE 27 – Lead Item Bidding for Seat Lift Devices and Relative Difference in Fees

HCPCS		Features	Allowed Services for 2012	Average of 2015 Rental Fees	Fee Relative to Lead Item
E0627 (lead item)		Electric, in chair	49,162	$372.22	1.00
E0629		Non-electric	5,901	$366.70	0.99
E0628		Electric	5,091	$372.22	1.00

In summary, we propose to revise §414.412(d) to add this bidding method as an alternative to the current method for submitting bid amounts for each item in the seven groupings of similar items identified above. Suppliers participating in future CBPs may be required to use

this method when submitting bids for these groups of similar items. Also, we propose to revise §414.416(b) to add the method for calculating SPAs for items within each grouping of similar items based on the SPAs for lead items within each grouping of similar items. We believe that the proposed method would better accomplish the CBP objectives, which include reducing the amount Medicare pays for DMEPOS and limiting the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the CBP (72 FR 17996).

We believe this approach to bidding would safeguard beneficiaries from receiving items with fewer features simply because of the price inversions. We also believe that the proposed lead item bidding method would greatly reduce the burden on suppliers of formulating and submitting multiple bids for similar items because it would require less time to enter bids and would reduce the chances of keying errors when submitting bids. Finally, we believe this approach would safeguard beneficiaries and the Trust Fund from paying higher amounts for items with fewer features.

We are soliciting comments on this section.

VIII. Bid Limits for Individual Items under the DMEPOS Competitive Bidding Program

A. Background

Under the DMEPOS CBP, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in CBAs based on bids submitted and accepted by Medicare. For competitively bid items, these new payment amounts, referred to as single payment amounts (SPAs), replace the fee schedule payment methodology. Section 1847(b)(5) of the Act provides that Medicare payment for these competitively bid items and services is made on an assignment-related basis and is equal to 80 percent of the applicable single payment amount, less any unmet Part B deductible described in section 1833(b) of the Act. Section

1847(b)(2)(A)(iii) of the Act prohibits the Secretary from awarding a contract to an entity unless the Secretary finds that the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. This requirement guarantees savings to both the Medicare program and its beneficiaries. The CBP also includes provisions to ensure beneficiary access to quality DMEPOS items and services: section 1847 of the Act directs the Secretary to award contracts to entities only after a finding that the entities meet applicable quality and financial standards and beneficiary access to a choice of multiple suppliers in the area is maintained.

We implemented Round 1 of the DMEPOS CBP on January 1, 2011, and the Round 1 Recompete on January 1, 2014. Round 2 of the DMEPOS CBP and the national mail order program were implemented on July 1, 2013, and Round 2 and national mail order Recompete will be implemented on July 1, 2016. The programs phased in under Round 1 and 2 are in place in approximately 100 metropolitan statistical areas (MSAs) throughout the nation, including Honolulu, Hawaii. A 60-day bidding window allows bidders adequate time to prepare and submit their bids. §414.412 specifies the rules for submission of bids under a CBP. Each bid submission is evaluated and contracts are awarded to qualified suppliers in accordance with the requirements of section 1847(b)(2) of the Act and §414.414, which specifies conditions for awarding contracts.

Sections 1847(b)(6)(A)(i) and (b)(6)(A)(ii) of the Act provide that payment will not be made under Medicare Part B for items and services furnished under a CBP unless the supplier has submitted a bid to furnish those items and has been awarded a contract. Therefore, in order for a supplier that furnishes competitively bid items in a CBA to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have

been awarded a contract to do so.

B. Adjusting Fee Schedule Amounts and Bid Limits Established under the Competitive Bidding Program

The April 10, 2007 final rule (Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Final Rule) finalized requirements for providers to submit bids under the DMEPOS CBP (§414.412(b)) (79 FR 18026). §414.412 outlines the requirements associated with submitting bids under the competitive bidding process. Furthermore, §414.412(b)(2) states that the bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of Part 414, which is the fee schedule amount. Therefore, under our current policy, bid amounts that are submitted under the CBP cannot exceed the fee schedule amount. Contracts cannot be awarded in a CBA if total payments under the contracts are expected to be greater than what would otherwise be paid. In the preamble of the CY 2015 final rule that implemented the methodologies to adjust fee schedule amounts using information from CBPs, we indicated that the adjusted fee schedule amounts become the new bid limits (79 FR 66232).

Sections 1834(a)(1)(F)(ii) and (iii), 1834(h)(2)(H)(ii), and 1842(s)(3)(B) of the Act mandate adjustments to the fee schedule amounts for certain DMEPOS items furnished on or after January 1, 2016, in areas that are not CBAs, based on information from CBPs. Section 1842(s)(3)(B) of the Act also provides authority for making adjustments to the fee schedule amounts for enteral nutrients, equipment, and supplies (enteral nutrition) based on information from the CBPs. In the CY 2015 final rule (79 FR 66223), we finalized the methodologies for adjusting DMEPOS fee schedule amounts using information from CBPs at §414.210(g).

C. Current Issues

If the fee schedule amounts are adjusted as new SPAs are implemented under the CBPs, and these fee schedule amounts and subsequent adjusted fee schedule amounts continue to serve as the bid limits under the programs, the SPAs under the programs can only be lower under future competitions because the bidders cannot exceed the bid limits in the CBP. To continue using the adjusted fee schedule amounts as the bid limits for future competitions does not allow SPAs to fluctuate up or down as the cost of furnishing items and services goes up or down over time.

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under the program if total payments to contract suppliers in an area are expected to be more than would otherwise be paid. For the purpose of implementing section 1847(b)(2)(A)(iii) of the Act, we propose to revise §414.412(b) to use the unadjusted fee schedule amounts (the fee schedule amounts that would otherwise apply if no adjustments to the fee schedule amounts based on information from CBPs had been made) for the purpose of establishing limits on bids for individual items for future competitions (including re-competes). We are proposing this change because we believe the general purpose of the DMEPOS CBP is to establish reasonable payment amounts for DMEPOS items and services based on competitions among suppliers for furnishing these items and services, with bids from suppliers being based in part on the suppliers' costs of furnishing the items and services at that point in time. We believe the intent of the program is to replace unreasonably high fee schedule amounts for DMEPOS items and services with lower, more reasonable amounts as a result of the competitive bidding. We believe that as long as the amounts established under CBPs are lower than the fee schedule amounts that would otherwise apply had the DMEPOS CBP not been implemented, savings will continue to be generated by

the programs.

For competitions held thus far for contract periods starting on January 1, 2011, July 1, 2013, January 1, 2014, and July 1, 2016, the unadjusted fee schedule amounts were used as the bid limits for all items in all CBAs, and the SPAs for each subsequent competition were generally lower than the SPAs for the preceding competitions. We believe that competition for contracts under the programs will continue to keep bid amounts low and, together with utilizing unadjusted fee schedule amounts as bid limits, ensure that total payments under the program will be less than what would otherwise be paid. We believe that prices established through the competitions should be allowed to fluctuate both up and down over time as long as they do not exceed the previous fee schedule amounts that would otherwise have been paid if the CBP had not been implemented, and savings below the previous fee schedule amounts are achieved. This would not apply to drugs included in a CBP which would otherwise be paid under Subpart I of Part 414 of 42 CFR based on 95 percent of the average wholesale price in effect on October 1, 2003.

In addition, the amount of the SPAs established under the program is only one factor affecting total payments made to suppliers for furnishing DMEPOS items and services. Although the bid limits were created and are used for implementation of section 1847(b)(2)(A)(iii) of the Act, they are not the only factor that affects total payments to suppliers. The DMEPOS CBP is effective in reducing fraud and abuse by limiting the number of entities that can submit claims for payment, while ensuring beneficiary access to necessary items and services in CBAs. Section 1847(b)(5) of the Act requires that payment to contract suppliers be made on an assignment-related basis and limits beneficiary cost sharing to 20 percent of the SPA. We plan to take all of these factors into account before awarding contracts for subsequent

competitions in order to determine if total payments to contract suppliers in an area are expected to be less than would otherwise be paid.

D. Summary of Proposed Bid Limits

We are proposing to revise §414.412(b) to specify that the bids submitted for each individual item of DMEPOS other than drugs cannot exceed the fee schedule amounts established in accordance with sections 1834(a), 1834(h), or 1842(s) of the Act for DME, off-the-shelf (OTS) orthotics, and enteral nutrition, respectively, as if adjustments to these amounts based on information from CBPs had not been made. Specifically, the bid limits for DME would be based on the 2015 fee schedule amounts established in accordance with section 1834(a)(1)(B)(ii) of the Act, prior to application of section 1834(a)(1)(F)(ii) and (iii), but updated for subsequent years based on the factors provided at section 1834(a)(14) of the Act. In other words, the bid limits would be based on fee schedule amounts established in accordance with section 1834(a), without applying the adjustments mandated by section 1834(a)(1)(F)(ii) of the Act. The bid limits for OTS orthotics would also be based on the 2015 fee schedule amounts established in accordance with section 1834(h)(1)(B)(ii) of the Act, prior to application of section 1834(h)(1)(H), but updated for subsequent years based on the factors provided at section 1834(h)(4) of the Act. In other words, the bid limits would be based on fee schedule amounts established in accordance with section 1834(h), without applying the adjustments authorized by section 1834(h)(1)(H) of the Act. The bid limits for enteral nutrients, equipment, and supplies (enteral nutrition) would be based on the 2015 fee schedule amounts established in accordance with section 1842(s)(1) of the Act, prior to application of section 1842(s)(3), but updated for subsequent years based on the factors provided at section 1842(s)(1)(B)(ii) of the Act. In other words, the bid limits would be based on fee schedule amounts established in accordance with

section 1842(s)(1), without applying the adjustments authorized by section 1842(s)(3)(B) of the Act.

Finally, with respect to the alternative bidding rules proposed in section VII. above, when evaluating bids for a grouping of similar items in a product category submitted in the form of a single bid for the highest volume item in the grouping, or lead item, we propose to use the weighted average fee schedule amounts for the grouping of similar items in order to establish the bid limit for the purpose of implementing this proposed provision. We are proposing to revise §414.412(b)(2) to use total nationwide allowed services for all areas for the individual items, initially from calendar year 2012, to weight the fee schedule amount for each item for the purpose of determining a bid limit for the lead item based on the weighted average fee schedule amounts for the entire grouping of similar items. This would ensure that the payment amounts established under the CBPs do not exceed the fee schedule amounts that would otherwise apply to the grouping of similar items as a whole. Table 28 below illustrates the data that would be used to calculate the bid limit for the lead item (code E0143) in the grouping of walkers for a CBA located in the state of Maryland using 2015 fee schedule amounts for illustration purposes. The item weight for each code is based on 2012 total nationwide allowed services for the code divided by total nationwide allowed services for 2012 for all of the codes in the grouping.

TABLE 28 – Data Used to Calculate Bid Limit for Lead Item for Walkers for Maryland

HCPCS	Features	Total Nationwide Allowed Services for 2012	2015 Purchase Fees (MD)	Item weight
E0143 (lead item)	Folding With Wheels	958,112	$115.02	0.90734
E0135	Folding	56,399	$77.51	0.05341
E0149	Heavy Duty With Wheels	23,144	$213.53	0.02192
E0141	Rigid With Wheels	6,319	$110.30	0.00598
E0148	Heavy Duty	4,366	$121.56	0.00413

HCPCS	Features	Total Nationwide Allowed Services for 2012	2015 Purchase Fees (MD)	Item weight
E0147	Heavy Duty With Braking & Variable Wheel Resistance	4,066	$549.90	0.00385
E0140	With Trunk Support	1,483	$345.08	0.00140
E0144	Enclosed With Wheels & Seat	1,275	$304.80	0.00121
E0130	Rigid	788	$67.19	0.00075
	Total	1,055,952		

Summing the 2015 fee schedule amounts multiplied by the weights for each item results in a bid limit of $117.37 for lead item E0143. Bids submitted for the lead item E0143 for walkers for a CBA located in the state of Maryland would not be able to exceed $117.37 in this example. We therefore propose to amend §414.412(b) to establish this method for determining bid limits for lead items identified in accordance with proposed §414.412(d)(2) in section VII above.

We are soliciting comments on this proposed rule.

IX. Access to Care Issues for DME

A. Background

The Medicare and Medicaid programs generally serve distinct populations, but more than ten million individuals ("dual eligible beneficiaries") were enrolled in both programs in 2014.[10] As a group, dual eligible beneficiaries comprise a population with complex chronic care needs and functional impairments.[11] Compared to Medicare-only or Medicaid-only beneficiaries, dual

10*Data Analysis Brief: Medicare-Medicaid Dual Enrollment from 2006 through 2013*, Medicare-Medicaid Coordination Office (MMCO), Centers for Medicare and Medicaid Services, December 2014 at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-, Medicaid-Coordination-Office/Downloads/DualEnrollment20062013.pdf

11 Overall these individuals have higher prevalence of many conditions (including, but not limited to diabetes, pulmonary disease, stroke, Alzheimer's disease, and mental illness) than their Medicare-only and Medicaid-only peers. Medicare-Medicaid enrollees' health costs are four times greater than all other people with Medicare. Medicare Medicaid Enrollee State Profile: The National Summary – 2008, Centers for Medicare and Medicaid Services at https://www.cms.gov/Medicare-Medicaid-CoordiNation/Medicare-and-Medicaid-CoordiNation/Medicare-Medicaid-CoordiNation-Office/Downloads/2008NationalSummary.pdf.

eligible beneficiaries are more likely to experience multiple chronic health conditions, mental illness, functional limitations, and cognitive impairments.

Both Medicare and Medicaid cover Durable Medical Equipment (DME), which can be essential to dual eligible beneficiaries' mobility, respiratory function, and activities of daily living. However, the programs' different eligibility, coverage, and supplier rules can impact access to medically-appropriate DME and repairs of existing equipment for the population enrolled in both benefits.

B. Request for Information

CMS seeks to examine how overlapping but differing coverage standards for DME under Medicare and Medicaid may affect access to care for beneficiaries and administrative processes for providers and suppliers. In response to a May 2011 Request for Information, CMS received over one hundred comments from a range of stakeholders regarding 29 areas of program alignment opportunities, including DME.[12] In the intervening years, CMS has continued to engage stakeholders – including beneficiaries, payers, suppliers, and states – to understand opportunities and challenges caused by differing program requirements.

According to stakeholders, a common barrier to DME access stems from conflicting approval processes among Medicare and Medicaid that can leave suppliers uncertain about whether and how either program will cover items. Medicare is the primary payer for DME and other medical benefits covered by both programs. Medicaid typically pays Medicare cost-sharing amounts and may cover DME that Medicare does not, including certain specialized equipment that promotes independent living. Medicaid pays secondary to most other legally liable payers, including Medicare, and requires those payers to pay to the limit of their legal

12 https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FederalRegisterNoticeforComment052011.pdf

liability before any Medicaid payment is available. Many of the Medicare requirements related to DME, including the definition and scope of the benefit, are mandated by the statute; therefore, we do not have the authority to bypass or alter these requirements. Medicare generally only processes claims after the equipment is delivered. Because suppliers lack assurance regarding how Medicare or Medicaid will cover DME at the point of sale – and dual eligible beneficiaries cannot pay out-of-pocket up front – suppliers may refuse to provide needed DME.

Other barriers may emerge for beneficiaries who have Medicaid first and get DME prior to enrolling in Medicare. Stakeholders report that many individuals may have difficulty getting coverage for repairs on equipment obtained through Medicaid coverage, since Medicare will only pay for repairs after making a new medical necessity determination. Additionally, not all Medicaid-approved DME suppliers are Medicare-approved suppliers, meaning beneficiaries may need to change suppliers after enrolling in Medicare.

CMS seeks to obtain additional information to help target efforts to promote timely access to DME benefits for people dually eligible for Medicare and Medicaid.

Please provide comments on the scope of the following issues related to DME access for dual eligible beneficiaries:

- Obstacles to timely receipt of needed DME and repairs due to conflicting program requirements;
- Challenges or opportunities faced by Medicaid beneficiaries who newly qualify for Medicare, including challenges related to new and preexisting items, repairs, and providers;
- The percentage of Medicare competitive bidding contractors in the state which accept Medicaid;

- The role of prior authorization policies under either program and whether these policies offer suppliers sufficient advance notice regarding coverage;
- Impacts on beneficiaries from delayed access to needed equipment and repairs;
- If access problems are more pronounced for certain categories of equipment, the categories of DME for which the access problems arise the most frequently or are most difficult to resolve;
- Challenges faced by suppliers in meeting different supporting documentation and submission requirements, and
- Other prevalent access challenges due to DME program misalignments.

We also invite feedback regarding potential regulatory or legislative reforms to address DME program misalignments including:

- State Medicaid program policies that promote coordination of benefits and afford beneficiaries full access to benefits;
- Strategies to promote access to timely, effective repairs, including from suppliers who that did not originally furnish the equipment;
- Policies to address challenges faced when beneficiaries transition from Medicaid-only to dual eligible status; and
- Other ways to promote timely DME access for dual eligible beneficiaries, without introducing new program integrity risks or increasing total expenditures in either Medicare or Medicaid.

Please include specific examples when possible while avoiding the transmission of protected information. Please also include a point of contact who can provide additional information upon request.

X. Comprehensive End-Stage Renal Disease Care Model and Future Payment Models

A. Background

CMS seeks input on innovative approaches to care delivery and financing for beneficiaries with end-stage renal disease (ESRD). This input could include ideas related to innovations that would go above and beyond the Comprehensive ESRD Care (CEC) Model with regard to financial incentives, populations or providers engaged, or the scale of change, among other topics. We will consider information received as we develop future payment models in this area, and as we launch solicitation for a second round of entry into the CEC Model to begin on January 1, 2017.

The CEC Model is a CMS test of a dialysis-specific Accountable Care Organization (ACO) model. In the model, dialysis clinics, nephrologists and other providers join together to create an End-Stage Renal Disease Seamless Care Organization (ESCO) to coordinate care for aligned beneficiaries. ESCOs are accountable for clinical quality outcomes and financial outcomes measured by Medicare Part A and B spending, including all spending on dialysis services for their aligned ESRD beneficiaries. This model encourages dialysis providers to think beyond their traditional roles in care delivery and supports them as they provide patient-centered care that will address beneficiaries' health needs, both in and outside of the dialysis clinic.

B. Provisions of the Notice

Section 1115A of the Social Security Act (the Act), as added by section 3021 of the Affordable Care Act, authorizes the Innovation Center to test innovative payment and service delivery models that reduce spending under Medicare, Medicaid or The Children's Health Insurance Program (CHIP), while preserving or enhancing the quality of care. We seek to

gather responses to the following questions that will help us to develop and refine innovative payment models related to kidney care.

Questions:

1. How could participants in alternative payment models (APMs) and advanced alternative payment models (AAPMs) coordinate care for beneficiaries with chronic kidney disease and to improve their transition into dialysis?

2. How could participants in APMs and AAPMs target key interventions for beneficiaries at different stages of chronic kidney disease?

3. How could participants in APMs and AAPMs better promote increased rates of renal transplantation?

4. How could CMS build on the CEC Model or develop alternative approaches for improving the quality of care and reducing costs for ESRD beneficiaries?

5. Are there specific innovations that are most appropriate for smaller dialysis organizations?

6. How could primary-care based models better integrate with APMs or AAPMs focused on kidney care to help prevent development of chronic kidney disease in patients and progression to ESRD? Primary-care based models may include patient-centered medical homes or other APMs.

7. How could APMs and AAPMs help reduce disparities in rates of CKD/ESRD and adverse outcomes among racial/ethnic minorities?

8. Are there innovative ways APMs and AAPMs can facilitate changes in care delivery to improve the quality of life for CKD and ESRD patients?

9. Are there specific innovations that are most appropriate for evaluating patients for suitability for home dialysis and promoting its use in appropriate populations?

10. Are there specific innovations that could most effectively be tested in a potential mandatory model?

For additional information on the Comprehensive ESRD Care Model and how to apply, click on the Request for Applications located on the Innovation Center website at: innovation.cms.gov/initiatives/comprehensive-ESRD-care.

XI. Technical Correction for 42 CFR 413.194 and 413.215

In the CY 2013 ESRD PPS final rule (77 FR 67520), we revised § 413.89(h)(3) to set forth the percentage reduction in allowable bad debt payment required by section 1861(v)(1)(W) of the Act for ESRD facilities for cost reporting periods beginning during fiscal year 2013, fiscal year 2014 and subsequent fiscal years. We also revised § 413.89(h)(3) to set forth the applicability of the cap on bad debt reimbursement to ESRD facilities for cost reporting periods beginning between October 1, 2012 and December 31, 2012. In addition, in that rule, we removed and reserved § 413.178, since there were revised provisions set out at § 413.89.

As a part of these revisions, we intended to correct the cross-reference in section §§ 413.194 and 413.215 so that § 413.89(h)(3) was referenced instead of § 413.178. We inadvertently omitted the regulations text that would have made those changes. Therefore, in this rule, we are proposing a technical correction to revise the regulations text at §§ 413.194 and 413.215 to correct the cross-reference to the Medicare bad debt reimbursement regulation, so that §§ 413.194 and 413.215 would reference 42 CFR 413.89(h)(3) instead of the current outdated reference to § 413.178.

XII. Advancing Health Information Exchange

HHS has a number of initiatives designed to improve health and health care quality through the adoption of health information technology (health IT) and nationwide health information exchange. As discussed in the August 2013 Statement "Principles and Strategies for Accelerating Health Information Exchange" (available at http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf), HHS believes that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health IT that facilitates the secure, efficient, and effective sharing and use of health-related information when and where it is needed is an important tool for settings across the continuum of care, including ESRD facilities.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Version 1.0 (Roadmap) (available at https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf) which describes barriers to interoperability across the current health IT landscape, the desired future state that the industry believes will be necessary to enable a learning health system, and a suggested path for moving from the current state to the desired future state. In the near term, the Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Moreover, the vision described in the Roadmap significantly expands the types of electronic health information, information sources, and information users well beyond clinical information derived from

electronic health records (EHRs). This shared strategy is intended to reflect important actions that both public and private sector stakeholders can take to enable nationwide interoperability of electronic health information such as: (1) establishing a coordinated governance framework and process for nationwide health IT interoperability; (2) improving technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhancing incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarifying privacy and security requirements that enable interoperability.

In addition, ONC has released the 2016 Interoperability Standards Advisory (available at https://www.healthit.gov/sites/default/files/2016-interoperability-standards-advisory-final-508.pdf), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these "best available standards" into account as they implement interoperable health information exchange across the continuum of care.

We encourage stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures, and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce standards through relevant policies and programs.

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 and III of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2017 as well as the inclusion of Subpart K for AKI. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, this proposed rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP

a. Wage Estimates

In the CY 2016 ESRD PPS Final Rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data[13], are the individuals tasked with submitting measure data to CROWNWeb and NHSN for purposes of the Data Validation Studies rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients.[14] The mean hourly wage of a Medical Records and Health Information Technician is $18.68 per hour. Under OMB Circular 76-A, in calculating direct labor, agencies should not only include salaries and wages, but also "other entitlements" such as fringe benefits.[15] This Circular provides that the civilian position full fringe benefit cost factor is 36.25 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $25.45 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP.

b. Time Required to Submit Data Based on Proposed Reporting Requirements

In the CY 2016 ESRD PPS Final Rule (80 FR 69070), we estimated that the time required to submit measure data using CROWNWeb is 2.5 minutes per data element submitted, which takes into account the small percentage of data that is manually reported, as well as the human interventions required to modify batch submission files such that they meet CROWNWeb's internal data validation requirements.

c. Data Validation Requirements for the PY 2019 ESRD QIP

Section IV.C.8. in this proposed rule outlines our data validation proposals for PY 2019. Specifically, for the CROWNWeb validation, we propose to randomly sample records from 300 facilities as part of our continuing pilot data-validation program. Each sampled facility would be

13 http://www.bls/gov/ooh/healthcare/medical-records-and-health-information-technicians.htm
14 http://www.bls.gov/ooh/healthcare/registered-nurses.htm.
15 http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.

required to produce approximately 10 records, and the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities x 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the CROWNWeb data validation would be approximately $19,088 (750 hours x $25.45/hour) total of approximately $64 ($19,088/300 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request (OMB control number 0938-1289).

Under the proposed data validation study for validating data reported to the NHSN Dialysis Event Module, we propose to randomly select 150 facilities. A CMS contractor will send these facilities requests for medical records for all patients with "candidate events" during the evaluation period. 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. We estimate that it will take each facility approximately 60 minutes to comply with this requirement (30 minutes from each of the two quarters in the evaluation period). If 150 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 150 hours (150 facilities x 1 hour). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the NHSN data validation would be $3,817.50 (150 hours x

$25.45/hour) total of $25.45 ($3,817.50/150 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request (OMB control number 0938-NEW).

d. Proposed Ultrafiltration Rate Reporting Measure

We proposed to include, beginning with the PY 2020 ESRD QIP, a reporting measure requiring facilities to report in CROWNWeb an ultrafiltration rate at least once per month for each qualifying patient. We estimate the burden associated with this measure to be the time and effort necessary for facilities to collect and submit the information required for the Ultrafiltration Rate Reporting Measure. We estimated that approximately 6,454 facilities will treat 548,430 ESRD patients nationwide in PY 2020. The Ultrafiltration Rate Reporting Measure requires facilities to report 13 elements per patient per month (156 elements per patient per year) and we estimate it will take facilities approximately 0.042 hours (2.5 minutes) to submit data for each data element. Therefore, the estimated total annual burden associated with reporting this measure in PY 2020 is approximately 3,593,313 hours (548,430 ESRD patients nationwide x 156 data elements/year x 0.042 hours per element), or approximately 553 hours per facility. We anticipate that Medical Records and Health Information Technicians or similar administrative staff will be responsible for this reporting. We therefore believe the cost for all ESRD facilities to comply with the reporting requirements associated with the ultrafiltration rate reporting measure would be approximately $91,449,815.80 (3,593,313 x $25.45/hour), or $14,082.20 per facility. The burden associated with these requirements is captured in an information collection request (OMB control number 0938-NEW).

XV. Response to Comments

Because of the large number of public comments we normally receive on Federal

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

XVI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as economically significant); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants,

user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is not economically significant within the meaning of section 3(f)(1) of the Executive Order, since it does not meet the $100 million threshold. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact. We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

This rule proposes a number of routine updates and several policy changes to the ESRD PPS in CY 2017. The proposed routine updates include the CY 2017 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Other proposed policy changes include implementation of policy related to payment for hemodialysis treatments furnished more than three times per week and changes to the home dialysis training policy. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2017 for renal dialysis services furnished to ESRD patients and to patients with AKI in accordance with section 1861(s)(2)(F) of the Act.

This rule proposes to implement the provisions in TPEA which provide for coverage and payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish would result in a failure to comply with the requirements of the Act, as added by the TPEA.

This rule proposes to implement requirements for the ESRD QIP, including a proposal to adopt a measure set for the PY 2020 program, as directed by section 1881(h) of the Act. Failure to propose requirements for the PY 2020 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2019. In addition, proposing requirements for the PY 2020 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

This rule proposes a requirement for the DMEPOS CBP for bid surety bonds and state licensure in accordance with section 1847 of the Act, as amended by section 522(a) of MACRA. The rule also proposes an appeals process for all breach of contract actions CMS may take.

This rule also proposes a methodology for adjusting DMEPOS fee schedule amounts for similar items with different features using information from the DMEPOS CBPs, a methodology for determining single payment amounts for similar items with different features under the DMEPOS CBPs, and revising bid limits for individual items under DMEPOS CBP.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in an increase of approximately $50 million in payments to ESRD facilities in CY 2017, which includes the amount associated with updates to the outlier thresholds, home dialysis training policy, payment for hemodialysis treatments furnished more than 3 times per week, and updates to the wage index. We are estimating approximately $2.0 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

For PY 2019, we anticipate that the new burdens associated with the collection of information requirements will be approximately $21 thousand, totaling an overall impact of

approximately $15.5 million as a result of the PY 2019 ESRD QIP.[16] For PY 2020, we estimate that the proposed requirements related to the ESRD QIP will cost approximately $91 million dollars, and the payment reductions will result in a total impact of approximately $22 million across all facilities, resulting in a total impact from the proposed ESRD QIP of approximately $113 million.

We anticipate that DMEPOS CBP bidding entities will be impacted by the bid surety bond requirement. The state licensure requirement will have no new impact on the supplier community because this is already a basic supplier eligibility requirement at §414.414(b)(3), and the appeals process for breach of contract actions may have a beneficial, positive impact on suppliers.

Overall, the bid surety bond requirement may have a positive financial impact on the CBP as we anticipate that the requirement will provide an additional incentive for bidding entities to submit substantiated bids. However, there will be an administrative burden for implementation of the bid surety bond requirement for CMS. We expect minimal administrative costs associated with the state licensure and appeals process for breach of DMEPOS CBP contract proposed rules.

We do not anticipate that the proposed DMEPOS Competitive Bidding regulations will have an impact on Medicare beneficiaries.

We estimate that our proposal for a methodology for adjusting DMEPOS fee schedule amounts for similar items with different features using information from the DMEPOS CBPs, proposed change for determining single payment amounts for similar items with different

16 We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The previously finalized aggregate impact of $15.5 million reflects the PY 2019 estimated payment reductions and the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure.

features under the DMEPOS CBPs, and proposed revision to the bid limits for items under the DMEPOS CBP will have no significant impact on the suppliers, beneficiaries, Part B trust fund and economy as a whole.

B. Detailed Economic Analysis

1. CY 2017 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 2016 to estimated payments in CY 2017. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2016 and CY 2017 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used the December 2015 update of CY 2015 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2015 claims to 2016 and 2017 using various updates. The updates to the ESRD PPS base rate are described in section II.B.3 of this proposed rule. Table 29 shows the impact of the estimated CY 2017 ESRD payments compared to estimated payments to ESRD facilities in CY 2016.

Table 29 – Impact of Proposed Changes in Payment to ESRD Facilities for CY 2017 Proposed Rule

Facility Type	Number of Facilities A	Number of Treatments (in millions) B	Effect of 2017 Changes in Outlier Policy C	Effect of 2017 Changes in Wage Indexes D	Effect of Total 2017 Proposed Changes (Outlier, Wage Indexes, Training Adjustment and Routine Updates to the Payment Rate)[4] E
All Facilities	6,453	40.0	0.2%	0.0%	0.5%
Type					
Freestanding	6,022	37.8	0.2%	0.0%	0.5%
Hospital based	431	2.2	0.3%	0.1%	0.7%
Ownership Type					
Large dialysis organization	4,541	28.6	0.2%	0.0%	0.5%
Regional chain	990	6.2	0.2%	0.0%	0.6%
Independent	568	3.5	0.2%	-0.1%	0.4%
Hospital based[1]	354	1.8	0.3%	0.1%	0.7%
Geographic Location					
Rural	1,260	6.0	0.2%	0.0%	0.6%
Urban	5,193	34.0	0.2%	0.0%	0.5%
Census Region					
East North Central	1,045	5.5	0.2%	0.0%	0.6%
East South Central	522	3.0	0.2%	-0.1%	0.5%
Middle Atlantic	702	4.9	0.2%	-0.3%	0.2%
Mountain	368	2.0	0.1%	-0.1%	0.4%
New England	182	1.3	0.2%	-0.5%	0.1%
Pacific[2]	782	5.7	0.1%	0.5%	1.0%
Puerto Rico and Virgin Islands	49	0.3	0.2%	-0.2%	0.3%
South Atlantic	1,458	9.4	0.2%	-0.2%	0.4%
West North Central	469	2.1	0.2%	0.0%	0.6%
West South Central	876	5.8	0.2%	0.1%	0.7%
Facility Size					
Less than 4,000 treatments[3]	1,211	2.7	0.2%	0.0%	0.6%
4,000 to 9,999 treatments	2,401	11.0	0.2%	0.0%	0.6%
10,000 or more treatments	2,680	26.1	0.2%	0.0%	0.5%
Unknown	161	0.2	0.2%	-0.1%	0.5%
Percentage of Pediatric Patients					
Less than 2%	6,349	39.7	0.2%	0.0%	0.5%
Between 2% and19%	44	0.3	0.2%	0.1%	0.7%
Between 20% and 49%	9	0.0	0.0%	0.3%	0.6%
More than 50%	51	0.0	0.0%	0.0%	0.3%

1. Includes hospital based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

2. Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

3. Of the 1,211 ESRD facilities with less than 4,000 treatments, only 396 qualify for the low-volume payment adjustment. The low-volume payment adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low volume facilities is

a 0.5 percent increase in payments.

4. Includes adjustment of training add-on from $50.16 to $95.57 per treatment and a payment rate update of 0.35 percent.

Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.3.c of this proposed rule is shown in column C. For CY 2017, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.2 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2017 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed CY 2017 wage indices. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.5 percent decrease to a 0.5 percent increase due to these proposed updates.

Column E reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed wage index, the effect of the change in the home dialysis training add-on from $50.16 to $95.57 and the effect of the payment rate update. The ESRD PPS payment rate update is 0.35 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2017 of 2.1 percent, the 1.25 percent reduction as required by the section 1881(b)(14)(F)(i)(I) of the Act, and the MFP adjustment of 0.5 percent. We expect that overall ESRD facilities would experience a 0.5 percent increase in estimated payments in 2017. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.1 percent to an increase of 1.0 percent in their 2017 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal

dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2017, we estimate that the proposed ESRD PPS would 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 2017 would be approximately $9.7 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.5 percent in CY 2017.

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 0.5 percent overall increase in the proposed ESRD PPS payment amounts in CY 2017, we estimate that there will be an increase in beneficiary co-insurance payments of 0.5 percent in CY 2017, which translates to approximately $10 million.

e. Alternatives Considered

In section II.B.1 of this proposed rule, we propose payment for hemodialysis furnished more than 3 times per week. We considered not proposing the payment changes; however, without the proposed changes, facilities would continue to be unable to appropriately bill all of the HD treatments they furnish causing the total number of treatments in our claims data to be understated, and thus the improvement to payment and data collection would not be achieved.

In section II.B.2, we propose changes to the home dialysis training add-on based on the average number of hours for PD and HD and weighted by the percentage of total treatments for

each modality. We considered an approach to update the current training add-on amount annually using the market basket increase or the wage and price proxy in the market basket. However, under either approach, the increase to the training add-on payment was small and would not incentivize home dialysis training.

2. Proposed Coverage and Payment for Renal Dialysis Services Furnished to Individuals with AKI

a. Effects on ESRD Facilities

We analyzed CY 2015 hospital outpatient claims to identify the number of treatments furnished historically for AKI patients. We identified 7,155 outpatient claims with AKI that also had dialysis treatments that were furnished in CY 2015. Since the data for 2015 is not complete, we inflated the 7,155 treatments by 22 percent to 8,729 treatments. This inflation factor was determined by comparing the 2014 treatment counts submitted and processed by June 30, 2015 to the 2014 treatment counts submitted and processed by January 8, 2015. We then further inflated the 8,729 treatments to 2017 values using estimated population growth for fee-for service non-ESRD beneficiaries. This results in an estimated 8,938 treatments that would now be paid to ESRD facilities for furnishing dialysis to beneficiaries with AKI. Using the CY 2017 proposed ESRD base rate of $231.04 and an average wage index multiplier, we are estimating approximately $2.0 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

Ordinarily, we would provide a table showing the impact of this provision on various categories of ESRD facilities. Because we have no way to project how many patients with AKI requiring dialysis will choose to have dialysis treatments at an ESRD facility, we are unable to provide a table at this time.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing a payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are furnished is made by the patient and their physician. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We anticipate an estimated $2.0 million being redirected from hospital outpatient departments to ESRD facilities in CY 2017 as a result of some AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus continuing to receive those services in the hospital outpatient setting.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the Outpatient Prospective Payment System's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

In section III.B.2 of this proposed rule, we propose policy related to the implementation of section 808(b) of TPEA, which amended section 1834 by adding a new paragraph (r) which provides payment for renal dialysis services furnished by ESRD facilities to beneficiaries with

AKI. We considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, other adjustments at 1881(b)(14)(D), as well as not paying separately for AKI specific drugs and labs. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate.

3. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2020 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 the PY 2020 ESRD QIP is described in sections III.F.6 and III.F.7 of this proposed rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2020 ESRD QIP would apply to ESRD PPS payments made to the facility in CY 2020.

We estimate that, of the total number of dialysis facilities (including those not receiving a TPS), approximately 48 percent or 2,840 of the facilities would likely receive a payment reduction in PY 2020. 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 6,454 dialysis facilities paid through the PPS. Table 30 shows the overall estimated distribution of payment reductions resulting from the PY 2020 ESRD QIP.

TABLE 30: Estimated Distribution of PY 2020 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	3174	52.8%
0.5%	1576	26.2%
1.0%	903	15.0%
1.5%	280	4.7%
2.0%	81	1.4%

Note: This table excludes 477 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 2020, 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 31.

TABLE 31: Data Used to Estimate PY 2020 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 2014-Dec 2014	Jan 2015-Dec 2015
%Catheter	Jan 2014-Dec 2014	Jan 2015-Dec 2015
Kt/V Composite	Jan 2013-Dec 2013	Jan 2014-Dec 2014
Hypercalcemia	Jan 2014-Dec 2014	Jan 2015-Dec 2015
Standardized Transfusion Ratio	Jan 2013-Dec 2013	Jan 2014-Dec 2014
ICH CAHPS Survey	NA	NA
Standardized Readmission Ratio	Jan 2013-Dec 2013	Jan 2014-Dec 2014
NHSN Bloodstream Infection	Jan 2014-Dec 2014	Jan 2014-Dec 2014
SHR	Jan 2013-Dec 2013	Jan 2014-Dec 2014

Clinical measure topic areas with less than 11 cases for a facility were not included in that facility's Total Performance Score. Each facility's Total Performance Score was compared to an estimated minimum Total Performance Score and an estimated payment reduction table that were consistent with the proposals outlined in Section III.G.9 of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2015. 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 2020 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the one-year period between January 2015 and December 2015 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 2015 through December 2015 times the estimated payment reduction percentage). For PY 2020, the total payment reduction for all of the 1,996 facilities expected to receive a reduction is approximately $22 million ($21,990,410). Further, we estimate that the total costs associated with the collection of information requirements for PY 2020 described in section VIII.1.b of this proposed rule would be approximately $91,449,815 million for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $113 million ($91,449,815 + $21,990,410 = $113,440,225) in PY 2020, as a result of the PY 2020 ESRD QIP.

Table 32 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2020. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital

based/freestanding facilities). Given that the time periods used for these calculations will differ from those we propose to use for the PY 2020 ESRD QIP, the actual impact of the PY 2020 ESRD QIP may vary significantly from the values provided here.

TABLE 32: Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2020

	Number of Facilities	*Number of Treatments 2015 (in millions)*	*Number of Facilities with QIP Score*	*Number of Facilities Expected to Receive a Payment Reduction*	*Payment Reduction (percent change in total ESRD payments)*
All Facilities	6,454	40.0	5,977	1,996	-0.24%
Facility Type:					
Freestanding	6,023	37.8	5,807	1,943	-0.24%
Hospital-based	431	2.2	170	53	-0.23%
Ownership Type:					
Large Dialysis	4,542	28.6	4,403	1,416	-0.22%
Regional Chain	989	6.2	923	299	-0.23%
Independent	568	3.5	526	241	-0.42%
Hospital-based (non-chain)	354	1.8	125	40	-0.23%
Facility Size:					
Large Entities	5,531	34.8	5,326	1,715	-0.22%
Small Entities[1]	922	5.2	651	281	-0.39%
Rural Status:					
1) Yes	1,261	6.0	1,137	254	-0.16%
2) No	5,193	34.0	4,840	1,742	-0.25%
Census Region:					
Northeast	883	6.2	785	324	-0.29%
Midwest	1,512	7.6	1,341	451	-0.24%
South	2,855	18.2	2,724	953	-0.25%
West	1,143	7.6	1,080	234	-0.15%
US Territories[2]	61	0.4	47	34	-0.62%
Census Division:					
East North Central	1,045	5.5	939	374	-0.29%
East South Central	522	3.0	512	162	-0.20%
Middle Atlantic	702	4.9	621	277	-0.32%
Mountain	368	2.0	334	53	-0.10%

	Number of Facilities	*Number of Treatments 2015 (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)*
New England	183	1.3	165	47	-0.17%
Pacific	782	5.7	751	182	-0.17%
South Atlantic	1,458	9.4	1,378	547	-0.29%
West North Central	469	2.1	402	77	-0.13%
West South Central	875	5.8	834	244	-0.20%
US Territories[2]	49	0.3	41	33	-0.69%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,211	2.7	975	217	-0.17%
4,000-9,999 treatments	2,402	11.0	2,324	759	-0.24%
Over 10,000 treatments	2,680	26.1	2,605	1,003	-0.26%
Unknown	161	0.2	73	17	-0.18%

[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.

4. DMEPOS Competitive Bidding Bid Surety Bond, State Licensure and Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions

a. Effects on Competitive Bidding Program Suppliers

Bid Surety Bonds. It is difficult to estimate the precise financial impact the bid surety bond requirement will have on competitive bidding entities as this type of bond is not currently available. Based on our research of the bond industry, as well as the structure of the existing CMS DMEPOS surety bond requirement for all DMEPOS suppliers, we anticipate that the cost to obtain a bid surety bond will be based on a percentage of the total bond amount. This percentage may be adjusted by the authorized surety based upon certain criteria such as: (1) the number of bid surety bonds purchased by a bidding entity, (2) the credit score of the bidding entity and,(3) the prior contracting experience the bidding entity has had with the DMEPOS

CBP, that is, history of accepting/rejecting contracts.

For instance, an authorized surety may establish a preliminary charge amount of 2 percent of the total bond amount to obtain a $100,000 bid surety bond. We anticipate that the authorized surety may adjust their charge percentage based on the number of CBAs in which a bidding entity bids, that is, a bulk discount. Bidding entities that purchase multiple bid surety bonds from the authorized surety would likely receive a reduced charge per bid surety bond as compared to a bidding entity that only purchases a single bid surety bond. We also expect that authorized sureties will evaluate each bidding entity's credit score(s) to either establish an appropriate charge percentage or to decide not to issue a bond if the bidding entity's credit score is too low. Lastly, we anticipate that an authorized surety may also request documentation from prior rounds of bidding to understand the bidding entity's experience with contract acceptance. Bidding entities that have accepted more contract offers in the prior round without any contract rejections may be viewed by an authorized surety as less risky than a bidding entity who has rejected numerous contract offers with few or no contract acceptance.

On January 1, 2019, CMS will be combining all CBAs into a consolidated round of competition. As a result, we estimate the aggregate total out of pocket cost for bidding entities to bid in this competition to be $26,000,000. This estimate is based upon the approximately 13,000 distinct bidders for CBAs included in both the Round 2 Recompete and Round 1 2017 multiplied by a $2,000 per bid surety bond price. Given the unknown variables with this new type of bond, we are seeking comments on how the authorized sureties will set the purchase amount for bidding entities in order to finalize a more accurate estimate.

We do anticipate that there will be an impact on small suppliers. We are seeking comments on whether we should have a reduced bid surety bond amount for a particular subset

of suppliers, for example, small suppliers as defined by the CBP. In terms of a small supplier obtaining a bond, the Small Business Administration (SBA) has a statement on their website stating that their guarantee "encourages surety companies to bond small businesses," and as such we anticipate that small suppliers will be able to reach out to the SBA if they encounter difficulty in obtaining a bond.

As a result of the implementation of this proposed rule, we anticipate that this requirement may deter some suppliers from bidding, which would result in a lower number of bids submitted to the DMEPOS CBP. We are seeking comments on the impact of the bid surety bond requirement on supplier participation in the DMEPOS CBP.

State Licensure. Contract suppliers in the CBP are already required to have the proper state licensure in order to be eligible for a contract award. We do not anticipate that conforming the language of the regulation to the language in section 1847(b)(2)(A), as added by section 522 of MACRA, will have any additional impact beyond what is already being imposed on suppliers.

Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions. We believe the expansion of the appeal rights for breach of contract may have a positive impact on contract suppliers by providing the formal opportunity to appeal any of the actions that CMS may take as a result of a breach of contract.

b. Effects on the Medicare Program

Bid Surety Bonds. We anticipate that the bid surety bond requirement will result in bidding entities being more conscientious when formulating their bid amounts. In addition, given the already high historic contract acceptance rate exceeding 90 percent per round, we anticipate that the bid surety bond provision will result in an even higher rate of contract acceptance.

As a result of the implementation of this proposed rule, we anticipate that this regulation may deter some bidding entities from bidding, which would result in a lower number of bids submitted to the DMEPOS CBP. This reduction could reduce competition and lead to a decreased number of contract suppliers and, as a result, less savings from the program.

Additionally, we expect that there will be an administrative burden for implementing the bid surety bond requirement, which includes educating bidding entities, updating CMS bidding and contracting systems, and verifying that the bonds are valid.

State Licensure. We do not anticipate that conforming the language of the regulation to the language in section 1847(b)(2)(A), as added by section 522 of MACRA, will have any additional impact beyond what is already being imposed on suppliers. Therefore, the burden of meeting this statutory requirement has already been estimated in previous regulations and this proposed rule does not add to the burden.

Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions. We expect that there may be some de minimis costs to expand the appeals process. We anticipate that overall this proposed rule will have a positive impact on the program by allowing suppliers a full appeals process for any breach of contract action that CMS may take pursuant to §414.422(g)(2).

c. Effects on Medicare Beneficiaries

The proposed CBP requirements for bid surety bond, state licensure and appeals process for a breach of contract actions are not expected to have an impact on Medicare beneficiaries.

d. Alternatives Considered

Section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, provides that a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid

submission, the entity has (1) obtained a bid surety bond, and (2) provided proof of having obtained the bid surety bond for each CBA associated with its bid(s) in a form specified by the Secretary. No alternatives to this bid surety bond requirement were considered. However, while we are proposing that the bid surety bond be in an amount of $100,000, we are seeking comments on whether a lower bond amount for a certain subset of bidding entities, for example, small suppliers as defined by 42 CFR §414.402, would be appropriate. Additionally, we are seeking comments on the impact of the bid surety bond requirement on participation in the DMEPOS CBP. No alternatives were considered for the state licensure requirement, as §414.414(b)(3) of the regulations already requires suppliers to have state and local licensure.

For appeals for breach of contract actions, we believe that it would be beneficial to expand the appeals process to any of the breach of contract actions that CMS may take pursuant to §414.422(g)(2). The alternative is to retain the current appeals process for terminations, while still allowing suppliers to appeal other breach of contract actions through an undefined process. However, in order to provide an opportunity for notice and comment, we believe that the better option is to revise the current regulations to allow for a clear and defined appeals process for any breach of contract action that CMS may take.

5. DMEPOS Provisions

a. Effects of the Methodology for Adjusting DMEPOS Fee Schedule Amounts For Similar Items with Different Features Using Information from the DMEPOS Competitive Bidding Programs

We estimate that our proposal for a methodology for adjusting DMEPOS fee schedule amounts for certain groupings of similar items with different features using information from the DMEPOS CBPs will generate small savings by lowering the price of similar items to be equal to the weighted average of the SPAs for the items based on the item weights assigned under

competitive bidding. The reduced price causes lower copayments to the beneficiary. We believe our proposal would also prevent beneficiaries from potentially receiving lower cost items at higher coinsurance rates. Suppliers will be impacted little by the methodological change because the proposal has a small saving attached to it.

b. Effects of the Proposal for Determining Single Payment Amounts for Similar Items with Different Features under the DMEPOS Competitive Bidding Program

We estimate that our proposal for a methodology for determining single payment amounts for certain groupings of similar items with different features under the DMEPOS CBPs will generate small savings by not allowing SPAs for similar items without features to be priced higher than items with features. Our proposal would benefit beneficiaries who would have lower coinsurance payments as a result of this proposal. We believe our proposal would also prevent beneficiaries from potentially receiving lower cost items at higher coinsurance rates. Suppliers will have a reduced administrative burden due to the fact that bidding is simplified.

c. Effects of the Proposed Revision to the Bid Limits under the DMEPOS Competitive Bidding Program

We estimate our proposed revision to the bid limits for items under the DMEPOS CBP will not have a significant fiscal impact on the Medicare program because we anticipate little change in Medicare payment due to the revised bid limits. This revision will provide clearer limits. We estimate our proposed revision to the bid limits at the unadjusted fee level would have little fiscal impact in that competitions will continue to reduce prices. This proposed rule would benefit suppliers and beneficiaries because payments would be allowed to fluctuate somewhat to account for increases in the costs of furnishing items, including newer technology items.

C. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 33 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 33 Accounting Statement: Classification of Estimated Transfers and Costs/Savings			
ESRD PPS and AKI for CY 2017			
Category	**Transfers**		
Annualized Monetized Transfers	$50 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 2019[17]			
Category	**Transfers**		
Annualized Monetized Transfers	$-15.5 million		
Category	**Costs**		
Annualized Monetized ESRD Provider Costs	$21 thousand		
ESRD QIP for PY 2020			
Category	**Transfers**		
Annualized Monetized Transfers	$-22 million		
From Whom to Whom	Federal government to ESRD providers		
Category	**Costs**		
Annualized Monetized ESRD Provider Costs	$91 million		
DME Provisions			
Category	**Transfer**		
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $Millions)	Estimates	Year Dollar	Discount Rate
	-$1.9	2016	7%
	-$1.9	2016	3%
From Whom to Whom	Beneficiaries to Medicare providers		
	Transfers		
Annualized Monetized Transfer Payments (in	Estimates	Year Dollar	Discount Rate
	-$7.5	2016	7%

17 We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The values presented here capture those previously finalized impacts plus the collection of information requirements related for PY 2018 presented in this notice of proposed rulemaking.

$Millions)	-$7.8	2016	3%
From Whom to Whom	Federal government to Medicare providers.		

XVII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 15 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $38.5 million in any 1 year. Individuals and States are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at http://www.sba.gov/content/small-business-size-standards (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 15 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 32. Using the definitions in this ownership category, we consider the 568 facilities that are independent and the 354 facilities that

are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 0.7 percent increase in payments for CY 2017. An independent facility (as defined by ownership type) is also estimated to receive a 0.4 percent increase in payments for CY 2017.

We are unable to estimate whether patients will go to ESRD facilities for AKI dialysis, however, we have estimated there is a potential for $2.0 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities. As a result, this proposed rule is not estimated to have a significant impact on small entities.

We estimate that of the 2,840 ESRD facilities expected to receive a payment reduction in the PY 2020 ESRD QIP, 349 are ESRD small entity facilities. We present these findings in Table 21 (“Estimated Distribution of PY 2020 ESRD QIP Payment Reductions”) and Table 23 (“Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2020”) above. We estimate that the payment reductions will average approximately $11,510 per facility across the 2,840 facilities receiving a payment reduction, and $13,884 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 922 small entity facilities with the aggregate ESRD payments to all small entity facilities. We estimate that there are a total of 922 small entity facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.49 percent in PY 2020.

We anticipate that the bid surety bond provision will have an impact on all suppliers, including small suppliers; therefore, we are requesting comments regarding the bid bond amount. The state licensure and appeal of preclusion proposed rules are not expected to have an impact on any supplier.

We expect our proposals for a methodology for adjusting DMEPOS fee schedule amounts for certain groupings of similar items with different features using information from the DMEPOS CBPs, our proposed change for submitting bids for a grouping of two or more similar items with different features, our proposal for determining single payment amounts for similar items with different features under the DMEPOS CBPs, and our proposed revision to the bid limits for items under the DMEPOS CBP will not 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 more equitable using the proposals established as a result of this rule. We believe that these rules will have a positive impact on suppliers because it reduces the burden and time it takes for suppliers to submit bids and data entry. It will also allow for suppliers to furnish items necessary to beneficiaries while getting compensated a reasonable payment.

Therefore, the Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities. We solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of

the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 139 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 139 rural hospital-based dialysis facilities will experience an estimated 0.1 percent decrease in payments. As a result, this proposed rule is not estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

XVIII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. This proposed rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $141 million.

XIX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not

have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

XX. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

XXI. 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 ESRDPayment@cms.hhs.gov.

List of Subjects

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, Reporting and recordkeeping requirements

42 CFR Part 494

Conditions for Coverage for End-Stage Renal Disease Facilities

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

1. The authority citation for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C. 1395g; 42 U.S.C. 1395l(a), (i), and (n); 42 U.S.C. 1395x(v); 42 U.S.C. 1395hh; 42 U.S.C. 1395rr; 42 U.S.C. 1395tt; 42 U.S.C. 1395ww; sec. 124 of Pub. L. 106–113, 113 Stat. 1501A– 332; sec. 3201 of Pub. L. 112–96, 126 Stat. 156; sec. 632 of Pub. L. 112–240, 126 Stat. 2354; sec. 217 of

Pub. L. 113–93, 129 Stat. 1040; sec. 204 of Pub. L. 113–295, 128 Stat. 4010; and sec. 808 of Pub. L. 114-27, 129 Stat. 362.

2. The heading for part 413 is revised to read as set forth above:

3. Section 413.194 is amended by revising paragraph (a)(1) to read as follows:

§ 413.194 Appeals.

(a) * * *

(1) A facility that disputes the amount of its allowable Medicare bad debts reimbursed by CMS under §413.89(h)(3) may request review by the contractor or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R of part 405 of this chapter.

* * * * *

4. Section 413.215 is amended by revising paragraph (b) to read as follows:

§ 413.215 Basis of payment.

* * * * *

(b) In addition to the per-treatment payment amount, as described in §413.215(a), the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in §413.89(h)(3) of this part.

5. Add Subpart K to part 413 to read as follows:

Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

Sec.

413.370 Scope.

413.371 Definition.

413.372 AKI dialysis payment rate.

413.373 Other adjustments to the AKI dialysis payment rate

413.374 Renal dialysis services included in the AKI dialysis payment rate

413.375 Notification of changes in rate-setting methodologies and payment rates.

Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

§ 413.370 Scope.

This subpart implements section 1834(r) of the Act by setting forth the principles and authorities under which CMS is authorized to establish a payment amount for renal dialysis services furnished to beneficiaries with an acute kidney injury in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in § 413.171.

§ 413.371 Definition.

For purposes of the subpart, the following definition applies:

Individual with Acute Kidney Injury. The term individual with acute kidney injury means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Act.

§ 413.372 AKI dialysis payment rate.

The amount of payment for AKI dialysis services shall be the base rate for renal dialysis services determined for such year under section 1881(b)(14), that is, the ESRD base rate as set forth in §413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373.

§ 413.373 Other adjustments to the AKI dialysis payment rate

The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

§413.374 Renal dialysis services included in the AKI dialysis payment rate

(a) The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act.

(b) Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in §413.171, but that are related to their dialysis treatment as a result of their AKI, would be separately payable, that is, drugs, biologicals, laboratory services, and supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting.

§413.375 Notification of changes in rate-setting methodologies and payment rates.

(a) Changes to the methodology for payment for renal dialysis services furnished to beneficiaries with AKI as well as any adjustments to the AKI payment rate other than wage index will be adopted through notice and comment rulemaking.

(b) Annual updates in the AKI dialysis payment rate as described in § 413.372 that do not include those changes described in paragraph (a) are announced by notice published in the **Federal Register** without opportunity for public comment.

(c) Effective for cost reporting periods beginning on or after January 1, 2017, on an annual basis CMS updates the AKI dialysis payment rate.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

7. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

8. Section 414.210 is amended by revising paragraph (g)(6) to read as follows:

§414.210 General payment rules.

* * * * *

(g) * * *

(6) Adjustments of single payment amounts resulting from price inversions under the DMEPOS Competitive Bidding Program.

(i) In situations where a price inversion defined in §414.402 occurs under the DMEPOS Competitive Bidding Program in a competitive bidding area (CBA) following a competition for a grouping of similar items identified in paragraph (g)(6)(ii) of this section, prior to adjusting the fee schedule amounts under §414.210(g) the single payment amount for each item in the grouping of similar items in the CBA is adjusted to be equal to the weighted average of the single payment amounts for the items in the grouping of similar items in the CBA.

(ii) The groupings of similar items subject to this rule include-

(A) Enteral infusion pumps (HCPCS codes B9000 and B9002).

(B) Hospital beds (HCPCS codes E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, and E0304).

(C) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373)

(D) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, and K0823).

(E) Seat lift mechanisms (HCPCS codes E0627, E0628, and E0629).

(F) TENS devices (HCPCS codes E0720 and E0730).

(G) Walkers (HCPCS codes E0130, E0135, E0141, and E0143).

(iii) The weight for each item (HCPCS code) used in calculating the weighted average described in paragraph (g)(6)(ii) of this section is equal to the proportion of total nationwide allowed services furnished in calendar year 2012 for the item (HCPCS code) in the grouping of similar items, relative to the total nationwide allowed services furnished in calendar year 2012 for each of the other items (HCPCS codes) in the grouping of similar items.

* * * * *

9. Section 414.402 is amended by adding the definitions of "Bidding entity," "Price Inversion," and "Total nationwide allowed service" in alphabetical order to read as follows:

§414.402 Definitions.

* * * * *

Bidding entity means the entity whose legal business name is identified in the "Form A: Business Organization Information" section of the bid.

* * * * *

Price inversion means any situation where the following occurs: One item (HCPCS code) in a grouping of similar items (e.g., walkers, enteral infusion pumps, or power wheelchairs) in a product category includes a feature that another, similar item in the same product category does not have (e.g., wheels, alarm, or Group 2 performance); the average of the 2015 fee schedule amounts (or initial, unadjusted fee schedule amounts for subsequent years for new items) for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and, following a competition, the SPA for the code with the feature is lower than the SPA for the code without that feature.

* * * * *

Total nationwide allowed services means the total number of services allowed for an item furnished in all states, territories, and the District of Columbia where Medicare beneficiaries reside and can receive covered DMEPOS items and services.

10. Section 414.412 is amended by revising paragraphs (b)(2) and (d) and adding paragraph (h) to read as follows:

§414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(2) The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C, without the application of §414.210(g), or Subpart D, without the application of §414.105, or Subpart I of this part. The bids submitted for items in accordance with paragraph (d)(2) of this section cannot exceed the weighted average, weighted by total nationwide allowed services, as defined in §414.202, of the payment amounts that would otherwise apply to the grouping of similar items under Subpart C, without the application of §414.210(g), or Subpart D, without the application of §414.105.

* * * * *

(d) Separate bids. (1) Except as provided in paragraph (d)(2) of this section, for each product category that a supplier is seeking to furnish under a Competitive Bidding Program, the supplier must submit a separate bid for each item in that product category.

(2) An exception to paragraph (d)(1) of this section can be made in situations where price inversions defined in §414.402 have occurred in past competitions for items within groupings of similar items within a product category. In these situations, an alternative method for submitting

bids for these combinations of codes may be announced at the time the competition begins. Under this alternative method, the combination of codes for the similar items is the item for bidding purposes, as defined under §414.402. Suppliers submit bids for the code with the highest total nationwide allowed services for calendar year 2012 (the "lead item") within the grouping of codes for similar items, and the bids for this code are used to calculate the single payment amounts for this code in accordance with §414.416(b)(1). The bids for this code would also be used to calculate the single payment amounts for the other codes within the grouping of similar items in accordance with §414.416(b)(3). For subsequent competitions, the lead item is identified as the code with the highest total nationwide allowed services for the most recent and complete calendar year that precedes the competition. The groupings of similar items subject to this rule include-

(i) Enteral infusion pumps (HCPCS codes B9000 and B9002).

(ii) Hospital beds (HCPCS codes E0250, E0251, E0255, E0256, E0260, E0261, E0266, E0265, E0290, E0291, E0292, E0293, E0294, E0295, E0296, E0297, E0301, E0302, E0303, and E0304).

(iii) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373).

(iv) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, K0823, K0824, K0825, K0826, K0827, K0828, and K0829).

(v) Seat lift mechanisms (HCPCS codes E0627, E0628, and E0629).

(vi) TENS devices (HCPCS codes E0720 and E0730).

(vii) Walkers (HCPCS codes E0130, E0135, E0140, E0141, E0143, E0144, E0147, E0148, and E0149).

* * * * *

(h) Requiring bid surety bonds for bidding entities. (1) Bidding requirements. For competitions beginning on or after January 1, 2017, and no later than January 1, 2019, a bidding entity may not submit a bid(s) for a CBA unless it obtains a bid surety bond for the CBA from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provides proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission.

(2) Bid surety bond requirements. (i) The bid surety bond issued must include at a minimum:

(A) The name of the bidding entity as the principal/obligor;

(B) The name and National Association of Insurance Commissioners number of the authorized surety;

(C) CMS as the named obligee;

(D) The conditions of the bond;

(E) The CBA covered by the bond;

(F) The bond number;

(G) The date of issuance; and

(H) The bid bond value of $100,000.00.

(ii) The bid surety bond must be maintained until it is either collected upon due to forfeiture or the liability is returned for not meeting bid forfeiture conditions.

(3) Forfeiture of bid surety bond. (i) When a bidding entity is offered a contract for a CBA/product category ("competition") and its composite bid for the competition is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts within the competition and the bidding entity does not accept the contract

offer, its bid surety bond submitted for that CBA will be forfeited and CMS will collect on the bond via Electronic Funds Transfer (EFT) from the respective bonding company. As one bid surety bond is required for each CBA in which the bidding entity is submitting a bid, the failure to accept a contract offer for any product category within the CBA when the entity's bid is at or below the median composite bid rate will result in forfeiture of the bid surety bond for that CBA.

(ii) Where the bid(s) does not meet the specified forfeiture conditions in paragraph (h)(3)(i) of this section, the bid surety bond liability will be returned within 90 days of the public announcement of contract suppliers for the CBA. CMS will notify the bidding entity that it did not meet the specified forfeiture requirements and the bid surety bond will not be collected by CMS.

(4) Penalties. (i) A bidding entity that has been determined to have falsified its bid surety bond may be prohibited from participation in the DMEPOS Competitive Bidding Program for the current round of the Competitive Bidding Program in which it submitted a bid and also from participating in the next round of the Competitive Bidding Program. Offending suppliers will also be referred to the Office of Inspector General and Department of Justice for further investigation.

(ii) A bidding entity, whose composite bid is at or below the median composite bid rate, that-

(A) Accepts a contract award and

(B) Is found to be in breach of contract for nonperformance of the contract to avoid forfeiture of the bid surety bond will have its contract terminated and will be precluded from participation in the DMEPOS Competitive Bidding Program.

11. Section 414.414 is amended by revising paragraph (b)(3) to read as follows:

§414.414 – Conditions for awarding contracts.

* * * * *

(b) * * *

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids. CMS may not award a contract to any entity in a CBA unless the entity meets applicable State licensure requirements.

* * * * *

12. Section 414.416 is amended by adding a new paragraph (b)(3) to read as follows:

§414.416 Determination of competitive bidding payment amounts.

* * * * *

(b) * * *

(3) In the case of competitions where bids are submitted for an item that is a combination of codes for similar items within a product category as identified under §414.412(d)(2), the single payment amount for each code within the combination of codes is equal to the single payment amount for the lead item or code with the highest total nationwide allowed services multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (i.e., all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the code to the average of the 2015 fee schedule amounts for all areas for the lead item.

13. Section 414.422 is amended by revising paragraph (g) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(g) Breach of contract. (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions, which will be specified in the notice of breach of contract:

(i) Suspend the contract supplier's contract;

(ii) Terminate the contract;

(iii) Preclude the contract supplier from participating in the competitive bidding program; or

(iv) Avail itself of other remedies allowed by law.

14. Section 414.423 is revised to read as follows:

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

This section implements an appeals process for suppliers that CMS has determined are in breach of their Medicare DMEPOS Competitive Bidding Program contract and where CMS has issued a notice of breach of contract indicating its intent to take action(s) pursuant to §414.422(g)(2).

(a) Breach of contract. CMS may take one or more of the actions specified in §414.422(g)(2) as a result of a supplier's breach of their DMEPOS Competitive Bidding Program contract.

(b) Notice of breach of contract. (1) CMS notification. If CMS determines a supplier to be in breach of its contract, it will notify the supplier of the breach of contract in a notice of breach of contract.

(2) Content of the notice of breach of contract. The CMS notice of breach of contract will include the following:

(i) The details of the breach of contract.

(ii) The action(s) that CMS is taking as a result of the breach of the contract pursuant to §414.422(g)(2), and the duration of or timeframe(s) associated with the action(s), if applicable.

(iii) The right to request a hearing by a CBIC hearing officer and, depending on the nature of the breach, the supplier may also be allowed to submit a corrective action plan (CAP) in lieu of requesting a hearing by a CBIC hearing officer, as specified in paragraph (c)(1)(i) of this section.

(iv) The address to which the written request for a hearing must be submitted.

(v) The address to which the CAP must be submitted, if applicable.

(vi) The effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless:

(A) A timely hearing request has been filed; or

(B) A CAP has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.

(c) Corrective action plan (CAP). (1) Option for a CAP. (i) CMS has the option to allow a supplier to submit a written CAP to remedy the deficiencies identified in the notice at its sole discretion, including where CMS determines that the delay in the effective date of the breach of contract action(s) caused by allowing a CAP will not cause harm to beneficiaries. CMS will not allow a CAP if the supplier has been excluded from any Federal program, debarred by a Federal agency, or convicted of a healthcare-related crime, or for any other reason determined by CMS.

(ii) If a supplier chooses not to submit a CAP, if CMS determines that a supplier's CAP is insufficient, or if CMS does not allow the supplier the option to submit a CAP, the supplier may request a hearing on the breach of contract action(s).

(2) Submission of a CAP. (i) If allowed by CMS, a CAP must be submitted within 30 days from the date on the notice of breach of contract. If the supplier decides not to submit a CAP the supplier may, within 30 days of the date on the notice, request a hearing by a CBIC hearing officer.

(ii) Suppliers will only have the opportunity to submit a CAP when they are first notified that they have been determined to be in breach of contract. If the CAP is not acceptable to CMS or is not properly implemented, suppliers will receive a subsequent notice of breach of contract. The subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant to paragraph (1)(i) of this section.

(d) The purpose of the CAP. The purpose of the CAP is: (1) For the supplier to remedy all of the deficiencies that were identified in the notice of breach of contract.

(2) To identify the timeframes by which the supplier will implement each of the components of the CAP.

(e) Review of the CAP. (1) The CBIC will review the CAP. Suppliers may only revise their CAP one time during the review process based on the deficiencies identified by the CBIC. The CBIC will submit a recommendation to CMS for each applicable breach of contract action concerning whether the CAP includes the steps necessary to remedy the contract deficiencies as identified in the notice of breach of contract.

(2) If CMS accepts the CAP, including the supplier's designated timeframe for its completion, the supplier must provide a follow-up report within 5 days after the supplier has

fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS.

(3) If the supplier does not implement a CAP that was accepted by CMS, or if CMS does not accept the CAP submitted by the supplier, then the supplier will receive a subsequent notice of breach of contract, as specified in paragraph (b) of this section.

(f) Right to request a hearing by the CBIC Hearing Officer. (1) A supplier who receives a notice of breach of contract (whether an initial notice of breach of contract or a subsequent notice of breach of contract under § 414.422(e)(3)) has the right to request a hearing before a CBIC hearing officer who was not involved with the original breach of contract determination.

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be received by the CBIC within 30 days from the date of the notice of breach of contract.

(3) A request for hearing must be in writing and submitted by an authorized official of the supplier.

(4) The appeals process for the Medicare DMEPOS Competitive Bidding Program is not to be used in place of other existing appeals processes that apply to other parts of Medicare.

(5) If the supplier is given the opportunity to submit a CAP and a CAP is not submitted and the supplier fails to timely request a hearing, the breach of contract action(s) will take effect 45 days from the date of the notice of breach of contract.

(g) The CBIC Hearing Officer schedules and conducts the hearing**.** (1) Within 30 days from the receipt of the supplier's timely request for a hearing the hearing officer will contact the parties to schedule the hearing.

(2) The hearing may be held in person or by telephone at the parties' request.

(3) The scheduling notice to the parties must indicate the time and place for the hearing and must be sent to the parties at least 30 days before the date of the hearing.

(4) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing, but must give the parties to the hearing 30 days' notice of the change.

(5) The hearing officer's scheduling notice must provide the parties to the hearing the following information:

(i) A description of the hearing procedure.

(ii) The specific issues to be resolved.

(iii) The supplier has the burden to prove it is not in violation of the contract or that the breach of contract action(s) is not appropriate.

(iv) The opportunity for parties to the hearing to submit additional evidence to support their positions, if requested by the hearing officer.

(v) A notification that all evidence submitted, both from the supplier and CMS, will be provided in preparation for the hearing to all affected parties at least 15 days prior to the scheduled date of the hearing.

(h) Burden of proof and evidence submission. (1) The burden of proof is on the Competitive Bidding Program contract supplier to demonstrate to the hearing officer with convincing evidence that it has not breached its contract or that the breach of contract action(s) is not appropriate.

(2) The supplier's evidence must be submitted with its request for a hearing.

(3) If the supplier fails to submit the evidence at the time of its submission, the Medicare DMEPOS supplier is precluded from introducing new evidence later during the hearing process, unless permitted by the hearing officer.

(4) CMS also has the opportunity to submit evidence to the hearing officer within 10 days of receiving the scheduling notice.

(5) The hearing officer will share all evidence submitted by the supplier and/or CMS, with all parties to the hearing at least 15 days prior to the scheduled date of the hearing.

(i) Role of the Hearing Officer. The hearing officer will conduct a thorough and independent review of the evidence including the information and documentation submitted for the hearing and other information that the hearing officer considers pertinent for the hearing. The role of the hearing officer includes, at a minimum, the following:

(1) Conduct the hearing and decide the order in which the evidence and the arguments of the parties are presented;

(2) Determine the rules on admissibility of the evidence;

(3) Examine the witnesses, in addition to the examinations conducted by CMS and the contract supplier;

(4) The CBIC may assist CMS in the appeals process including being present at the hearing, testifying as a witness, or performing other, related ministerial duties;

(5) Determine the rules for requesting documents and other evidence from other parties;

(6) Ensure a complete record of the hearing is made available to all parties to the hearing;

(7) Prepare a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the hearing officer and considered as part of the hearing; and

(8) Comply with all applicable provisions of 42 USC Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

(j) Hearing officer recommendation. (1) The hearing officer will issue a written recommendation(s) to CMS within 30 days of the close of the hearing unless an extension has been granted by CMS because the hearing officer has demonstrated that an extension is needed due to the complexity of the matter or heavy workload. In situations where there is more than one breach of contract action presented at the hearing, the hearing officer will issue separate recommendations for each breach of contract action.

(2) The recommendation(s) will explain the basis and the rationale for the hearing officer's recommendation(s).

(3) The hearing officer must include the record of the hearing, along with all evidence and documents produced during the hearing along with its recommendation(s).

(k) CMS' final determination. (1) CMS' review of the hearing officer's recommendation(s) will not allow the supplier to submit new information.

(2) After reviewing the hearing officer's recommendation(s), CMS' decision(s) will be made within 30 days from the date of receipt of the hearing officer's recommendation(s). In situations where there is more than one breach of contract action presented at the hearing, and the hearing officer issues multiple recommendations, CMS will render separate decisions for each breach of contract action.

(3) A notice of CMS' decision will be sent to the supplier and the hearing officer. The notice will indicate:

(i) If any breach of contract action(s) included in the notice of breach of contract, specified in paragraph (b)(1) of this section, still apply and will be effectuated, and

(ii) The effective date for any breach of contract action specified in paragraph (k)(3)(i) of this section.

(4) This decision(s) is final and binding.

(l) Effect of breach of contract action(s). (1) Effect of contract suspension. (i) All locations included in the contract cannot furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items for the duration of the contract suspension.

(ii) The supplier must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items on a recurring basis of the suspension of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice.

(B) The notice to the beneficiary must inform the beneficiary that they must select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(2) Effect of contract termination. (i) All locations included in the contract can no longer furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items after the effective date of the termination.

(ii) The supplier 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.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice of termination.

(B) The notice to the beneficiary must inform the beneficiary that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(3) Effect of preclusion. A supplier who is precluded will not be allowed to participate in a specific round of the Competitive Bidding Program, which will be identified in the original notice of breach of contract, as specified in paragraph (b)(1) of this section.

(4) Effect of other remedies allowed by law. If CMS decides to impose other remedies under §414.422(g)(2)(iv), the details of the remedies will be included in the notice of breach of contract, as specified in paragraph (b)(2) of this section.

PART 494— CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

15. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. l302 and l395hh).

16. Amend § 494.1 by revising paragraph (a)(3) and adding paragraph (a)(7) to read as follows:

§494.1 Basis and Scope.

(a) * * *

(3) Section 1861(s)(2)(F) of the Act, which describes "medical and other health services" covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B)), including such renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid under section 1881(b)(14) to an individual

with acute kidney injury (as defined in section 1834(r)(2)).

* * * * *

(7) Section 1861(s)(2)(F) of the Act, which authorizes coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI.

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Dated: June 16, 2016

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Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: June 22, 2016

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Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

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